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DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Rural Housing Service

Rural Utilities Service

Farm Service Agency

7 CFR Part 1970

RIN 0572–AC44

Rural Development Environmental Regulation for Rural Infrastructure Projects

AGENCY: Rural Business-Cooperative Service, Rural Housing Service, Rural Utilities Service, Farm Service Agency, USDA.

ACTION: Direct final rule.

SUMMARY: The United States Department of Agriculture (USDA) Rural Development (RD), comprised of the Rural Business-Cooperative Service (RBS), Rural Housing Service (RHS), and Rural Utilities Service (RUS), hereafter referred to as the Agency, is issuing a direct final rule to update the Agency's Environmental Policies and Procedures regulation (7 CFR 1970) to allow the Agency Administrators limited flexibility to obligate federal funds for infrastructure projects prior to completion of the environmental review while ensuring full compliance with National Environmental Policy Act (NEPA) procedures prior to project construction and disbursement of any RD funding. This change will allow RD to more fully meet the Administration's goals to speed the initiation of infrastructure projects and encourage planned community economic development without additional cost to taxpayers or change to environmental review requirements.

DATES: This rule is effective January 7, 2019, without further action, unless the Agency receives significant adverse comments or, an intent to submit a significant adverse comment, by December 24, 2018. Written significant adverse comments or, an intent to submit a significant adverse comment, must be received by Rural Development or carry a postmark or equivalent no later than December 24, 2018. If significant adverse comments are received, the Agency will publish a timely **Federal Register** document withdrawing this rule. The Agency is publishing a proposed rule contemporaneously with this final rule.

ADDRESSES: Submit your comments on this rule by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and, in the lower ''Search Regulations and Federal Actions'' box, select ''Rural Utilities Service'' from the agency drop-down menu, then click on ''Submit.'' In the Docket ID column, select RUS–18–AGENCY–0005 to submit or view public comments and to view supporting and related materials available electronically. Information on using *Regulations.gov*, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.
- *Postal Mail/Commercial Delivery:* Please send your comment addressed to Michele Brooks, Rural Development Innovation Center, Regulations Team Lead, U.S. Department of Agriculture, 1400 Independence Ave. SW, Stop 1522, Room 1562, Washington, DC 20250. Please state that your comment refers to Docket No. RUS–18–AGENCY–0005.

Other Information: Additional information about Rural Development and its programs is available on the internet at *https://www.usda.gov/topics/rural.*

FOR FURTHER INFORMATION CONTACT: Kellie McGinness Kubena, Director, Engineering and Environmental Staff, Rural Utilities Service, USDA Rural Development, 1400 Independence Ave SW, Mail Stop 1571, Room 2242, Washington, DC 20250–1571 Phone: 202–720–1649.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This final rule has been determined to be not significant for the purposes of Executive Order 12866, Regulatory Planning and Review, and therefore has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. The Agency has determined that this rule meets the applicable standards provided in section 3 of the Executive Order. In addition, all state and local laws and regulations that are in conflict with this rule will be preempted. No retroactive effect will be given to this rule and, in accordance with section 212(e) of the Department of Agriculture Reorganization Act of 1994 (7 U.S.C. 6912(e)), administrative appeal procedures must be exhausted before an action against the Department or its agencies may be initiated.

Executive Order 12372

This final rule is not subject to the requirements of Executive Order 12372, ''Intergovernmental Review,'' as implemented under USDA's regulations at 2 CFR part 415, subpart C, because this rule provides general guidance on NEPA and related environmental reviews of applicants' proposals. Applications for Agency programs will be reviewed individually under Executive Order 12372 as required by program procedures.

Regulatory Flexibility Act Certification

The Agency has determined that this final rule will not have a significant economic impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act (5 U.S.C. §§ 601 *et seq.*), given that the amendment is only an administrative, procedural change on the government's part with respect to obligation of funds.

National Environmental Policy Act

In this final rule, the Agency proposes to create limited flexibility for the timing of obligation of funds relative to the completion of environmental review. The Council on Environmental Quality (CEQ) does not direct agencies to prepare a NEPA analysis before establishing agency procedures that supplement the CEQ regulations for implementing NEPA. The requirements for establishing agency NEPA procedures are set forth at 40 CFR 1505.1 and 1507.3. The determination that establishing agency NEPA

procedures does not require NEPA analysis and documentation has been upheld in *Heartwood, Inc.* v. *U.S. Forest Service,* 73 F. Supp. 2d 962, 972–73 (S.D. III. 1999), aff'd, 230 F.3d 947, 954–55 (7th Cir. 2000).

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance (CFDA) numbers assigned to the RD Programs affected by this rulemaking are as follows:

10.760—Water & Waste Disposal System Systems for Rural Communities.
10.761—Technical Assistance and Training Grants.
10.762—Solid Waste Management Grants.
10.763—Emergency Community Water Assistance Grants.
10.770—Water & Waste Disposal Loan and Grants (Section 306C).
10.766—Community Facilities Loans and Grants.
10.850—Rural Electrification Loans and Loan Guarantees.
10.851—Rural Telephone Loans and Loan Guarantees.
10.855—Distance Learning & Telemedicine Grants.
10.857—State Bulk Fuel Revolving Loan Fund.
10–858—Assistance to High Energy Cost-Rural Communities.
10.863—Community Connect Grants.
10.865—Biorefinery, Renewable Chemical, & Biobased Product Manufacturing Assistance Program.
10.866—Repowering Assistance Program.
10.867—Advanced Biofuel Payment Program.
10.868—Rural Energy for America Program.
10.886—Rural Broadband Access Loan and Loan Guarantee Program.

All active CFDA programs can be found at *www.cfda.gov*. The Catalog is available on the internet at *http://www.cfda.gov* and the General Services Administration's (GSA's) free CFDA website at *http://www.cfda.gov*. The CFDA website also contains a PDF file version of the Catalog that, when printed, has the same layout as the printed document that the Government Publishing Office (GPO) provides. GPO prints and sells the CFDA to interested buyers. For information about purchasing the Catalog of Federal Domestic Assistance from GPO, call the Superintendent of Documents at 202–512–1800 or toll free at 866–512–1800, or access GPO's online bookstore at *http://bookstore.gpo.gov*.

Rural Development infrastructure programs not listed in this section nor on the CFDA website, but which are enacted pursuant to the Rural Electrification Act of 1936, 7 U.S.C. 901 *et seq.,* the Consolidated Farm and Rural Development Act of 1972, 7 U.S.C. 1921 *et seq.,* or any other Congressional act for Rural Development, will be covered by the requirements of this action when enacted.

Unfunded Mandates Reform Act

This final rule contains no Federal mandates (under the regulatory provisions of Title II of the Unfunded Mandates Reform Act of 1995) for state, local, and tribal governments or the private sector. Therefore, this rule is not subject to the requirements of §§ 202 and 205 of the Unfunded Mandates Reform Act of 1995.

E-Government Act Compliance

The Agency is committed to the E-Government Act, which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible.

Executive Order 13132, Federalism

The policies contained in this final rule do not have any substantial direct effect on states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Nor does this final rule impose substantial direct compliance costs on state and local governments. Therefore, consultation with the states is not required.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule has been reviewed in accordance with the requirements of Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments.'' Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes. The latest revision of the Agency's Environmental Policies and Procedures in 2016 involved Tribal consultation via comment period and webinar as a baseline for future consultation on individual program actions. The creation of limited flexibility for the timing of obligation of funds relative to the completion of environmental review is only an administrative, procedural change on the government's part and in no way abridges or alters that agreement. Therefore, no further consultation is necessary on this rule change. The policies contained in this final rule do not have Tribal implications that preempt Tribal law. The Agency will continue to work directly with Tribes and Tribal applicants to improve access to Agency programs. This includes providing focused outreach to Tribes regarding implementation of this rule change. Additionally, the Agency will respond in a timely and meaningful manner to all Tribal government requests for consultation concerning this rule. For further information on the Agency's Tribal consultation efforts, please contact Rural Development's Native American Coordinator at (720) 544–2911 or *AIAN@wdc.usda.gov*.

USDA Non-Discrimination Policy

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

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To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *http://www.ascr.usda.gov/complaint_filing_cust.html* and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To

request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by: (1) Mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; (2) fax: (202) 690–7442; or (3) email: *program.intake@usda.gov*.

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Information Collection and Recordkeeping Requirements

In accordance with the Paperwork Reduction Act, the paperwork burden associated with this final rule has been approved by the Office of Management and Budget (OMB) under the currently approved OMB Control Number 0575–0197. The Agency has determined that changes contained in this regulatory action do not substantially change current data collection that would require approval under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Background

The United States Department of Agriculture (USDA) Rural Development (RD) programs provide loans, grants and loan guarantees to support investment in rural infrastructure to spur rural economic development, create jobs, improve the quality of life, and address the health and safety needs of rural residents. Infrastructure investment is an important national policy priority. As directed by E.O. 13807 in 2017, USDA as a member of the Federal Permitting Improvement Steering Council has reviewed its NEPA implementing regulations and policies to identify impediments to efficient and effective environmental reviews and authorizations for infrastructure projects. This final rule is part of that effort to improve the efficiency and effectiveness of RD's environmental reviews and authorizations for infrastructure projects in rural America.

On April 25, 2017, the President created the Interagency Task Force on Agriculture and Rural Prosperity (Task Force) through E.O. 13790 and appointed the Secretary of Agriculture as the Task Force's Chair. Among the purposes and functions of the Task Force was to,

''. . . identify legislative, regulatory, and policy changes to promote in rural America agriculture, economic development, job growth, infrastructure improvements, technological innovation, energy security, and quality of life, including changes that remove barriers to economic prosperity and quality of life in rural America.''

The Task Force Report issued on October 21, 2017, included calls to action on achieving e-Connectivity for Rural America, improving rural quality of life, harnessing technological innovation and developing the rural economy.

Purpose of the Regulatory Action

This rulemaking fulfills the mandate of E.O. 13807 as well as the goals of the President's Interagency Task Force on Agriculture and Rural Prosperity by identifying regulatory changes that promote economic development and improve the quality of life in rural America. The RD infrastructure projects impacted by this rule are often critical to the health and safety and quality of life in rural communities. In some cases, funding decisions made by Rural Development are the first step upon which a much larger process of community economic development depends. This amendment to existing regulation will allow the Agency to obligate funding *conditioned upon* the full and satisfactory completion of environmental review for infrastructure projects. This change will give applicants, and often the distressed communities they represent, some comfort to proceed with an economic development strategy, including the planning process associated with NEPA, without fear that funds may be rescinded before the NEPA process is completed. With this change in place, RD can more fully meet the government's goals of speeding up the initiation of infrastructure projects, encouraging planned community economic development, and leveraging investment without additional cost to taxpayers or any change in environmental review requirements. Infrastructure projects covered by this final rule include those, such as broadband, telecommunications, electric, energy efficiency, smart grid, water, sewer, transportation, and energy capital investments in physical plant and equipment.

Changes to the Current Regulation

Nothing in this final rule reduces RD's obligation to complete the NEPA planning process prior to foreclosing reasonable alternatives to the federal action. The current regulation at 7 CFR 1970.6 (''Financial assistance'') states that the Agency defines the major decision point for completion of NEPA as the approval of financial assistance. Similarly, 7 CFR 1970.11(b) identifies Agency obligation as the point by which the environmental review must be concluded. As amended by this final rule, 7 CFR 1970.11(b) will now provide RD Administrators limited flexibility to obligate funds for infrastructure projects prior to the completion of the environmental review process where the assurance that funds will be available is important for community health, safety, or economic development. As a result, the environmental review process must be completed prior to disbursement of any RD funds, or any other action that would have adverse environmental impact or limit the choice of reasonable alternatives. The conditions of obligation will be defined in the documentation of the agreement approving the financial assistance between the Agency and the applicant. If, however, the conditions of obligation are not met, or the agency chooses not to proceed with the project after considering the results of the NEPA process, the Agency will rescind the obligated funds. With these conditions, the Agency retains control of the final decision to authorize construction and release funds based on the satisfactory completion of the environmental review. Note, this final rule will not, and does not, change any of the requirements for environmental reviews. Should an applicant choose to commence a project and thus foreclose reasonable alternatives, such action would result in de-obligation of federal funding, thereby eliminating any federal action for NEPA purposes on the part of Rural Development. Until the Agency concludes the environmental review and decides to proceed with the project, the obligated funds will be reserved for the infrastructure project and less susceptible to Congressional rescission.

List of Subjects in 7 CFR Part 1970

Administrative practice and procedure, Buildings and facilities, Environmental impact statements, Environmental protection, Grant programs, Housing, Loan programs, Natural resources, Utilities.

Accordingly, for reasons set forth in the preamble, chapter XVII, of subtitle B, title 7, Code of Federal Regulations is amended as follows:

PART 1970—ENVIRONMENTAL POLICIES AND PROCEDURES

■ 1. The authority citation for part 1970 continues to read as follows:

Authority: 7 U.S.C. 6941 *et seq.,* 42 U.S.C. 4241 *et seq.;* 40 CFR parts 1500–1508; 5 U.S.C. 301; 7 U.S.C. 1989; and 42 U.S.C. 1480.

■ 2. Revise § 1970.11(b) to read as follow:

§ 1970.11 Timing of the environmental review process.

* * * * *

(b) The environmental review process must be concluded before the obligation of funds; except for infrastructure projects where the assurance that funds will be available for community health, safety, or economic development has been determined as necessary by the Agency Administrator. At the discretion of the Agency Administrator, funds may be obligated contingent upon the conclusion of the environmental review process prior to any action that would have an adverse effect on the environment or limit the choices of any reasonable alternatives. Funds so obligated shall be rescinded if the Agency cannot conclude the environmental review process before the end of the fiscal year after the year in which the funds were obligated, or if the Agency determines that it cannot proceed with approval based on findings in the environmental review process. For the purposes of this section, infrastructure projects shall include projects such as broadband, telecommunications, electric, energy efficiency, smart grid, water, sewer, transportation, and energy capital investments in physical plant and equipment, but not investments authorized in the Housing Act of 1949.

* * * * *

Dated: November 9, 2018.

Anne C. Hazlett,

Assistant to the Secretary, Rural Development.

Bill Northey,

Under Secretary, Farm Production and Conservation.

[FR Doc. 2018–25523 Filed 11–21–18; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Part 34

[Docket No. OCC–2018–0031]

RIN 1557–AE53

FEDERAL RESERVE SYSTEM

12 CFR Part 226

[Docket No. R–1634]

RIN 7100–AF26

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1026

RIN 3170–AA91

Appraisals for Higher-Priced Mortgage Loans Exemption Threshold

AGENCY: Office of the Comptroller of the Currency, Treasury (OCC), Board of Governors of the Federal Reserve System (Board); and Bureau of Consumer Financial Protection (Bureau).

ACTION: Final rules, official interpretations and commentary.

SUMMARY: The OCC, the Board, and the Bureau are finalizing amendments to the official interpretations for their regulations that implement section 129H of the Truth in Lending Act (TILA). Section 129H of TILA establishes special appraisal requirements for ''higher-risk mortgages,'' termed ''higher-priced mortgage loans'' or ''HPMLs'' in the agencies' regulations. The OCC, the Board, the Bureau, the Federal Deposit Insurance Corporation (FDIC), the National Credit Union Administration (NCUA), and the Federal Housing Finance Agency (FHFA) (collectively, the Agencies) issued joint final rules implementing these requirements, effective January 18, 2014. The Agencies' rules exempted, among other loan types, transactions of $25,000 or less, and required that this loan amount be adjusted annually based on any annual percentage increase in the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI–W). If there is no annual percentage increase in the CPI–W, the OCC, the Board, and the Bureau will not adjust this exemption threshold from the prior year. However, in years following a year in which the exemption threshold was not adjusted, the threshold is calculated by applying the annual percentage increase in the CPI–W to the dollar amount that would have resulted, after rounding, if the decreases and any subsequent increases in the CPI–W had been taken into account. Based on the CPI–W in effect as of June 1, 2018, the exemption threshold will increase from $26,000 to $26,700, effective January 1, 2019.

DATES: This final rule is effective January 1, 2019.

FOR FURTHER INFORMATION CONTACT: *OCC:* MaryAnn Nash, Counsel, Chief Counsel's Office, (202) 649–6287; for persons who are deaf or hard of hearing TTY, (202) 649–5597. *Board:* Lorna M. Neill, Senior Counsel, Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, at (202) 452–3667; for users of Telecommunications Device for the Deaf (TDD) only, contact (202) 263–4869. *Bureau:* Shelley Thompson, Counsel, Office of Regulations, Bureau of Consumer Financial Protection, at (202) 435–7700.

SUPPLEMENTARY INFORMATION:

I. Background

The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act) amended the Truth in Lending Act (TILA) to add special appraisal requirements for ''higher-risk mortgages.'' [1] In January 2013, the Agencies issued a joint final rule implementing these requirements and adopted the term ''higher-priced mortgage loan'' (HPML) instead of ''higher-risk mortgage'' (the January 2013 Final Rule).[2] In July 2013, the Agencies proposed additional exemptions from the January 2013 Final Rule (the 2013 Supplemental Proposed Rule).[3] In December 2013, the Agencies issued a supplemental final rule with additional exemptions from the January 2013 Final Rule (the December 2013 Supplemental Final Rule).[4] Among other exemptions, the Agencies adopted an exemption from the new HPML appraisal rules for transactions of $25,000 or less, to be adjusted annually for inflation.

The OCC's, the Board's, and the Bureau's versions of the January 2013 Final Rule and December 2013 Supplemental Final Rule and corresponding official interpretations are substantively identical. The FDIC, NCUA, and FHFA adopted the Bureau's version of the regulations under the

[1] Public Law 111–203, section 1471, 124 Stat. 1376, 2185–87 (2010), codified at TILA section 129H, 15 U.S.C. 1639h.

[2] 78 FR 10368 (Feb. 13, 2013).

[3] 78 FR 48548 (Aug. 8, 2013).

[4] 78 FR 78520 (Dec. 26, 2013).

January 2013 Final Rule and December 2013 Supplemental Final Rule.[5]

The OCC's, Board's, and Bureau's regulations,[6] and their accompanying interpretations,[7] provide that the exemption threshold for smaller loans will be adjusted effective January 1 of each year based on any annual percentage increase in the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI–W) that was in effect on the preceding June 1. Any increase in the threshold amount will be rounded to the nearest $100 increment. For example, if the annual percentage increase in the CPI–W would result in a $950 increase in the threshold amount, the threshold amount will be increased by $1,000. However, if the annual percentage increase in the CPI–W would result in a $949 increase in the threshold amount, the threshold amount will be increased by $900. If there is no annual percentage increase in the CPI–W, the OCC, the Board, and the Bureau will not adjust the threshold amounts from the prior year.[8]

On November 30, 2016, the OCC, the Board, and the Bureau published a final rule in the **Federal Register** to memorialize the calculation method used by the agencies each year to adjust the exemption threshold to ensure that, as contemplated in the December 2013 Supplemental Final Rule (HPML Small Dollar Adjustment Calculation Rule), the values for the exemption threshold keep pace with the CPI–W.[9] The HPML Small Dollar Adjustment Calculation Rule memorialized the policy that, if there is no annual percentage increase in the CPI–W, the OCC, the Board, and Bureau will not adjust the exemption threshold from the prior year. The HPML Small Dollar Adjustment Calculation Rule also provided that, in years following a year in which the exemption threshold was not adjusted because there was a decrease in the CPI–W from the previous year, the threshold is calculated by applying the annual percentage change in the CPI–W to the dollar amount that would have resulted, after rounding, if the decreases and any subsequent increases in the CPI–W had been taken into account. If the resulting amount calculated, after rounding, is greater than the current threshold, then the threshold effective January 1 the following year will increase accordingly; if the resulting amount calculated, after rounding, is equal to or less than the current threshold, then the threshold effective January 1 the following year will not change, but future increases will be calculated based on the amount that would have resulted, after rounding.

II. 2019 Adjustment and Commentary Revision

Effective January 1, 2019, the exemption threshold amount is increased from $26,000 to $26,700. This is based on the CPI–W in effect on June 1, 2018, which was reported on May 10, 2018. The Bureau of Labor Statistics publishes consumer-based indices monthly, but does not report a CPI change on June 1; adjustments are reported in the middle of the prior month. The CPI–W is a subset of the CPI–U index (based on all urban consumers) and represents approximately 29 percent of the U.S. population. The CPI–W reported on May 10, 2018, reflects a 2.6 percent increase in the CPI–W from April 2017 to April 2018. Accordingly, the 2.6 percent increase in the CPI–W from April 2017 to April 2018 results in an exemption threshold amount of $26,700. The OCC, the Board, and the Bureau are revising the commentaries to their respective regulations to add new comments as follows:

- Comment 203(b)(2)–3.vi to 12 CFR part 34, Appendix C to Subpart G (OCC);
- Comment 43(b)(2)–3.vi to Supplement I of 12 CFR part 226 (Board); and
- Comment 35(c)(2)(ii)–3.vi to Supplement I of 12 CFR part 1026 (Bureau).

These new comments state that, from January 1, 2019, through December 31, 2019, the threshold amount is $26,700. These revisions are effective January 1, 2019.

III. Regulatory Analysis

Administrative Procedure Act

Under the Administrative Procedure Act, notice and opportunity for public comment are not required if an agency finds that notice and public comment are impracticable, unnecessary, or contrary to the public interest.[10] The amendments in this rule are technical and apply the method previously set forth in the 2013 Supplemental Proposed Rule [11] and the HPML Small Dollar Adjustment Calculation Rule. For these reasons, the OCC, the Board, and the Bureau have determined that publishing a notice of proposed rulemaking and providing opportunity for public comment are unnecessary. Therefore, the amendments are adopted in final form.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) does not apply to a rulemaking where a general notice of proposed rulemaking is not required.[12] As noted previously, the agencies have determined that it is unnecessary to publish a general notice of proposed rulemaking for this joint final rule. Accordingly, the RFA's requirements relating to an initial and final regulatory flexibility analysis do not apply.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995,[13] the agencies reviewed this final rule. No collections of information pursuant to the Paperwork Reduction Act are contained in the final rule.

Unfunded Mandates Reform Act

The OCC analyzes proposed rules for the factors listed in Section 202 of the Unfunded Mandates Reform Act of 1995, before promulgating a final rule for which a general notice of proposed rulemaking was published.[14] As discussed above, the OCC has determined that the publication of a general notice of proposed rulemaking is unnecessary.

Bureau Congressional Review Act Statement

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Bureau will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to the rule taking effect. The Office of Information and Regulatory Affairs (OIRA) has designated this rule as not a ''major rule'' as defined by 5 U.S.C. 804(2).

[5] *See* NCUA: 12 CFR 722.3; FHFA: 12 CFR part 1222. Although the FDIC adopted the Bureau's version of the regulation, the FDIC did not issue its own regulation containing a cross-reference to the Bureau's version. *See* 78 FR 10368, 10370 (Feb. 13, 2013).

[6] 12 CFR 34.203(b)(2) (OCC); 12 CFR 226.43(b)(2) (Board); and 12 CFR 1026.35(c)(2)(ii) (Bureau).

[7] 12 CFR part 34, Appendix C to Subpart G, comment 203(b)(2)–1 (OCC); 12 CFR part 226, Supplement I, comment 43(b)(2)–1 (Board); and 12 CFR part 1026, Supplement I, comment 35(c)(2)(ii)–1 (Bureau).

[8] *See* 78 FR 48548, 48565 (Aug. 8, 2013) (''Thus, under the proposal, if the CPI–W decreases in an annual period, the percentage increase would be zero, and the dollar amount threshold for the exemption would not change.'').

[9] *See* 81 FR 86250 (Nov. 30, 2016).

[10] 5 U.S.C. 553(b)(B).

[11] *See* 78 FR 48548, 48565 (Aug. 8, 2013) (''Thus, under the proposal, if the CPI–W decreases in an annual period, the percentage increase would be zero, and the dollar amount threshold for the exemption would not change.'').

[12] 5 U.S.C. 603 and 604.

[13] 44 U.S.C. 3506; 5 CFR part 1320.

[14] 2 U.S.C. 1532.

List of Subjects

12 CFR Part 34

Appraisal, Appraiser, Banks, Banking, Consumer protection, Credit, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations, Truth in lending.

12 CFR Part 226

Advertising, Appraisal, Appraiser, Consumer protection, Credit, Federal Reserve System, Mortgages, Reporting and recordkeeping requirements, Truth in lending.

12 CFR Part 1026

Advertising, Appraisal, Appraiser, Banking, Banks, Consumer protection, Credit, Credit unions, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations, Truth in lending.

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Authority and Issuance

For the reasons set forth in the preamble, the OCC amends 12 CFR part 34 as set forth below:

PART 34—REAL ESTATE LENDING AND APPRAISALS

■ 1. The authority citation for part 34 continues to read as follows:

Authority: 12 U.S.C. 1 *et seq.,* 25b, 29, 93a, 371, 1462a, 1463, 1464, 1465, 1701j–3, 1828(o), 3331 *et seq.,* 5101 *et seq.,* 5412(b)(2)(B) and 15 U.S.C. 1639h.

■ 2. In Appendix C to Subpart G, under *Section 34.203—Appraisals for Higher-Priced Mortgage Loans,* paragraph 34.203(b)(2), paragraph 3.vi is added to read as follows:

Appendix C to Subpart G—OCC Interpretations

* * * * *

Section 34.203—Appraisals for Higher-Priced Mortgage Loans

* * * * *

Paragraph 34.203(b)(2)

* * * * *

3. * * *

vi. From January 1, 2019, through December 31, 2019, the threshold amount is $26,700.

* * * * *

Board of Governors of the Federal Reserve System

Authority and Issuance

For the reasons set forth in the preamble, the Board amends Regulation Z, 12 CFR part 226, as set forth below:

PART 226—TRUTH IN LENDING (REGULATION Z)

■ 3. The authority citation for part 226 continues to read as follows:

Authority: 12 U.S.C. 3806; 15 U.S.C. 1604, 1637(c)(5), 1639(l), and 1639h; Pub. L. 111–24, section 2, 123 Stat. 1734; Pub. L. 111–203, 124 Stat. 1376.

■ 4. In Supplement I to part 226, under *Section 226.43—Appraisals for Higher-Risk Mortgage Loans,* paragraph 43(b)(2), paragraph 3.vi is added to read as follows:

Supplement I to Part 226—Official Staff Interpretations

* * * * *

Section 226.43—Appraisals for Higher-Risk Mortgage Loans

* * * * *

Paragraph 43(b)(2)

* * * * *

3. * * *

vi. From January 1, 2019, through December 31, 2019, the threshold amount is $26,700.

* * * * *

Bureau of Consumer Financial Protection

Authority and Issuance

For the reasons set forth in the preamble, the Bureau amends Regulation Z, 12 CFR part 1026, as set forth below:

PART 1026—TRUTH IN LENDING (REGULATION Z)

■ 5. The authority citation for part 1026 continues to read as follows:

Authority: 12 U.S.C. 2601, 2603–2605, 2607, 2609, 2617, 3353, 5511, 5512, 5532, 5581; 15 U.S.C. 1601 *et seq.*

■ 6. In Supplement I to part 1026, under *Section 1026.35—Requirements for Higher-Priced Mortgage Loans,* paragraph 35(c)(2)(ii), paragraph 3.vi is added to read as follows:

Supplement I to Part 1026—Official Interpretations

* * * * *

Section 1026.35—Requirements for Higher-Priced Mortgage Loans

* * * * *

Paragraph 35(c)(2)(ii)

* * * * *

3. * * *

vi. From January 1, 2019, through December 31, 2019, the threshold amount is $26,700.

* * * * *

Dated: November 6, 2018.

Joseph M. Otting,

Comptroller of the Currency.

By order of the Board of Governors of the Federal Reserve System under delegated authority, November 13, 2018.

Ann E. Misback,

Secretary of the Board.

Dated: November 9, 2018.

Mick Mulvaney,

Acting Director, Bureau of Consumer Financial Protection.

[FR Doc. 2018–25400 Filed 11–21–18; 8:45 am]

BILLING CODE 4810–33–P; 6210–01–P; 4810–AM–P

FEDERAL RESERVE SYSTEM

12 CFR Part 213

[Docket No. R–1632]

RIN 7100–AF24

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1013

RIN 3170–AA89

Consumer Leasing (Regulation M)

AGENCY: Board of Governors of the Federal Reserve System (Board); and Bureau of Consumer Financial Protection (Bureau).

ACTION: Final rules, official interpretations and commentary.

SUMMARY: The Board and the Bureau are finalizing amendments to the official interpretations and commentary for the agencies' regulations that implement the Consumer Leasing Act (CLA). The Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) amended the CLA by requiring that the dollar threshold for exempt consumer leases be adjusted annually by the annual percentage increase in the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI–W). If there is no annual percentage increase in the CPI–W, the Board and the Bureau will not adjust this exemption threshold from the prior year. However, in years following a year in which the exemption threshold was not adjusted, the threshold is calculated by applying the annual percentage change in the CPI–W to the dollar amount that would have resulted, after rounding, if the decreases and any subsequent increases in the CPI–W had been taken into account. Based on the annual percentage increase in the CPI–W as of June 1, 2018, the exemption threshold will increase from $55,800 to $57,200 effective January 1, 2019.

Because the Dodd-Frank Act also requires similar adjustments in the Truth in Lending Act's threshold for exempt consumer credit transactions, the Board and the Bureau are making similar amendments to each of their respective regulations implementing the Truth in Lending Act elsewhere in this issue of the **Federal Register**.

DATES: This final rule is effective January 1, 2019.

FOR FURTHER INFORMATION CONTACT:

Board: Vivian W. Wong, Senior Counsel, Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, at (202) 452–3667; for users of Telecommunications Device for the Deaf (TDD) only, contact (202) 263–4869.

Bureau: Shelley Thompson, Counsel, Office of Regulations, Bureau of Consumer Financial Protection, at (202) 435–7700.

SUPPLEMENTARY INFORMATION:

I. Background

The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act) increased the threshold in the Consumer Leasing Act (CLA) for exempt consumer leases, and the threshold in the Truth in Lending Act (TILA) for exempt consumer credit transactions,[1] from $25,000 to $50,000, effective July 21, 2011.[2] In addition, the Dodd-Frank Act requires that, on and after December 31, 2011, these thresholds be adjusted annually for inflation by the annual percentage increase in the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI–W), as published by the Bureau of Labor Statistics. In April 2011, the Board issued a final rule amending Regulation M (which implements the CLA) consistent with these provisions of the Dodd-Frank Act, along with a similar final rule amending Regulation Z (which implements TILA) (collectively, the Board Final Threshold Rules).[3]

Title X of the Dodd-Frank Act transferred rulemaking authority for a number of consumer financial protection laws from the Board to the Bureau, effective July 21, 2011. In connection with this transfer of rulemaking authority, the Bureau issued its own Regulation M implementing the CLA, 12 CFR part 1013, substantially duplicating the Board's Regulation M.[4] Although the Bureau has the authority to issue rules to implement the CLA for most entities, the Board retains authority to issue rules under the CLA for certain motor vehicle dealers covered by section 1029(a) of the Dodd-Frank Act, and the Board's Regulation M continues to apply to those entities.[5]

The Board's and the Bureau's regulations,[6] and their accompanying commentaries, provide that the exemption threshold will be adjusted annually effective January 1 of each year based on any annual percentage increase in the CPI–W that was in effect on the preceding June 1. They further provide that any increase in the threshold amount will be rounded to the nearest $100 increment. For example, if the annual percentage increase in the CPI–W would result in a $950 increase in the threshold amount, the threshold amount will be increased by $1,000. However, if the annual percentage increase in the CPI–W would result in a $949 increase in the threshold amount, the threshold amount will be increased by $900.[7] Since 2011, the Board and the Bureau have adjusted the Regulation M exemption threshold annually, in accordance with these rules.

On November 30, 2016, the Board and the Bureau published a final rule in the **Federal Register** to memorialize the calculation method used by the agencies each year to adjust the exemption threshold to ensure that, as contemplated by section 1100E(b) of the Dodd-Frank Act, the values for the exemption threshold keep pace with the CPI–W (Regulation M Adjustment Calculation Rule).[8] The Regulation M Adjustment Calculation Rule memorialized the policy that, if there is no annual percentage increase in the CPI–W, the Board and Bureau will not adjust the exemption threshold from the prior year. The Regulation M Adjustment Calculation Rule also provided that, in years following a year in which the exemption threshold was not adjusted because there was a decrease in the CPI–W from the previous year, the threshold is calculated by applying the annual percentage change in the CPI–W to the dollar amount that would have resulted, after rounding, if the decreases and any subsequent increases in the CPI–W had been taken into account. If the resulting amount calculated, after rounding, is greater than the current threshold, then the threshold effective January 1 the following year will increase accordingly; if the resulting amount calculated, after rounding, is equal to or less than the current threshold, then the threshold effective January 1 the following year will not change, but future increases will be calculated based on the amount that would have resulted, after rounding.

II. 2019 Adjustment and Commentary Revision

Effective January 1, 2019, the exemption threshold amount is increased from $55,800 to $57,200. This is based on the CPI–W in effect on June 1, 2018, which was reported on May 10, 2018. The Bureau of Labor Statistics publishes consumer-based indices monthly, but does not report a CPI change on June 1; adjustments are reported in the middle of the prior month. The CPI–W is a subset of the CPI–U index (based on all urban consumers) and represents approximately 29 percent of the U.S. population. The CPI–W reported on May 10, 2018 reflects a 2.6 percent increase in the CPI–W from April 2017 to April 2018. Accordingly, the 2.6 percent increase in the CPI–W from April 2017 to April 2018 results in an exemption threshold amount of $57,200. The Board and the Bureau are revising the commentaries to their respective regulations to add new comment 2(e)–11.x to state that, from January 1, 2019 through December 31, 2019, the threshold amount is $57,200. These revisions are effective January 1, 2019.

[1] Although consumer credit transactions above the threshold are generally exempt, loans secured by real property or by personal property used or expected to be used as the principal dwelling of a consumer and private education loans are covered by TILA regardless of the loan amount. *See* 12 CFR 226.3(b)(1)(i) (Board) and 12 CFR 1026.3(b)(1)(i) (Bureau).

[2] Public Law 111–203, section 1100E, 124 Stat. 1376, 2111 (2010).

[3] 76 FR 18349 (Apr. 4, 2011); 76 FR 18354 (Apr. 4, 2011).

[4] *See* 76 FR 78500 (Dec. 19, 2011); 81 FR 25323 (April 28, 2016).

[5] Section 1029(a) of the Dodd-Frank Act states: ''Except as permitted in subsection (b), the Bureau may not exercise any rulemaking, supervisory, enforcement, or any other authority * * * over a motor vehicle dealer that is predominantly engaged in the sale and servicing of motor vehicles, the leasing and servicing of motor vehicles, or both.'' 12 U.S.C. 5519(a). Section 1029(b) of the Dodd-Frank Act states: ''Subsection (a) shall not apply to any person, to the extent that such person (1) provides consumers with any services related to residential or commercial mortgages or self-financing transactions involving real property; (2) operates a line of business (A) that involves the extension of retail credit or retail leases involving motor vehicles; and (B) in which (i) the extension of retail credit or retail leases are provided directly to consumers; and (ii) the contract governing such extension of retail credit or retail leases is not routinely assigned to an unaffiliated third party finance or leasing source; or (3) offers or provides a consumer financial product or service not involving or related to the sale, financing, leasing, rental, repair, refurbishment, maintenance, or other servicing of motor vehicles, motor vehicle parts, or any related or ancillary product or service.'' 12 U.S.C. 5519(b).

[6] 12 CFR 213.2(e)(1) (Board) and 12 CFR 1013.2(e)(1) (Bureau).

[7] *See* comments 2(e)–9 in Supplements I of 12 CFR parts 213 and 1013.

[8] *See* 81 FR 86256 (Nov. 30, 2016).

III. Regulatory Analysis

Administrative Procedure Act

Under the Administrative Procedure Act, notice and opportunity for public comment are not required if the Board and the Bureau find that notice and public comment are impracticable, unnecessary, or contrary to the public interest.[9] The amendments in this rule are technical and apply the method previously set forth in the Board Final Threshold Rules and the Regulation M Adjustment Calculation Rule. For these reasons, the Board and the Bureau have determined that publishing a notice of proposed rulemaking and providing opportunity for public comment are unnecessary. Therefore, the amendments are adopted in final form.

Regulatory Flexibility Act

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

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995,[11] the agencies reviewed this final rule. No collections of information pursuant to the Paperwork Reduction Act are contained in the final rule.

Bureau Congressional Review Act Statement

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Bureau will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to the rule taking effect. The Office of Information and Regulatory Affairs (OIRA) has designated this rule as not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

12 CFR Part 213

Advertising, Consumer leasing, Consumer protection, Federal Reserve System, Reporting and recordkeeping requirements.

12 CFR Part 1013

Advertising, Consumer leasing, Reporting and recordkeeping requirements, Truth in lending.

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

Authority and Issuance

For the reasons set forth in the preamble, the Board amends Regulation M, 12 CFR part 213, as set forth below:

PART 213—CONSUMER LEASING (REGULATION M)

■ 1. The authority citation for part 213 continues to read as follows:

Authority: 15 U.S.C. 1604 and 1667f; Pub. L. 111–203 section 1100E, 124 Stat. 1376.

■ 2. In Supplement I to Part 213, under *Section 213.2—Definitions,* under *2(e) Consumer Lease,* paragraph 11.x is added to read as follows:

Supplement I to Part 213—Official Staff Interpretations

* * * * *

Section 213.2—Definitions

* * * * *

2(e) Consumer Lease

* * * * *

11. * * *

x. From January 1, 2019 through December 31, 2019, the threshold amount is $57,200.

* * * * *

BUREAU OF CONSUMER FINANCIAL PROTECTION

Authority and Issuance

For the reasons set forth in the preamble, the Bureau amends Regulation M, 12 CFR part 1013, as set forth below:

PART 1013—CONSUMER LEASING (REGULATION M)

■ 3. The authority citation for part 1013 continues to read as follows:

Authority: 15 U.S.C. 1604 and 1667f; Pub. L. 111–203 section 1100E, 124 Stat. 1376.

■ 4. In Supplement I to part 1013, under *Section 1013.2—Definitions,* under *2(e)—Consumer Lease,* paragraph 11.x is added to read as follows:

Supplement I to Part 1013—Official Interpretations

* * * * *

Section 1013.2—Definitions

* * * * *

2(e) Consumer Lease

* * * * *

11. * * *

x. From January 1, 2019 through December 31, 2019, the threshold amount is $57,200.

* * * * *

By order of the Board of Governors of the Federal Reserve System, under delegated authority, November 7, 2018.

Ann E. Misback,

Secretary of the Board.

Dated: November 9, 2018.

Mick Mulvaney,

Acting Director, Bureau of Consumer Financial Protection.

[FR Doc. 2018–25396 Filed 11–21–18; 8:45 am]

BILLING CODE 4810–AM–P; 6210–01–P

FEDERAL RESERVE SYSTEM

12 CFR Part 226

[Docket No. R–1633]

RIN 7100–AF25

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1026

RIN 3170–AA90

Truth in Lending (Regulation Z)

AGENCY: Board of Governors of the Federal Reserve System (Board); and Bureau of Consumer Financial Protection (Bureau).

ACTION: Final rules, official interpretations and commentary.

SUMMARY: The Board and the Bureau are publishing final rules amending the official interpretations and commentary for the agencies' regulations that implement the Truth in Lending Act (TILA). The Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) amended TILA by requiring that the dollar threshold for exempt consumer credit transactions be adjusted annually by the annual percentage increase in the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI–W). If there is no annual percentage increase in the CPI–W, the Board and the Bureau will not adjust this exemption threshold from the prior year. However, in years following a year in which the exemption threshold was not adjusted, the threshold is calculated by applying the annual percentage change in the CPI–W to the dollar amount that would have resulted, after rounding, if the decreases and any subsequent increases in the CPI–W had been taken into account.

[9] 5 U.S.C. 553(b)(B).

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

[11] 44 U.S.C. 3506; 5 CFR part 1320.

Based on the annual percentage increase in the CPI–W as of June 1, 2018, the exemption threshold will increase from $55,800 to $57,200 effective January 1, 2019.

Because the Dodd-Frank Act also requires similar adjustments in the Consumer Leasing Act's threshold for exempt consumer leases, the Board and the Bureau are making similar amendments to each of their respective regulations implementing the Consumer Leasing Act elsewhere in this issue of the **Federal Register**.

DATES: This final rule is effective January 1, 2019.

FOR FURTHER INFORMATION CONTACT:

Board: Vivian W. Wong, Senior Counsel, Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, at (202) 452–3667; for users of Telecommunications Device for the Deaf (TDD) only, contact (202) 263–4869.

Bureau: Shelley Thompson, Counsel, Office of Regulations, Bureau of Consumer Financial Protection, at (202) 435–7700.

SUPPLEMENTARY INFORMATION:

I. Background

The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act) increased the threshold in the Truth in Lending Act (TILA) for exempt consumer credit transactions,[1] and the threshold in the Consumer Leasing Act (CLA) for exempt consumer leases, from $25,000 to $50,000, effective July 21, 2011.[2] In addition, the Dodd-Frank Act requires that, on and after December 31, 2011, these thresholds be adjusted annually for inflation by the annual percentage increase in the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI–W), as published by the Bureau of Labor Statistics. In April 2011, the Board issued a final rule amending Regulation Z (which implements TILA) consistent with these provisions of the Dodd-Frank Act, along with a similar final rule amending Regulation M (which implements the CLA) (collectively, the Board Final Threshold Rules).[3]

Title X of the Dodd-Frank Act transferred rulemaking authority for a number of consumer financial protection laws from the Board to the Bureau, effective July 21, 2011. In connection with this transfer of rulemaking authority, the Bureau issued its own Regulation Z implementing TILA, 12 CFR part 1026, substantially duplicating the Board's Regulation Z.[4] Although the Bureau has the authority to issue rules to implement TILA for most entities, the Board retains authority to issue rules under TILA for certain motor vehicle dealers covered by section 1029(a) of the Dodd-Frank Act, and the Board's Regulation Z continues to apply to those entities.[5]

The Board's and the Bureau's regulations,[6] and their accompanying commentaries, provide that the exemption threshold will be adjusted annually effective January 1 of each year based on any annual percentage increase in the CPI–W that was in effect on the preceding June 1. They further provide that any increase in the threshold amount will be rounded to the nearest $100 increment. For example, if the annual percentage increase in the CPI–W would result in a $950 increase in the threshold amount, the threshold amount will be increased by $1,000. However, if the annual percentage increase in the CPI–W would result in a $949 increase in the threshold amount, the threshold amount will be increased by $900.[7] Since 2011, the Board and the Bureau have adjusted the Regulation Z exemption threshold annually, in accordance with these rules.

On November 30, 2016, the Board and the Bureau published a final rule in the **Federal Register** to memorialize the calculation method used by the agencies each year to adjust the exemption threshold to ensure that, as contemplated by section 1100E(b) of the Dodd-Frank Act, the values for the exemption threshold keep pace with the CPI–W (Regulation Z Adjustment Calculation Rule).[8] The Regulation Z Adjustment Calculation Rule memorialized the policy that, if there is no annual percentage increase in the CPI–W, the Board and Bureau will not adjust the exemption threshold from the prior year. The Regulation Z Adjustment Calculation Rule also provided that, in years following a year in which the exemption threshold was not adjusted because there was a decrease in the CPI–W from the previous year, the threshold is calculated by applying the annual percentage change in the CPI–W to the dollar amount that would have resulted, after rounding, if the decreases and any subsequent increases in the CPI–W had been taken into account. If the resulting amount calculated, after rounding, is greater than the current threshold, then the threshold effective January 1 the following year will increase accordingly; if the resulting amount calculated, after rounding, is equal to or less than the current threshold, then the threshold effective January 1 the following year will not change, but future increases will be calculated based on the amount that would have resulted, after rounding.

II. 2019 Adjustment and Commentary Revision

Effective January 1, 2019, the exemption threshold amount is increased from $55,800 to $57,200. This is based on the CPI–W in effect on June 1, 2018, which was reported on May 10, 2018. The Bureau of Labor Statistics publishes consumer-based indices monthly, but does not report a CPI change on June 1; adjustments are reported in the middle of the prior month. The CPI–W is a subset of the CPI–U index (based on all urban consumers) and represents approximately 29 percent of the U.S. population. The CPI–W reported on May 10, 2018 reflects a 2.6 percent increase in the CPI–W from April 2017 to April 2018. Accordingly, the 2.6 percent increase in the CPI–W from April 2017 to April 2018 results in an exemption threshold amount of $57,200. The Board and the Bureau are revising the commentaries to their respective regulations to add new comment 3(b)–

[1] Although consumer credit transactions above the threshold are generally exempt, loans secured by real property or by personal property used or expected to be used as the principal dwelling of a consumer and private education loans are covered by TILA regardless of the loan amount. *See* 12 CFR 226.3(b)(1)(i) (Board) and 12 CFR 1026.3(b)(1)(i) (Bureau).

[2] Public Law 111–203, section 1100E, 124 Stat. 1376, 2111 (2010).

[3] 76 FR 18354 (Apr. 4, 2011); 76 FR 18349 (Apr. 4, 2011).

[4] *See* 76 FR 79768 (Dec. 22, 2011); 81 FR 25323 (Apr. 28, 2016).

[5] Section 1029(a) of the Dodd-Frank Act states: ''Except as permitted in subsection (b), the Bureau may not exercise any rulemaking, supervisory, enforcement, or any other authority * * * over a motor vehicle dealer that is predominantly engaged in the sale and servicing of motor vehicles, the leasing and servicing of motor vehicles, or both.'' 12 U.S.C. 5519(a). Section 1029(b) of the Dodd-Frank Act states: ''Subsection (a) shall not apply to any person, to the extent that such person (1) provides consumers with any services related to residential or commercial mortgages or self-financing transactions involving real property; (2) operates a line of business (A) that involves the extension of retail credit or retail leases involving motor vehicles; and (B) in which (i) the extension of retail credit or retail leases are provided directly to consumers; and (ii) the contract governing such extension of retail credit or retail leases is not routinely assigned to an unaffiliated third party finance or leasing source; or (3) offers or provides a consumer financial product or service not involving or related to the sale, financing, leasing, rental, repair, refurbishment, maintenance, or other servicing of motor vehicles, motor vehicle parts, or any related or ancillary product or service.'' 12 U.S.C. 5519(b).

[6] 12 CFR 226.3(b)(1)(ii) (Board) and 12 CFR 1026.3(b)(1)(ii) (Bureau).

[7] *See* comments 3(b)–1 in Supplements I of 12 CFR parts 226 and 1026.

[8] *See* 81 FR 86260 (Nov. 30, 2016).

3.x to state that, from January 1, 2019 through December 31, 2019, the threshold amount is $57,200. These revisions are effective January 1, 2019.

III. Regulatory Analysis

Administrative Procedure Act

Under the Administrative Procedure Act, notice and opportunity for public comment are not required if the Board and the Bureau find that notice and public comment are impracticable, unnecessary, or contrary to the public interest.[9] The amendments in this rule are technical and apply the method previously set forth in the Board Final Threshold Rules and the Regulation Z Adjustment Calculation Rule. For these reasons, the Board and the Bureau have determined that publishing a notice of proposed rulemaking and providing opportunity for public comment are unnecessary. Therefore, the amendments are adopted in final form.

Regulatory Flexibility Act

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

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995,[11] the agencies reviewed this final rule. No collections of information pursuant to the Paperwork Reduction Act are contained in the final rule.

Bureau Congressional Review Act Statement

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Bureau will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to the rule taking effect. The Office of Information and Regulatory Affairs (OIRA) has designated this rule as not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

12 CFR Part 226

Advertising, Consumer protection, Federal Reserve System, Reporting and recordkeeping requirements, Truth in lending.

12 CFR Part 1026

Advertising, Appraisal, Appraiser, Banking, Banks, Consumer protection, Credit, Credit unions, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations, Truth in lending.

Board of Governors of the Federal Reserve System

Authority and Issuance

For the reasons set forth in the preamble, the Board amends Regulation Z, 12 CFR part 226, as set forth below:

PART 226—TRUTH IN LENDING (REGULATION Z)

■ 1. The authority citation for part 226 continues to read as follows:

Authority: 12 U.S.C. 3806; 15 U.S.C. 1604, 1637(c)(5), 1639(l) and 1639h; Pub. L. 111–24, section 2, 123 Stat. 1734; Pub. L. 111–203, 124 Stat. 1376.

■ 2. In Supplement I to part 226, under *Section 226.3—Exempt Transactions,* under *3(b) Credit over applicable threshold amount,* paragraph 3.x is added to read as follows:

Supplement I to Part 226—Official Staff Interpretations

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Subpart A—General

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Section 226.3—Exemption Transactions

* * * * *

3(b) Credit over applicable threshold amount.

* * * * *

3. * * *

x. From January 1, 2019 through December 31, 2019, the threshold amount is $57,200.

* * * * *

Bureau of Consumer Financial Protection

Authority and Issuance

For the reasons set forth in the preamble, the Bureau amends Regulation Z, 12 CFR part 1026, as set forth below:

PART 1026—TRUTH IN LENDING (REGULATION Z)

■ 3. The authority citation for part 1026 continues to read as follows:

Authority: 12 U.S.C. 2601, 2603–2605, 2607, 2609, 2617, 3353, 5511, 5512, 5532, 5581; 15 U.S.C. 1601 *et seq.*

■ 4. In Supplement I to part 1026, under *Section 1026.3—Exempt Transactions,* under *3(b)—Credit Over Applicable Threshold Amount,* paragraph 3.x is added to read as follows:

Supplement I to Part 1026—Official Interpretations

* * * * *

Section 1026.3—Exempt Transactions

* * * * *

3(b) Credit Over Applicable Threshold Amount

* * * * *

3. * * *

x. From January 1, 2019 through December 31, 2019, the threshold amount is $57,200.

* * * * *

By order of the Board of Governors of the Federal Reserve System, under delegated authority, November 7, 2018.

Ann E. Misback,

Secretary of the Board.

Dated: November 9, 2018.

Mick Mulvaney,

Acting Director, Bureau of Consumer Financial Protection.

[FR Doc. 2018–25398 Filed 11–21–18; 8:45 am]

BILLING CODE 4810–AM–P; 6210–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0298; Product Identifier 2017–NM–179–AD; Amendment 39–19488; AD 2018–23–02]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Airbus SAS Model A318 and A319 series airplanes; Model A320–211, A320–212, A320–214, A320–216, A320–231, A320–232, and A320–233 airplanes; and Model A321–111, A321–112, A321–131, A321–211, A321–212, A321–213, A321–231, and A321–232 airplanes. This AD was prompted by reports of missing assembly hardware on the trimmable horizontal stabilizer actuator (THSA). This AD requires repetitive inspections and checks of the lower and upper THSA attachments and applicable related investigative and corrective actions; a one-time inspection of the THSA lower attachment and

[9] 5 U.S.C. 553(b)(B).

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

[11] 44 U.S.C. 3506; 5 CFR part 1320.

replacement as applicable; and, for certain airplanes, activation of the electrical load sensing device (ELSD) and concurrent modifications. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 28, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 28, 2018.

ADDRESSES: For Airbus SAS service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com*.

For United Technologies Corporation Aerospace Systems (UTAS) service information identified in this AD, contact United Technologies Corporation Aerospace Systems (UTAS): Goodrich Corporation, Actuation Systems, Stafford Road, Fordhouses, Wolverhampton WV10 7EH, England; phone: +44 (0) 1902 624938; fax: +44 (0) 1902 788100; email: *techpubs.wolverhampton@goodrich.com;* internet: *http://www.goodrich.com/TechPubs*

You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0298.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0298; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus SAS Model A318 and A319 series airplanes; Model A320–211, A320–212, A320–214, A320–216, A320–231, A320–232, and A320–233 airplanes; and Model A321–111, A321–112, A321–131, A321–211, A321–212, A321–213, A321–231, and A321–232 airplanes. The NPRM published in the **Federal Register** on April 16, 2018 (83 FR 16251). The NPRM was prompted by reports of missing assembly hardware on the THSA. The NPRM proposed to require repetitive inspections and checks of the lower and upper THSA attachments and applicable related investigative and corrective actions; a one-time inspection of the THSA lower attachment and replacement as applicable; and, for certain airplanes, activation of the ELSD and concurrent modifications.

We are issuing this AD to address uncontrolled movement of the horizontal stabilizer as a result of the latent (undetected) failure of the THSA's primary load path and consequent loss of control of the airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2017–0237, dated December 4, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus SAS Model A318 and A319 series airplanes; Model A320–211, A320–212, A320–214, A320–216, A320–231, A320–232, A320–233 airplanes; and Model A321–111, A321–112, A321–131, A321–211, A321–212, A321–213, A321–231, and A321–232 airplanes. The MCAI states:

> The Trimmable Horizontal Stabilizer Actuator (THSA) of Airbus A320 Family aeroplanes has been rig-tested to check secondary load path behaviour in case of primary load path failure. In that configuration, the loads are transferred to the secondary load path, which should jam, preventing any Trimmable Horizontal Stabilizer motion. The test results showed that the secondary load path did not jam as expected, preventing detection of the primary load path failure. To verify the integrity of the THSA primary load path and the correct installation of the THSA, Airbus issued Service Bulletin (SB) A320–27–1164, later revised multiple times, and SB A320–27A1179, and EASA issued AD 2006–0223 [which corresponds to FAA AD 2007–06–02, Amendment 39–14983 (72 FR 12072, March 15, 2007) (''AD 2007–06–02'')], AD 2007–0178 [which corresponds to FAA AD 2008–09–16, Amendment 39–15497 (73 FR 24160, May 2, 2008)(''AD 2008–09–16'')], AD 2008–0150, and AD 2014–0147, each AD superseding the previous one, requiring one-time and repetitive inspections.
>
> Since EASA AD 2014–0147 was issued, Airbus designed a new device, called Electrical Load Sensing Device (ELSD), to introduce a new means of THSA upper secondary load path engagement detection. Consequently, Airbus issued several SBs (Airbus SB A320–27–1245, A320–27–1246, and A320–27–1247, depending on aeroplane configuration) providing instructions to install the wiring provision for ELSD installation and to install ELSD on the THSA, and SB A320–27–1248, providing instructions to activate the ELSD. Airbus also revised SB A320–27–1164, now at Revision 13, including instructions applicable for aircraft equipped with ELSD.
>
> Furthermore, following a visual inspection of the THSA, an operator reported that the THSA was found with a bush missing, inducing torqueing of the THSA lower attachment primary bolt against the THSA lug, which resulted in the application of a transverse force on the lug.
>
> Prompted by several other identical findings, Airbus released Alert Operator Transmission (AOT) A27N010–17 to provide instructions for inspection and associated corrective actions.
>
> For the reasons described above, this AD retains the requirements of EASA AD 2014–0147, which is superseded, and requires installation of ELSD on the THSA, ELSD activation, and a one-time inspection to verify the bush presence on the THSA lower attachment.

The unsafe condition is uncontrolled movement of the horizontal stabilizer as a result of the latent (undetected) failure of the THSA's primary load path and consequent loss of control of the airplane.

The required actions include repetitive inspections and checks of the lower and upper THSA attachments and applicable related investigative and corrective actions; a one-time inspection of the THSA lower attachment and replacement as applicable; and, for certain airplanes, activation of the ELSD and concurrent modifications.

Related investigative actions include an inspection of the upper THSA attachment, an inspection of the lower attachment, and a check of the upper and lower clearance between the secondary nut trunnion and the junction plate. Corrective actions include replacement of the THSA and repair.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0298.

Comments

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

Support for the NPRM

The Air Line Pilots Association, International, stated its support for the NPRM. United Airlines stated that it has no objection to the NPRM.

Request To Allow Future Revisions of Service Information

Delta Air Lines (DAL) requested that the proposed AD allow operators the opportunity to utilize the latest data and instructions available without the need to request an alternative method of compliance (AMOC). DAL proposed that after each reference made to service information in paragraphs (g), (h), (i), (j), (k), (m)(1), and (m)(2) of the proposed AD, the following statement is included:

Or using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA).

DAL noted that the service information has been revised multiple times or has been revised within a short period of time. DAL observed that the statement quoted above is based on language used in paragraph (g) of AD 2018–03–12, Amendment 39–19185 (83 FR 5906, February 12, 2018) (''AD 2018–03–12''), and should be considered as standard wording for future ADs, as applicable.

We disagree with the commenter's request. We infer that the commenter is requesting a way for operators to comply with the requirements of an AD by using service information revisions that are issued after an AD is published without having to request an AMOC. We may not refer to any document that does not yet exist. In general terms, we are required by Office of the Federal Register (OFR) regulations for approval of materials ''incorporated by reference,'' as specified in 1 CFR 51.1(f), to either publish the service document contents as part of the actual AD language; or submit the service document to the OFR for approval as ''referenced'' material, in which case we may only refer to such material in the text of an AD. The AD may refer to the service document only if the OFR approved it for ''incorporation by reference.'' See 1 CFR part 51. To allow operators to use later revisions of the referenced document (issued after publication of the AD), either we must revise the AD to reference specific later revisions, or operators must request approval to use later revisions as an AMOC with this AD. However, we may consider approving global AMOCs to allow operators to use future revisions of the service information. We reserve the use of the wording requested by the commenter for situations where no service information is available or a service document, such as an aircraft maintenance manual, cannot be incorporated by reference in an AD. Therefore, we have not changed this AD in this regard.

Request To Specify Required Paragraphs in Airbus Alert Operators Transmission

DAL requested that paragraph (k) of the proposed AD specify only paragraphs 4.2.2 and 4.2.3 of Airbus Alert Operators Transmission (AOT) A27N010–17, Revision 01, dated October 17, 2017, including AOT Appendix_A27N010–17, because, as a whole, the service information contains data that are unrelated to the inspection process. Paragraphs 4.2.2 and 4.2.3 of the service information provide the inspection activities and corrective actions.

We agree with the commenter that the primary instructions for inspection and corrective actions are contained in paragraphs 4.2.2 and 4.2.3 of Airbus AOT A27N010–17, Revision 01, dated October 17, 2017, including AOT Appendix_A27N010–17. We have revised paragraph (k) of this AD to require only paragraphs 4.2.2 and 4.2.3 of Airbus AOT A27N010–17, Revision 01, dated October 17, 2017, including AOT Appendix_A27N010–17. Note that there is relevant information outside of those two paragraphs, such as references to part numbers, aircraft maintenance manual procedures, and an appendix. Procedures outside of paragraphs 4.2.2 and 4.2.3 can be deviated from, using accepted methods provided in an operator's maintenance or inspection program, provided the required AD actions can be done and the airplane can be put back in service in an airworthy condition.

Request To Modify Language Regarding Contacting the Manufacturer

DAL noted that paragraph (o) of the proposed AD provides exceptions to two Airbus service information documents—Airbus Service Bulletin A320–27–1164, Revision 13, dated August 8, 2016; and Airbus AOT A27N010–17, Revision 01, dated October 17, 2017, including AOT Appendix_A27N010–17, with respect to contacting the manufacturer. DAL proposed that this paragraph be rewritten to state:

Any approved method which specifies to contact the manufacturer: Before further flight, accomplish the corrective actions in accordance with the procedures specified in paragraph (v)(2) of this AD.

We acknowledge the commenter's request to clarify paragraph (o) of this AD. When specifying exceptions to required service information, we are unable to generalize the required documents by stating ''any approved method,'' as requested by the commenter. We must identify the specific service information. Therefore, we have not changed this AD in this regard.

Request for Clarification of Service Information Instructions

DAL observed that Airbus Service Bulletin A320–27–1245, Revision 00, dated March 6, 2017, indicates multiple configurations for certain aircraft. As an example, DAL pointed out that aircraft manufacturer serial number (MSN) 118 is shown as both configuration 078 and configuration 082. DAL stated the service information does not provide clear guidance on determining if both or only one set of material/instructions is applicable. DAL requested that the service bulletin be revised to clarify the intent of the multiple configurations and how to address them.

We disagree with the commenter's request to revise the service information; however, we agree to clarify. The referenced service information is adequate because different aircraft configurations can be determined based on the type of placard installed. Airbus Service Bulletin A320–27–1245, Revision 00, dated March 6, 2017, provides airplane configuration definitions in paragraph 1.A.(5), ''Configuration Definition,'' of the ''Planning Information'' section. According to the configuration definition, configuration 078 has placard 33LM PN D11311117A00 installed and configuration 082 has placard 33LM PN 002051–09 installed. Once the placard installation is determined, an operator can follow the instructions based on each respective configuration. We have not changed this AD in this regard.

Request for One Comprehensive AD To Address THSA System

DAL noted that the Model A319, A320, and A321 THSA system has had a continually complicated maintenance and regulatory history. The THSA system has been subject to numerous ADs throughout the years that address numerous individual shortcomings. The

proposed AD encompasses several different aspects (inspections and alterations), yet there are still other regulatory actions such as the replacement of No-Back Brake components or overhaul restrictions, which complicate the operators' maintenance activities. DAL requested that future regulatory actions related to the system be reviewed with a goal of providing a singular, coordinated over-arching regulatory and maintenance requirement.

We agree that there have been several ADs issued on the THSA system addressed in this AD, and we acknowledge the commenter's concerns. We understand that the EASA and the airplane manufacturer are making an effort to combine as many THSA issues as possible into a single rulemaking action to simplify the THSA requirements. In response to their efforts, we may consider additional rulemaking in the future to simplify the THSA requirements. However, at this time, we are issuing this final rule AD to address the specified unsafe condition. No change has been made to this AD in this regard.

Request To Refer to Revised Service Information

Airbus noted that two of the service bulletins referred to in the NPRM were revised and requested that the revised service bulletins be referred to in the final rule. The current revision levels are Airbus Service Bulletin A320–27–1164, Revision 14, dated January 16, 2018; and Airbus Service Bulletin A320–27–1248, Revision 01, dated April 16, 2018.

We agree with the commenter's request. In the NPRM we referred to Airbus Service Bulletin A320–27–1164, Revision 13, dated August 8, 2016; and Service Bulletin A320–27–1248, Revision 00, dated March 6, 2017. Airbus Service Bulletin A320–27–1164, Revision 14, dated January 16, 2018, includes clarifications regarding reporting inspection results but does not change the proposed reporting requirements of the NPRM and otherwise adds no substantive changes compared with the previous version. Airbus Service Bulletin A320–27–1248, Revision 01, dated April 16, 2018, clarifies the instructions, but adds no substantive changes compared with the previous version. We have therefore revised the ''Related Service Information under 1 CFR part 51'' paragraph in this final rule to refer to Airbus Service Bulletin A320–27–1164, Revision 14, dated January 16, 2018; and Airbus Service Bulletin A320–27–1248, Revision 01, dated April 16, 2018. We have also revised paragraphs (g), (h), (i), (j), and (o)(1) of this AD to refer to Airbus Service Bulletin A320–27–1164, Revision 14, dated January 16, 2018. In addition, we revised paragraph (m) of this AD to refer to Airbus Service Bulletin A320–27–1248, Revision 01, dated April 16, 2018.

Furthermore, we revised paragraph (s), ''Credit for Previous Actions,'' of this AD to include Airbus Service Bulletin A320–27–1164, Revision 13, dated August 8, 2016; and Service Bulletin A320–27–1248, Revision 00, dated March 6, 2017. Specifically, we revised paragraph (s)(1) to provide credit for actions done before the effective date of this AD using Airbus Service Bulletin A320–27–1164, Revision 10, dated March 27, 2014; Revision 11, dated December 15, 2014; Revision 12, dated March 23, 2016; or Revision 13, dated August 8, 2016. We also added paragraph (s)(3) to this AD to provide credit for actions required by paragraph (m)(1) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320–27–1248, Revision 00, dated March 6, 2017. We redesignated subsequent paragraphs of this AD accordingly.

Request To Supersede Affected ADs

Airbus requested that the FAA consider aligning with EASA's decision of superseding affected ADs instead of keeping the obsolete ADs active. We infer that Airbus is requesting that we supersede AD 2007–06–02 and AD 2008–09–16 instead of issuing this stand-alone AD that terminates the requirements of AD 2007–06–02 and AD 2008–09–16.

We acknowledge the commenter's request. Although paragraph (u) of this AD states ''Accomplishing the initial actions required by paragraphs (g) and (h) of this AD, and accomplishing the applicable actions required by paragraphs (i) and (j) of this AD, terminates all requirements of AD 2007–06–02 and AD 2008–09–16,'' it does not supersede those ADs. The purpose of issuing stand-alone AD actions is to reduce the complexity involved with superseding certain ADs. After certain compliance times in this AD have passed, we may consider rescinding AD 2007–06–02 and AD 2008–09–16 since they are terminated by certain actions in this AD. In addition, if we converted this AD to a supersedure, we would need to issue another notice for public comment, which would further delay issuance of this final rule. Therefore, we have not changed this AD in this regard.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule with the changes described previously and minor editorial changes. We have determined that these minor changes:

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

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this final rule.

Related Service Information Under 1 CFR Part 51

Airbus has issued Alert Operators Transmission (AOT) A27N010–17, Revision 01, dated October 17, 2017, including AOT Appendix_A27N010–17. This service information describes the procedure for a one-time general visual inspection of the THSA lower attachment to measure the gap between the THSA lower attachment tab washer and attachment plates and replacement of the THSA lower attachment if the measured gap is less than 0.5 mm. The replacement includes doing an inspection of the THSA parts to confirm the bushing is missing and applicable corrective actions (*i.e.,* repair).

Airbus has also issued Service Bulletin A320–27–1164, Revision 14, dated January 16, 2018. This service information describes procedures for a general visual inspection of the upper THSA attachment for correct installation, cracks, damage and metallic particles; a general visual inspection of the lower and upper THSA attachments for correct installation; a check of the clearance between secondary nut trunnions and junction plates and correct installation of the lower THSA attachment; a general visual inspection of the THSA ball screw to check for the absence of dents; and applicable related investigative and corrective actions.

In addition, Airbus has issued Service Bulletin A320–27–1245, Revision 00, dated March 6, 2017. This service information describes the procedure to modify the wiring provisions for the ELSD.

Airbus has also issued Service Bulletin A320–27–1246, Revision 01, dated November 4, 2016. This service information describes the procedures to adapt the wiring provision of the ELSD

and THSA to accommodate the correct installation of the ELSD.

Airbus has issued Service Bulletin A320–27–1247, Revision 00, dated March 6, 2017. This service information describes the procedure to modify the upper attachment secondary load path of the THSA to accommodate the correct installation of the ELSD.

Airbus has issued Service Bulletin A320–27–1248, Revision 01, dated April 16, 2018. This service information describes the procedure to activate the ELSD.

UTAS has issued United Technologies Corporation (UTC) Aerospace Systems Repair Instructions RF–DSC–1361–17, Version 00, including Appendix A, dated May 24, 2017. This service information describes the repair instructions to follow if the bushing is missing, as specified in AOT A27N010–17, Revision 01, dated October 17, 2017.

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

Costs of Compliance

We estimate that this AD affects 1,180 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections, check, activation, and modifications.	Up to 59 work-hours × $85 per hour = $5,015.	Up to $15,353 ...	Up to $20,368 ...	Up to $24,034,240.
Reporting	1 work-hour × $85 per hour = $85	0	85	100,300.

We estimate the following costs to do any necessary replacements that would be required based on the results of the inspections. We have no way of determining the number of aircraft that might need this replacement:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	11 work-hours × $85 per hour = $935	$240,000	$240,935

We have received no definitive data that would enable us to provide cost estimates for the on-condition repairs specified in this AD.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this AD is 2120–0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave., SW, Washington, DC 20591, ATTN: Information Collection Clearance Officer, AES–200.

Authority for This Rulemaking

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

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2018–23–02 Airbus SAS: Amendment 39–19488; Docket No. FAA–2018–0298; Product Identifier 2017–NM–179–AD.

(a) Effective Date

This AD is effective December 28, 2018.

(b) Affected ADs

This AD affects AD 2007–06–02, Amendment 39–14983 (72 FR 12072, March 15, 2007) (''AD 2007–06–02''); and AD 2008–09–16, Amendment 39–15497 (73 FR 24160, May 2, 2008) (''AD 2008–09–16'').

(c) Applicability

This AD applies to Airbus SAS Model A318–111, A318–112, A318–121, and A318–122 airplanes; Model A319–111, A319–112, A319–113, A319–114, A319–115, A319–131, A319–132, and A319–133 airplanes; Model A320–211, A320–212, A320–214, A320–216, A320–231, A320–232, and A320–233 airplanes; and Model A321–111, A321–112, A321–131, A321–211, A321–212, A321–213, A321–231, and A321–232 airplanes; certificated in any category, all manufacturer serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls.

(e) Reason

This AD was prompted by reports of missing assembly hardware on the trimmable horizontal stabilizer actuator (THSA). We are issuing this AD to address uncontrolled movement of the horizontal stabilizer as a result of the latent (undetected) failure of the THSA's primary load path and consequent loss of control of the airplane.

(f) Compliance

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

(g) Repetitive Actions: Lower THSA Attachment

Before exceeding 20 months since airplane first flight, or since airplane first flight following last THSA replacement, or within 20 months after the last inspection of the lower THSA attachment as specified in the instructions of Airbus Service Bulletin A320–27–1164, Revision 02 up to Revision 09, whichever occurs latest, do the actions specified in paragraphs (g)(1), (g)(2), and (g)(3) of this AD concurrently, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–27–1164, Revision 14, dated January 16, 2018. Repeat the actions thereafter at intervals not to exceed 20 months.

(1) Check the clearance between the secondary nut trunnions and the junction plates at the lower THSA attachment.

(2) Do a general visual inspection of the lower THSA attachment for correct installation of attachment parts.

(3) Do a general visual inspection of the THSA ball screw for dents.

(h) Repetitive Inspections: Upper THSA Attachment

Before exceeding 10 months since airplane first flight, or since airplane first flight following last THSA replacement, or within 10 months after the last inspection of the upper THSA attachment as specified in the instructions of Airbus Service Bulletin A320–27–1164, Revision 02 up to Revision 09, whichever occurs latest, do the actions specified in paragraphs (h)(1) and (h)(2) of this AD concurrently, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–27–1164, Revision 14, dated January 16, 2018. Repeat the inspections thereafter at intervals not to exceed 10 months.

(1) Do a general visual inspection of the upper THSA attachment for correct installation, cracks, damage, and metallic particles.

(2) Do a general visual inspection of the upper THSA attachment for correct installation of attachment parts.

(i) Related Investigative and Corrective Actions

If, during any action required by paragraph (g) or (h) of this AD, any discrepancy is detected (*e.g.,* any installation deviation, cracking, damage, metallic particles, or dent is found), before further flight, accomplish all applicable related investigative and corrective actions in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–27–1164, Revision 14, dated January 16, 2018; except as required by paragraph (o)(1) of this AD.

(j) Reporting Requirements for Actions Required by Paragraphs (g) and (h) of This AD

In case of any findings during any action required by paragraph (g) or (h) of this AD, report the inspection results to Airbus SAS using the applicable ''Inspection Reporting Sheet'' of Airbus Service Bulletin A320–27–1164, Revision 14, dated January 16, 2018, at the applicable time specified in paragraph (j)(1) or (j)(2) of this AD. If operators have reported findings as part of obtaining any corrective actions approved by the EASA Design Organization Approval (DOA), operators are not required to report those findings as specified in this paragraph.

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

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

(k) One-Time Inspection and Replacement

For airplanes on which the THSA has been replaced or reinstalled since the date of issuance of the original certificate of airworthiness, or the date of issuance of the original export certificate of airworthiness: Within 6 months after the effective date of this AD, accomplish a detailed inspection of the THSA lower attachment gap clearances, in accordance with paragraphs 4.2.2 and 4.2.3 of Airbus Alert Operators Transmission (AOT) A27N010–17, Revision 01, dated October 17, 2017, including AOT Appendix_A27N010–17. If the measured gap is less than 0.5 mm, before further flight, replace the THSA, including doing an inspection of the THSA parts to confirm the bushing is missing and applicable corrective actions, in accordance with the instructions of Airbus AOT A27N010–17, Revision 01, dated October 17, 2017, including AOT Appendix_A27N010–17; and United Technologies Corporation (UTC) Aerospace Systems Repair Instructions RF–DSC–1361–17, Version 00, including Appendix A, dated May 24, 2017, as applicable, except as required by paragraph (o)(2) of this AD.

(l) Definition of Groups

For the purpose of this AD: Group 1 airplanes are those that, on the effective date of this AD, do not have the electrical load sensing device (ELSD) activated. Group 2 airplanes are those that, on the effective date of this AD, have the ELSD activated.

(m) Activation and Concurrent Modification

For Group 1 airplanes (see paragraph (l) of this AD): Do the actions specified in paragraphs (m)(1) and (m)(2) of this AD.

(1) Within 4 years after the effective date of this AD, activate the ELSD of the THSA on the airplane, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–27–1248, Revision 01, dated April 16, 2018.

(2) Concurrently with or before the activation of the ELSD required by paragraph (m)(1) of this AD, modify the airplane, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–27–1245, Revision 00, dated March 6, 2017; or Airbus Service Bulletin A320–27–1246, Revision 01, dated November 4, 2016; as applicable.

(n) Concurrent Requirement for Airplanes Equipped With THSAs That do Not Have ELSDs

For an airplane equipped with a THSA having a part number listed in figure 1 to paragraphs (n), (p), and (q) of this AD: Concurrently with or before the activation required by paragraph (m)(1) of this AD, modify the airplane, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–27–1247, Revision 00, dated March 6, 2017.

Figure 1 to paragraphs (n), (p), and (q) of this AD: *Part Numbers for THSAs without ELSDs*

47145-021	47145-140
47145-030	47145-141
47145-031	47145-142
47145-032	47145-143
47145-033	47145-144
47145-034	47145-145
47145-035	47145-146
47145-036	47145-147
47145-037	47145-148
47145-050	47145-150
47145-051	47145-151
47145-052	47145-152
47145-053	47145-153
47145-054	47145-154
47145-055	47145-155
47145-056	47145-156
47145-057	47145-157
47145-121	47145-160
47145-130	47145-161
47145-131	47145-162
47145-132	47145-163
47145-133	47145-164
47145-134	47145-165
47145-135	47145-166
47145-136	47145-167
47145-137	47145-168

(o) Exceptions to Service Information

(1) Where Airbus Service Bulletin A320–27–1164, Revision 14, dated January 16, 2018, specifies to contact Airbus SAS for appropriate action, and specifies that action as ''RC'' (Required for Compliance): Before further flight, accomplish corrective actions in accordance with the procedures specified in paragraph (v)(2) of this AD.

(2) Where Airbus AOT A27N010–17, Revision 01, dated October 17, 2017, specifies to contact Airbus SAS for appropriate action: Before further flight, accomplish corrective actions in accordance with the procedures specified in paragraph (v)(2) of this AD.

(p) Parts Installation

Do not install on any airplane a THSA with a part number listed in figure 1 to paragraphs (n), (p), and (q) of this AD and do not deactivate the ELSD at the times specified in paragraph (p)(1) or (p)(2) of this AD, as applicable.

(1) Group 1 airplanes (see paragraph (l) of this AD): After modification of the airplane as required by paragraph (m)(1) of this AD.

(2) Group 2 airplanes (see paragraph (l) of this AD): From the effective date of this AD.

(q) Method of Compliance

An airplane on which Airbus SAS Modification 155955 has been embodied in production is considered compliant with paragraphs (m)(1), (m)(2), and (n) of this AD, provided that it is determined that no THSA with a part number listed in figure 1 to paragraphs (n), (p), and (q) of this AD is installed on that airplane, and that the ELSD remains activated. A review of airplane maintenance records is acceptable to make this determination, provided those records can be relied upon for that purpose.

(r) Airplanes Not Affected by the Requirements of Paragraph (k) of This AD

The inspection required by paragraph (k) of this AD is not required for airplanes on which the THSA has been installed, as specified in the instructions of Airbus A320 Airplane Maintenance Manual (AMM) 27–44–51–400–001, dated May 2017, or subsequent.

(s) Credit for Previous Actions

(1) This paragraph provides credit for the initial actions required by paragraphs (g), (h), (i), and (j) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320–27–1164, Revision 10, dated March 27, 2014; Revision 11, dated December 15, 2014; Revision 12, dated March 23, 2016; or Revision 13, dated August 8, 2016.

(2) This paragraph provides credit for actions required by paragraph (k) of this AD, if those actions were performed before the effective date of this AD using Airbus AOT A27N010–17, dated March 27, 2017.

(3) This paragraph provides credit for actions required by paragraph (m)(1) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320–27–1248, Revision 00, dated March 6, 2017.

(4) This paragraph provides credit for actions required by paragraph (m)(2) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320–27–1246, dated March 20, 2015.

(t) No Terminating Action for Repetitive Inspections in This AD

Accomplishment on an airplane of the one-time inspection and replacement, as applicable, specified in paragraph (k) of this AD and the modifications specified in paragraphs (m)(1), (m)(2), and (n) of this AD, as applicable, do not constitute terminating action for the repetitive inspections required by paragraphs (g) and (h) of this AD for that airplane.

(u) Terminating Action for Other FAA ADs

Accomplishing the initial actions required by paragraphs (g) and (h) of this AD, and accomplishing the applicable actions required by paragraphs (i) and (j) of this AD, terminate all requirements of AD 2007–06–02 and AD 2008–09–16.

(v) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (x)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus SAS's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(3) Paperwork Reduction Act Burden Statement: A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW, Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(4) Required for Compliance (RC): Except as specified in paragraph in (o)(1) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(w) Special Flight Permits

Special flight permits, as described in Section 21.197 and Section 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199), are not allowed.

(x) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2017–0237, dated December 4, 2017, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0298.

(2) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone and fax: 206–231–3223.

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

(y) Material Incorporated by Reference

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

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

(i) Airbus Alert Operators Transmission (AOT) A27N010–17, Revision 01, dated October 17, 2017, including AOT Appendix_A27N010–17.

(ii) Airbus Service Bulletin A320–27–1164, Revision 14, dated January 16, 2018.

(iii) Airbus Service Bulletin A320–27–1245, Revision 00, dated March 6, 2017.

(iv) Airbus Service Bulletin A320–27–1246, Revision 01, dated November 4, 2016.

(v) Airbus Service Bulletin A320–27–1247, Revision 00, dated March 6, 2017.

(vi) Airbus Service Bulletin A320–27–1248, Revision 01, dated April 16, 2018.

(vii) United Technologies Corporation Aerospace Systems (UTAS) United Technologies Corporation (UTC) Aerospace Systems Repair Instructions RF–DSC–1361–17, Version 00, including Appendix A, dated May 24, 2017.

(3) For Airbus SAS service information identified in this AD, contact Airbus SAS, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.*

(4) For United Technologies Corporation Aerospace Systems service information identified in this AD, contact United Technologies Corporation Aerospace Systems: Goodrich Corporation, Actuation Systems, Stafford Road, Fordhouses, Wolverhampton WV10 7EH, England; phone: +44 (0) 1902 624938; fax: +44 (0) 1902 788100; email: *techpubs.wolverhampton@goodrich.com;* internet: *http://www.goodrich.com/TechPubs.*

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

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

Issued in Des Moines, Washington, on October 24, 2018.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–24486 Filed 11–21–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0764; Product Identifier 2018–NM–074–AD; Amendment 39–19502; AD 2018–23–15]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Airbus SAS Model A330–200 Freighter series airplanes, Model A330–200 and –300 series airplanes, and Model A340–200 and –300 series airplanes. This AD was prompted by defects found during production tests of ram air turbine (RAT) units; investigation revealed that the defects were due to certain RAT hydraulic pumps having an alternative manufacturing process of the pump pistons. This AD requires replacing any defective RAT hydraulic pump with a serviceable part and re-identifying the RAT module part number. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 28, 2018.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 28, 2018.

ADDRESSES: For Airbus SAS service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com*; internet *http://www.airbus.com*. For UTC Aerospace service information identified in this final rule, contact UTC Aerospace Systems Goodrich Corporation, Actuation Systems, Stafford Road, Fordhouses, Wolverhampton, West Midlands WV10 7EH, England; phone: +44 (0) 1902 624644938; fax: +44 (0) 1902 788100624947; email: *techpubs.wolverhampton@goodrich.com*; internet: *https://www.customers.utcaerospacesystems.com*. You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0764.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0764; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax: 206–231–3229.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus SAS Model A330–200 Freighter series airplanes, Model A330–200 and –300 series airplanes, and Model A340–200 and –300 series airplanes. The NPRM published in the **Federal Register** on August 31, 2018 (83 FR 44514). The NPRM was prompted by defects found during production tests of RAT units; investigation revealed that the defects were due to certain RAT hydraulic pumps having an alternative manufacturing process of the pump pistons. The NPRM proposed to require replacing any defective RAT hydraulic pump with a serviceable part and re-identifying the RAT module part number. We are issuing this AD to address low performance of the pump, which, following a total engine flame-out, or during a total loss of normal electrical power generation, could result in reduced control of the airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0062, dated March 20, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus SAS Model A330–200 Freighter series airplanes, Model A330–200 and –300 series airplanes, and Model A340–200 and –300 series airplanes. The MCAI states:

> Four A330 RAT units were returned to the supplier due to low discharge pressure. These defects were detected during Airbus production tests. Subsequent investigations by the RAT manufacturer UTAS (formerly Hamilton Sundstrand) revealed that some RAT hydraulic pumps, [part number] P/N 5916430, were involved in an alternative manufacturing process of the pump pistons. This resulted in form deviations (rough surface finish and sharp edges), which caused excessive wear and damage to the bore where the pistons moved.
>
> This condition, if not corrected, could lead to low performance of the pump, possibly resulting in reduced control of the aeroplane, particularly if occurring following a total engine flame out, or during a total loss of normal electrical power generation.
>
> To address this potential unsafe condition, Airbus published [Service Bulletin] SB A330–29–3130 and SB A340–29–4098, providing instructions for identification and replacement of the affected parts.
>
> For the reasons described above, this [EASA] AD requires replacement of the affected parts. This [EASA] AD also requires re-identification of the RAT module.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0764.

Comments

We gave the public the opportunity to participate in developing this final rule. We have considered the comment received. The Air Line Pilots Association, International indicated its support for the NPRM.

New Service Information

We received UTC Aerospace Systems Service Bulletin ERPS06M–29–22, Revision 2, dated May 24, 2018. We referred to UTC Aerospace Systems Service Bulletins ERPS06M–29–22, dated March 17, 2017; and Revision 1, dated June 27, 2017; as the appropriate sources of service information for identifying certain affected serial numbers and parts therein. Revision 2 of the service information adds Hamilton Sundstrand and Parker hydraulic pump part number (P/N) 5917648 (Parker P/N 4207905) and alternate Hamilton Sundstrand and Parker hydraulic pump P/N 5916485 (Parker P/N 4207903) to table 3 and table 6 for clarification.

We have added UTC Aerospace Systems Service Bulletin ERPS06M–29–22, Revision 2, dated May 24, 2018, to the Related Service Information under 1 CFR part 51 section of this AD as an appropriate source of service information. We have also added Revision 2 of the service information to the definitions specified in paragraph (g)(1) of this AD.

Conclusion

We reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this final rule with the change described previously and minor editorial changes. We have determined that these minor changes:

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

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this final rule.

Related Service Information Under 1 CFR Part 51

Airbus SAS has issued Service Bulletins A330–29–3130 and A340–29–4098, both dated May 3, 2017. This service information describes procedures for replacing any affected RAT hydraulic pump with a serviceable part and re-identifying the RAT module part number. These documents are distinct since they apply to different airplane models.

UTC Aerospace Systems has issued Service Bulletins ERPS06M–29–22, dated March 17, 2017; Revision 1, dated June 27, 2017; and Revision 2, dated May 24, 2018. This service information identifies affected part and serial numbers for the RAT hydraulic pump. These documents are distinct since each one applies to different hydraulic pump part numbers.

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

Costs of Compliance

We estimate that this AD affects 103 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 14 work-hours × $85 per hour = Up to $1,190.	$0	Up to $1,190	Up to $122,570.

Authority for This Rulemaking

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

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2018–23–15 Airbus SAS: Amendment 39–19502; Docket No. FAA–2018–0764; Product Identifier 2018–NM–074–AD.

(a) Effective Date

This AD is effective December 28, 2018.

(b) Affected ADs

This AD affects AD 2016–14–01, Amendment 39–18582 (81 FR 44983, July 12, 2016; corrected August 16, 2016 (81 FR 51097, August 3, 2016)) (''AD 2016–14–01'').

(c) Applicability

This AD applies to the airplanes identified in paragraphs (c)(1), (c)(2), (c)(3), (c)(4), and (c)(5) of this AD, certificated in any category, all manufacturer serial numbers.

(1) Airbus SAS Model A330–223F and –243F airplanes.

(2) Airbus SAS Model A330–201, –202, –203, –223, and –243 airplanes.

(3) Airbus SAS Model A330–301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes.

(4) Airbus SAS Model A340–211, –212, –213 airplanes.

(5) Airbus SAS Model A340–311, –312, and –313 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 29, Hydraulic Power.

(e) Reason

This AD was prompted by defects found during production tests of ram air turbine (RAT) units; investigation revealed that the defects were due to certain RAT hydraulic pumps having an alternative manufacturing process of the pump pistons. We are issuing this AD to prevent low performance of the pump, which, following a total engine flame-out, or during a total loss of normal electrical power generation, could result in reduced control of the airplane.

(f) Compliance

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

(g) Definitions for This AD

(1) An affected part is a RAT hydraulic pump having part number (P/N) 5916430 and a serial number identified in UTC Aerospace Systems Service Bulletin ERPS06M–29–22, dated March 17, 2017; Revision 1, dated June 27, 2017; or Revision 2, dated May 24, 2018.

(2) A serviceable part is a RAT hydraulic pump identified as acceptable in Airbus Service Bulletin A330–29–3130 or A340–29–4098, both dated May 3, 2017, as applicable.

(3) Group 1 airplanes are airplanes on which an affected part is installed.

(4) Group 2 airplanes are airplanes on which no affected part is installed. A Model A330 airplane on which Airbus SAS Modification 206604 has been embodied in production is a Group 2 airplane, provided that the airplane remains in that configuration.

(h) Replacement and Re-identification for Group 1 Airplanes

(1) Within 18 months after the effective date of this AD, replace any affected RAT hydraulic pump with a serviceable part, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–29–3130 or A340–29–4098, both dated May 3, 2017, as applicable.

(2) Concurrently with the replacement required by paragraph (h)(1) of this AD, re-identify the part number of the RAT module, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–29–3130 or A340–29–4098, both dated May 3, 2017, as applicable.

Note 1 to paragraph (h)(2) of this AD: Airbus Service Bulletins A330–29–3130 and A340–29–4098, both dated May 3, 2017, provide guidance for re-identification of the part numbers of the RAT hydraulic pumps that are not affected, and the part numbers of the RAT modules that are not equipped with an affected hydraulic pump.

(i) Compliance With AD 2016–14–01

After re-identification of a RAT module on an airplane, as required by paragraph (h)(2) of this AD, the airplane remains compliant with the RAT module re-identification requirements of AD 2016–14–01 for that airplane.

(j) Parts Installation Prohibition

(1) For Group 1 airplanes: After replacement of any affected RAT hydraulic pump as required by paragraph (h)(1) of this AD, do not install any affected RAT hydraulic pump.

(2) For Group 2 airplanes: As of the effective date of this AD, do not install any affected RAT hydraulic pump.

(k) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to the attention of the person identified in paragraph (l)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or The European Aviation Safety Agency (EASA); or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2018–0062, dated March 20, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0764.

(2) For more information about this AD, contact Vladimir Ulyanov, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax: 206–231–3229.

(m) Material Incorporated by Reference

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

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

(i) Airbus Service Bulletin A330–29–3130, dated May 3, 2017.

(ii) Airbus Service Bulletin A340–29–4098, dated May 3, 2017.

(iii) UTC Aerospace Systems Service Bulletin ERPS06M–29–22, dated March 17, 2017.

(iv) UTC Aerospace Systems Service Bulletin ERPS06M–29–22, Revision 1, dated June 27, 2017.

(v) UTC Aerospace Systems Service Bulletin ERPS06M–29–22, Revision 2, dated May 24, 2018.

(3) For Airbus SAS service information identified in this AD, contact Airbus SAS, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.*

(4) For UTC Aerospace service information identified in this final rule, contact UTC Aerospace Systems Goodrich Corporation, Actuation Systems, Stafford Road, Fordhouses, Wolverhampton, West Midlands WV10 7EH, England; phone: +44 (0) 1902 624644938; fax: +44 (0) 1902 788100624947; email: *techpubs.wolverhampton@goodrich.com;* internet: *https://www.customers.utcaerospacesystems.com.*

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

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

Issued in Des Moines, Washington, on November 8, 2018.

Chris Spangenberg,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–25387 Filed 11–21–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0632; Product Identifier 2017–NE–16–AD; Amendment 39–19487; AD 2018–23–01]

RIN 2120–AA64

Airworthiness Directives; Zodiac Seats France Cabin Attendant Seats

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Zodiac Seats France 536 Series Cabin Attendant Seats. This AD was prompted by cracks found in a highly concentrated stress area of the seat pan hinges. This AD requires repetitive inspections and replacement of the seat pan. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 28, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 28, 2018.

ADDRESSES: For service information identified in this final rule, contact Zodiac Seats France, Rue Robert Marechal Senior B.P. 69, 36100 Issoudun, France; phone: +33 (0) 2 54 03 39 39; fax: +33 (0) 2 54 03 39 00; email: *zs.tac@zodiacaerospace.com;* internet: *https://services.zodiacaerospace.com.* You may view this service information at the FAA, Engine & Propeller Standards Branch, 1200 District Avenue, Burlington, MA, 01803. For information on the availability of this material at the FAA, call 781–238–7759. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0632.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0632; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–

30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, 20590.

FOR FURTHER INFORMATION CONTACT: Dorie Resnik, Aerospace Engineer, Boston ACO Branch, FAA, 1200 District Avenue, Burlington, MA, 01803; phone: 781–238–7693; fax: 781–238–7199; email: *dorie.resnik@faa.gov*.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking NPRM to amend 14 CFR part 39 by adding an AD that would apply to certain Zodiac Seats France 536 Series Cabin Attendant Seats. The NPRM published in the **Federal Register** on December 22, 2017 (82 FR 60690). The NPRM was prompted by cracks found in a highly concentrated stress area of the seat pan hinges. The NPRM proposed to require repetitive inspections of the affected cabin attendant seats and, depending on findings, replacement of the seat pan. We are issuing this AD to address the unsafe condition on these products.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2017–0001, dated January 6, 2017 (referred to after this as ''the MCAI'') to correct an unsafe condition for the specified products. The MCAI states:

> Cases of cracks were found on Zodiac Seats France cabin attendant seats 536 series installed on some ATR 42 and ATR 72 aeroplanes. The detected damage was located in the area of the seat pan hinges. Investigations identified that fatigue had caused these cracks in a highly concentrated stress area.
>
> This condition, if not detected and corrected, could lead to failure of the seat, possibly resulting in injury to the seat occupant.
>
> To address this potential unsafe condition, Zodiac Seats France issued Service Bulletin (SB) 536–25–003 to provide inspection and replacement instructions. Consequently, EASA issued AD 2016–0164, requiring repetitive visual inspections of the affected cabin attendant seats and, depending on findings, replacement of the seat pan.
>
> Since that AD was issued, Zodiac Seats France developed a reinforced seat pan, and revised SB 536–25–003 accordingly. After installation of a reinforced seat pan, the seat P/N amendment status is updated.
>
> For the reason described above, this AD retains the requirements of EASA AD 2016–0164, which is superseded, prohibits installation of unreinforced seat pans on seats already modified, and introduces the reinforced seat pan installation as optional terminating action for the repetitive inspections.

You may obtain further information by examining the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0632.

Comments

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

Conclusion

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

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

Related Service Information Under 1 CFR Part 51

We reviewed Zodiac Seats France Service Bulletin (SB) No. 536–25–003, Rev. 3, dated June 2, 2017. The SB describes procedures for inspection, modification, or replacement of the seat pan of certain model seats known to be installed on ATR 42 and ATR 72 airplanes. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 55 seat assemblies installed on, but not limited to, ATR 42 and ATR 72 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Seat inspection, modification, or replacement	1.2 work-hours × $85 per hour = $102	$1,500	$1,602	$88,110

According to the manufacturer, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

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

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

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to engines, propellers, and associated appliances to the Manager, Engine and Propeller Standards Branch, Policy and Innovation Division.

Regulatory Findings

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

For the reasons discussed above, I certify this AD:

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2018–23–01 Zodiac Seats France (formerly SICMA Aero Seat): Amendment 39–19487; Docket No. FAA–2017–0632; Product Identifier 2017–NE–16–AD.

(a) Effective Date

This AD is effective December 28, 2018.

(b) Affected ADs

None.

(c) Applicability

(1) This AD applies to all Zodiac Seats France Cabin Attendant Seats, 536 Series, part numbers (P/N) 53600, all dash numbers, and all serial numbers, with seat pan P/N F0433453, installed.

(2) These appliances are installed on, but not limited to, ATR 42 and ATR 72 airplanes of U.S. registry.

(d) Subject

Joint Aircraft System Component (JASC) Code 2500, Cabin Equipment/Furnishings.

(e) Unsafe Condition

This AD was prompted by cracks found in a highly concentrated stress area of the seat pan hinges. We are issuing this AD to prevent failure of affected seats. The unsafe condition, if not addressed, could result in injury to the seat occupants.

(f) Compliance

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

(g) Required Actions

(1) Before exceeding 2,500 flight cycles (FCs), or within 100 FCs after the effective date of this AD, whichever occurs later, inspect the seat pan structure in both deployed and stowed positions using paragraph 2.A., Accomplishment Instructions, of Zodiac Seats France Service Bulletin (SB) No. 536–25–003, Rev. 3, dated June 2, 2017.

(2) If cracks are found, before the next flight:

(i) Replace seat pan with reinforced seat pan, P/N F0511530, using paragraph 2.B., Accomplishment Instructions, of Zodiac Seats France SB No. 536–25–003, Rev. 3, dated June 2, 2017.

(ii) Re-mark the seat using paragraph 2.C., Accomplishment Instructions, of Zodiac Seats France SB No. 536–25–003, Rev. 3, dated June 2, 2017.

(3) If no cracks are found, do the following:

(i) Re-mark the seat using paragraph 2.C., Accomplishment Instructions, of Zodiac Seats France SB No. 536–25–003, Rev. 3, dated June 2, 2017.

(ii) Reinspect the seat pan every 100 FCs since last inspection, or replace seat pan with reinforced seat pan, P/N F0511530, using paragraph 2.B., Accomplishment.

Instructions, of Zodiac Seats France SB No. 536–25–003, Rev. 3, dated June 2, 2017.

(4) After the effective date of this AD, and until compliance with this AD is accomplished, stow and secure an affected attendant seat in the retracted position to prevent occupancy, in accordance with the provisions and limitations of the applicable Master Minimum Equipment List item.

(h) Optional Terminating Action

Installation of a reinforced seat pan, P/N F0511530, using paragraph 2.B., Accomplishment Instructions, of Zodiac Seats France SB No. 536–25–003, Rev. 3, dated June 2, 2017, is terminating action to this AD.

(i) Credit for Previous Actions

You may take credit for inspections and modifications performed in accordance with Zodiac Seats France SB No. 536–25–003, Rev. 2, dated September 16, 2016, or earlier versions, if you performed these actions before the effective date of this AD.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO Branch, send it to the attention of the person identified in paragraph (k)(1) of this AD. You may email your request to: *9-ane-boston-aco-amocrequests@faa.gov.*

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

(k) Related Information

(1) For more information about this AD, contact Dorie Resnik, Aerospace Engineer, Boston ACO Branch, FAA, 1200 District Avenue, Burlington, MA, 01803; phone: 781–238–7693; fax: 781–238–7199; email: *dorie.resnik@faa.gov.*

(2) Refer to MCAI EASA AD 2017–0001, dated January 6, 2017, for more information. You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2017–0632.

(l) Material Incorporated by Reference

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

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

(i) Zodiac Seats France Service Bulletin No. 536–25–003, Rev. 3, dated June 2, 2017.

(ii) [Reserved.]

(3) For Zodiac Seats France service information identified in this AD, contact Zodiac Seats France, Rue Robert Marechal Senior B.P. 69, 36100 Issoudun, France; phone: +33 (0) 2 54 03 39 39; fax: +33 (0) 2 54 03 39 00; email: *zs.tac@zodiac*aerospace.com; internet: *https://services.zodiacaerospace.com.*

(4) You may view this service information at FAA, Engine & Propeller Standards Branch, 1200 District Avenue, Burlington, MA, 01803. For information on the availability of this material at the FAA, call 781–238–7759.

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

Issued in Burlington, Massachusetts, on November 16, 2018.

Robert J. Ganley,

Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2018–25436 Filed 11–21–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9392; Product Identifier 2016–NM–003–AD; Amendment 39–19499; AD 2018–23–12]

RIN 2120–AA64

Airworthiness Directives; Zodiac Aero Evacuation Systems (also known as Air Cruisers Company)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for Zodiac Aero Evacuation Systems (also known as Air Cruisers Company) fusible plugs installed on emergency evacuation equipment for various transport category airplanes. This AD was prompted by reports indicating that affected fusible plugs activated (vented gas) below the rated temperature. This AD requires an inspection of the fusible plugs to determine the part number and lot number, and replacement of all affected fusible plugs. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 28, 2018.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 28, 2018.

ADDRESSES: For service information identified in this final rule, contact Air Cruisers, 1747 State Route 34, Wall Township, NJ 07727–3935; phone 732–681–3527; email *technicalpublications@zodiacaerospace.com*. You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9392.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9392; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Darren Gassetto, Aerospace Engineer, Mechanical Systems and Admin Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7323; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov*.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to Zodiac Aero Evacuation Systems (also known as Air Cruisers Company) fusible plugs installed on emergency evacuation equipment for various transport category airplanes. The NPRM published in the **Federal Register** on November 18, 2016 (81 FR 81709). The NPRM was prompted by reports indicating that affected fusible plugs activated (vented gas) below the rated temperature. The NPRM proposed to require an inspection of the fusible plugs to determine the part number and lot number, and replacement of all affected fusible plugs.

We subsequently issued a supplemental NPRM (SNPRM) that was published in the **Federal Register** on January 24, 2018 (83 FR 3283). The SNPRM proposed to extend the compliance time, clarify the applicability, and clarify certain requirements.

We are issuing this AD to address fusible plugs that might activate below the rated temperature and render the evacuation system unusable.

Comments

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

Request to Extend Compliance Time

Airlines for America (A4A), on behalf of its members, requested that we extend the compliance time specified in paragraph (h) of the proposed AD (in the SNPRM). A4A stated that the extended compliance time of 42 months after the effective date (in paragraph (g) of the proposed AD (in the SNPRM)) had an unintended consequence in the re-worded compliance paragraph (h) of the proposed AD (in the SNPRM). A4A noted that while the allowance for maintenance records inspection was added, the words ''[b]efore further flight'' remained. A4A concluded that the current version means that either a planeside finding or a maintenance records discovery will each require action before further flight. A4A stated that while a finding by direct inspection will happen only in a shop and not affect operation of any aircraft, the accommodation for records review could immediately ground an in-service aircraft. A4A requested that we allow 42 months for the replacement if a records review was done.

We agree to revise the compliance time in paragraph (h) of this AD because we have determined that a compliance time of 42 months to replace the affected part addresses the unsafe condition and provides an acceptable level of safety. We have revised paragraph (h) of the AD to specify a 42-month compliance time for the replacement.

Request To Specify Serial Numbers

All Nippon Airways (ANA) requested that we revise paragraph (c) of the proposed AD (in the SNPRM) to refer to service information that specifies the serial numbers and not only the part numbers of the affected emergency equipment. ANA stated that identifying affected [parts] by only the part number means that even after expiration of the compliance time specified in the proposed AD, the inspection must be continued every time the affected emergency equipment is purchased. ANA stated that the serial number of the affected emergency equipment should be specified in the service information listed in paragraph (c) of the proposed AD (in the SNPRM) in order to prevent endless inspections.

We do not agree because specific serial numbers for the affected emergency equipment have not been identified. In addition, since the fusible plugs are rotable we cannot limit the applicability to only the known emergency equipment on which the fusible plugs were initially installed. Therefore, in order to address the identified unsafe condition, all fusible plugs installed on emergency evacuation equipment identified in the service information specified in paragraph (c) of this AD must be inspected as specified in paragraph (g) of this AD. When installing new equipment on an airplane, operators must ensure the newly installed part is not one of the affected parts by complying with the parts installation prohibition specified in paragraph (i) of this AD. We have not changed this AD in this regard.

Request To Refer to Service Information

Southwest Airlines (SWA) and A4A, on behalf of its members, requested that we refer to service information for accomplishing the actions specified in paragraph (g) of the proposed AD (in the SNPRM). SWA stated that the Air Cruisers service bulletins listed in paragraphs (c)(1) through (c)(16) of the proposed AD (in the SNPRM) have steps to inspect for the affected fusible plugs and to remove fusible plugs that are stamped with Lot PA–21 or PA–22. SWA noted that the service bulletins have been incorporated into the various

Air Cruisers component maintenance manuals (CMMs). A4A stated that the service bulletins and CMMs specify an inspection for the suspect fusible plug lot numbers and replacement if found.

A4A and SWA also stated that maintenance records would not indicate the level of detail of the fusible plug part numbers and lot numbers installed. SWA stated that the revision of the CMM used to make the components serviceable is noted on FAA Form 8130–3. A4A also stated that access to the fusible plug part number and lot number is not achievable planeside, and noted that the equipment manufacturer recommends the system to be unpacked and inspected in the slide shop. SWA and A4A requested that paragraph (g) of the proposed AD (in the SNPRM) be revised to specify accomplishing the inspection in accordance with the applicable service information specified in paragraphs (c)(1) through (c)(16) of the proposed AD (in the SNPRM) and/or the applicable component maintenance manuals.

We do not agree with revising paragraph (g) of this AD to mandate service information because this AD does not require operators to accomplish the inspection using a specific method. However, we do agree that operators should be aware of the service information that can be used to do the inspection specified in paragraph (g) of this AD. Therefore, we have added Note 1 to paragraph (g) of this AD to specify service bulletins and CMMs that provide guidance for performing the inspection. We have redesignated subsequent notes in this AD accordingly.

We also acknowledge the commenters' statement that the records review might not be conclusive. As stated in paragraph (g) of this AD, the records review is allowed only if operators can conclusively determine the part number and lot number. For operators that do not have records that can conclusively determine the part number and lot number, the inspection must be done.

Request To Remove Paragraph (h) of the Proposed AD (in the SNPRM)

SWA requested that we remove paragraph (h) of the proposed AD (in the SNPRM). SWA stated that paragraph (h) of the proposed AD (in the SNPRM) would require immediate removal of the emergency equipment if an inspection or a records review determines an affected part is installed. SWA suggested that paragraph (h) of the proposed AD (in the SNPRM) be deleted because it is unnecessary. SWA stated the emergency equipment must be removed from the aircraft in order to inspect for the affected fusible plug. SWA noted the component maintenance documents do not provide the level of detail of the fusible plug part numbers and lot numbers installed.

We do not agree with removing paragraph (h) of this AD because in order to address the unsafe condition the affected fusible plug must not only be removed but must also be replaced as required by paragraph (h) of this AD. We have not changed this AD in this regard. However, as stated previously, we have revised the compliance time in paragraph (h) of this AD to specify replacing within 42 months instead of requiring immediate action.

Request for Credit for Actions Done Using Certain Service Information

SWA requested that we give credit for inspections of the affected fusible plugs previously done per Air Cruisers service bulletins and/or CMMs incorporating the requirements of the Air Cruisers service bulletins.

We agree to clarify. We have not mandated specific service information for accomplishing the actions specified in paragraphs (g) and (h) of this AD; therefore, it is not necessary to give credit for using specific service information. For operators that have already accomplished the actions required by paragraphs (g) and (h) of this AD, credit is given as specified in paragraph (f) of this AD, which states to accomplish the required actions within the compliance times specified, ''unless already done.'' Therefore, if operators have accomplished the actions required for compliance with paragraphs (g) and (h) of this AD before the effective date of this AD, no further action is necessary.

Request To Revise Parts Installation Prohibition

A4A, on behalf of its members, requested that we revise paragraph (i) of the proposed AD (in the SNPRM) to specify that no person may install on any airplane any slide, slide/raft, or off-wing escape system unless the inspection of the fusible plug has been done per the applicable service information specified in paragraphs (c)(1) through (c)(16) of the proposed AD (in the SNPRM) and/or the applicable CMM listed in Air Cruisers Service Information Letter (SIL) 25–246, Rev. No. 2, dated January 24, 2017. A4A stated that paragraph (i) of the proposed AD (in the SNPRM) does not sufficiently close the door on direct inspection of the plug, which can only be accomplished by unpacking slides and complete disassembly. A4A stated that only the inspection of records (including service bulletin accomplishment information directly stamped on the slide) can reasonably accomplish the intention of the proposed AD in a practical manner.

We do not agree because we have not mandated the service information specified by the commenter. In order to comply with paragraph (i) of this AD, operators must prevent the installation of an affected part on an airplane. Paragraph (i) of this AD does not mandate a specific method for operators to follow to ensure the affected part is not installed. We have not changed this AD in this regard.

Request To Revise Cost Estimate

A4A, on behalf of its members, requested that we revise the cost estimate. A4A stated that the NPRM assumes one hour of labor per aircraft. A4A noted that because the actions need to be done at an appropriate facility (off wing and often not the operator's own shop), the cost should be per system, and include all facets from uninstalling through reinstallation. A4A stated the operator's actions will consume closer to 4 hours per slide (at $85/hour), with the addition of $500 each way shipping, and the vendor cost (Zodiac's typical billing is $2,900 per slide).

We agree with revising the cost estimate because operators that cannot do a records review will need to remove the affected emergency equipment to accomplish the inspection. We disagree with including the shipping and vendor costs because not all operators will need to ship the equipment in order to do the inspection or records review. We have revised the Costs of Compliance section in this final rule to specify up to 4 work-hours for the inspection.

Clarification of Replacement Part

In paragraph (h) of the proposed AD (in the SNPRM), we specified to replace the fusible plug with a new part that does not have P/N B13984–3, stamped with Lot PA–21 or PA–22. However, we have determined that it is not necessary for the replacement part to be a new part. Therefore, we have revised paragraph (h) of this AD to specify to replace the fusible plug with a serviceable fusible plug P/N B13984–3 that is not stamped with Lot PA–21 or PA–22.

Additional Affected Parts—Other Related Service Information

We have reviewed Air Cruisers Service Information Letter (SIL) 25–246, Rev. No. 2, dated January 24, 2017, which indicates additional fusible plugs

might be affected by the identified unsafe condition. We have determined that to delay this action in order to allow the public to comment on the merits of inspecting the additional fusible plugs would be inappropriate, since we have determined that an unsafe condition exists and that inspections must be conducted to ensure continued safety. We are considering additional rulemaking to address additional fusible plugs.

Clarification of Manufacturer's Name

In the Summary of the SNPRM, we noted that Zodiac Aero Evacuation Systems was formerly known as Air Cruisers. However, Zodiac Aero Evacuation Systems is also known as Air Cruisers Company. For clarity, we have referred to the manufacturer as Zodiac Aero Evacuation Systems (also known as Air Cruisers Company) throughout this final rule.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule with the changes described previously and minor editorial changes. We have determined that these minor changes:

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

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this final rule.

Related Service Information Under 1 CFR Part 51

We reviewed the following Air Cruisers service information. The service information identifies the affected fusible plugs. In addition, it describes procedures for inspecting and replacing affected fusible plugs. These documents are distinct since they apply to different airplane models or configurations.

- Air Cruisers Service Bulletin 737 103–25–50, dated August 27, 2010.
- Air Cruisers Service Bulletin 757 105–25–80, dated August 27, 2010.
- Air Cruisers Service Bulletin 757 105–25–81, dated August 27, 2010.
- Air Cruisers Service Bulletin 767 106–25–10, Rev. No. 1, dated October 15, 2010.
- Air Cruisers Service Bulletin 777 107–25–29, Rev. No. 1, dated July 8, 2011.
- Air Cruisers Service Bulletin A300/A310 001–25–19, dated August 27, 2010.
- Air Cruisers Service Bulletin A300/A310 003–25–33, dated August 27, 2010.
- Air Cruisers Service Bulletin A310 002–25–08, dated August 27, 2010.
- Air Cruisers Service Bulletin A320 004–25–87, Rev. No. 2, dated January 7, 2011.
- Air Cruisers Service Bulletin A321 005–25–21, dated August 27, 2010.
- Air Cruisers Service Bulletin BAe 146 201–25–23, dated December 10, 2010.
- Air Cruisers Service Bulletin F28 352–25–02, dated December 10, 2010.
- Air Cruisers Service Bulletin F100 351–25–07, dated December 10, 2010.
- Air Cruisers Service Bulletin Liferaft 35–25–79, dated August 27, 2010.
- Air Cruisers Service Bulletin MD11 305–25–35, dated August 27, 2010.
- Air Cruisers Service Bulletin MD80/90/717 304–25–45, dated August 27, 2010.

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

Costs of Compliance

We estimate that this AD affects 3,384 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Determination of part and lot number.	Up to 4 work-hours × $85 per hour = Up to $340.	$0	Up to $340	Up to $1,150,560.

We estimate the following costs per slide to do any necessary replacement of the fusible plug that would be required based on the results of the inspection. We have no way of determining the number of aircraft that might need these replacements:

ON-CONDITION COST

Action	Labor cost	Parts cost	Cost per product
Replacement	1 work-hour × $85 per hour = $85	Not available	$85

According to the manufacturer, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all available costs in our cost estimate.

Authority for This Rulemaking

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

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

products identified in this rulemaking action.

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2018–23–12 Zodiac Aero Evacuation Systems (also known as Air Cruisers Company): Amendment 39–19499; Docket No. FAA–2016–9392; Product Identifier 2016–NM–003–AD.

(a) Effective Date

This AD is effective December 28, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Zodiac Aero Evacuation Systems (also known as Air Cruisers Company) fusible plugs installed on emergency evacuation equipment identified in the service information specified in paragraphs (c)(1) through (c)(16) of this AD. These affected fusible plugs might be installed on the emergency evacuation equipment of the following manufacturers' airplanes: Airbus, The Boeing Company, BAE Systems (Operations) Limited, and Fokker Services B.V.

(1) Air Cruisers Service Bulletin 737 103–25–50, dated August 27, 2010.

(2) Air Cruisers Service Bulletin 757 105–25–80, dated August 27, 2010.

(3) Air Cruisers Service Bulletin 757 105–25–81, dated August 27, 2010.

(4) Air Cruisers Service Bulletin 767 106–25–10, Rev. No. 1, dated October 15, 2010.

(5) Air Cruisers Service Bulletin 777 107–25–29, Rev. No. 1, dated July 8, 2011.

(6) Air Cruisers Service Bulletin A300/A310 001–25–19, dated August 27, 2010.

(7) Air Cruisers Service Bulletin A300/A310 003–25–33, dated August 27, 2010.

(8) Air Cruisers Service Bulletin A310 002–25–08, dated August 27, 2010.

(9) Air Cruisers Service Bulletin A320 004–25–87, Rev. No. 2, dated January 7, 2011.

(10) Air Cruisers Service Bulletin A321 005–25–21, dated August 27, 2010.

(11) Air Cruisers Service Bulletin BAe 146 201–25–23, dated December 10, 2010.

(12) Air Cruisers Service Bulletin F28 352–25–02, dated December 10, 2010.

(13) Air Cruisers Service Bulletin F100 351–25–07, dated December 10, 2010.

(14) Air Cruisers Service Bulletin Liferaft 35–25–79, dated August 27, 2010.

(15) Air Cruisers Service Bulletin MD11 305–25–35, dated August 27, 2010.

(16) Air Cruisers Service Bulletin MD80/90/717 304–25–45, dated August 27, 2010.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings.

(e) Unsafe Condition

This AD was prompted by reports indicating that affected fusible plugs activated (vented gas) below the rated temperature. We are issuing this AD to address fusible plugs that might activate below the rated temperature and render the evacuation system unusable.

(f) Compliance

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

(g) Fusible Plug Identification

Within 42 months after the effective date of this AD, do an inspection to determine if any fusible plug has part number (P/N) B13984–3, stamped with Lot PA–21 or PA–22. A review of the airplane maintenance records is acceptable to make this determination if it can be conclusively determined from that review that a part not having P/N B13984–3, stamped with Lot PA–21 or PA–22, has been installed.

Note 1 to paragraph (g) of this AD: Guidance for performing the inspection specified in paragraph (g) of this AD can be found in applicable service information specified in paragraphs (c)(1) through (c)(16) of this AD and the applicable component maintenance manuals (CMMs) that have incorporated the appropriate Air Cruisers service information.

(h) Replacement of Affected Fusible Plug

If, during the inspection or records review required by paragraph (g) of this AD, it is determined that any fusible plug has part number (P/N) B13984–3, stamped with Lot PA–21 or PA–22: Within 42 months after the effective date of this AD, replace that fusible plug with a serviceable fusible plug P/N B13984–3 that is not stamped with Lot PA–21 or PA–22.

Note 2 to paragraph (h) of this AD: Guidance can be found in the applicable CMM for the replacement. In addition, Air Cruisers Service Information Letter (SIL) 25–246, Rev. No. 1, dated February 21, 2014, provides information regarding affected fusible plugs and guidance on the replacement.

(i) Parts Installation Prohibition

As of the effective date of this AD, no person may install on any airplane any fusible plug having P/N B13984–3, stamped with Lot PA–21 or PA–22.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7300; fax: 516–794–5531.

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

(k) Related Information

(1) For more information about this AD, contact Darren Gassetto, Aerospace Engineer, Mechanical Systems and Admin Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7323; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov*.

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

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this

paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to determine parts that are affected by this AD, unless the AD specifies otherwise.

(i) Air Cruisers Service Bulletin 737 103–25–50, dated August 27, 2010.

(ii) Air Cruisers Service Bulletin 757 105–25–80, dated August 27, 2010.

(iii) Air Cruisers Service Bulletin 757 105–25–81, dated August 27, 2010.

(iv) Air Cruisers Service Bulletin 767 106–25–10, Rev. No. 1, dated October 15, 2010.

(v) Air Cruisers Service Bulletin 777 107–25–29, Rev. No. 1, dated July 8, 2011.

(vi) Air Cruisers Service Bulletin A300/A310 001–25–19, dated August 27, 2010.

(vii) Air Cruisers Service Bulletin A300/A310 003–25–33, dated August 27, 2010.

(viii) Air Cruisers Service Bulletin A310 002–25–08, dated August 27, 2010.

(ix) Air Cruisers Service Bulletin A320 004–25–87, Rev. No. 2, dated January 7, 2011.

(x) Air Cruisers Service Bulletin A321 005–25–21, dated August 27, 2010.

(xi) Air Cruisers Service Bulletin BAe 146 201–25–23, dated December 10, 2010.

(xii) Air Cruisers Service Bulletin F28 352–25–02, dated December 10, 2010.

(xiii) Air Cruisers Service Bulletin F100 351–25–07, dated December 10, 2010.

(xiv) Air Cruisers Service Bulletin Liferaft 35–25–79, dated August 27, 2010.

(xv) Air Cruisers Service Bulletin MD11 305–25–35, dated August 27, 2010.

(xvi) Air Cruisers Service Bulletin MD80/90/717 304–25–45, dated August 27, 2010.

(3) For service information identified in this AD, contact Air Cruisers, 1747 State Route 34, Wall Township, NJ 07727–3935; phone 732–681–3527; email *technical publications@zodiacaerospace.com*.

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

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

Issued in Des Moines, Washington, on November 8, 2018.

Chris Spangenberg,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–25003 Filed 11–21–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 35, 101, 154, 201, and 352

[Docket No. PL19–2–000]

Accounting and Ratemaking Treatment of Accumulated Deferred Income Taxes and Treatment Following the Sale or Retirement of an Asset

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Policy statement.

SUMMARY: In this Policy Statement, the Federal Energy Regulatory Commission (Commission) states its policy regarding the treatment of Accumulated Deferred Income Taxes for both accounting and ratemaking purposes as to Commission-jurisdictional public utilities, natural gas pipelines and oil pipelines, in light of the Tax Cuts and Jobs Act of 2017. In addition, the Commission addresses the accounting and ratemaking treatment of Accumulated Deferred Income Taxes following the sale or retirement of an asset.

DATES: This Policy Statement will become applicable November 23, 2018.

FOR FURTHER INFORMATION CONTACT:

Sharli Silva (Legal Information), Office of the General Counsel, 888 First Street NE, Washington, DC 20426, (202) 502–8719, *Sharli.Silva@ferc.gov*.

Bryan Wheeler (Technical Information), Office of Energy Markets Regulation, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8497, *Bryan.Wheeler@ferc.gov*.

Monil Patel (Technical Information), Office of Energy Markets Regulation, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8296, *Monil.Patel@ferc.gov*.

Kimberly Horner (Technical Information), Office of Enforcement, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8623, *Kimberly.Horner@ferc.gov*.

SUPPLEMENTARY INFORMATION:

1. In this Policy Statement, the Federal Energy Regulatory Commission (Commission) states its policy regarding the treatment of Accumulated Deferred Income Taxes (ADIT) for both accounting and ratemaking purposes as to Commission-jurisdictional public utilities, natural gas pipelines, and oil pipelines, in light of the Tax Cuts and Jobs Act of 2017.[1] The Commission also addresses the accounting and ratemaking treatment of ADIT following the sale or retirement of an asset.

I. Background

A. Tax Cuts and Jobs Act

2. On December 22, 2017, the President signed into law the Tax Cuts and Jobs Act. The Tax Cuts and Jobs Act, among other things, reduced the federal corporate income tax rate from 35 percent to 21 percent, effective January 1, 2018.[2] This means that, beginning January 1, 2018, companies subject to the Commission's jurisdiction will compute income taxes owed to the Internal Revenue Service (IRS) based on a 21 percent tax rate. The tax rate reduction will result in less corporate income tax expense going forward.

3. Importantly, the tax rate reduction will also result in a reduction in ADIT liabilities and ADIT assets on the books of rate-regulated companies. ADIT balances are accumulated on the regulated books and records of such regulated companies based on the requirements of the Uniform System of Accounts (USofA).[3] ADIT arises from timing differences between the method of computing taxable income for reporting to the IRS and the method of computing income for regulatory accounting and ratemaking purposes.[4] As a result of the Tax Cuts and Jobs Act reducing the federal corporate income tax rate from 35 percent to 21 percent, a portion of an ADIT liability that was collected from customers will no longer be due from public utilities, natural gas pipelines and oil pipelines to the IRS and is considered excess ADIT.

B. Order No. 144

4. The purpose of tax normalization is to match the tax effects of costs and revenues with the recovery in rates of those same costs and revenues.[5] As

[1] An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018, Public Law 115–97, 131 Stat. 2054 (2017) (Tax Cuts and Jobs Act).

[2] *Id.* Sec. 13001, 131 Stat. at 2096.

[3] *See* Definition of Accounts 182.3 and Account 254, 18 CFR part 101, *Uniform System of Accounts Prescribed for Public Utilities and Licensees Subject to the Provisions of the Federal Power Act; see* Definition of Accounts 182.3 and Account 254, 18 CFR part 201, *Uniform System of Accounts Prescribed for Natural Gas Companies Subject to the Provisions of the Natural Gas Act; see* General Instructions 1–12, Accounting for Income Taxes, 18 CFR part 352, *Uniform Systems of Accounts Prescribed for Oil Pipeline Companies Subject to the Provisions of the Interstate Commerce Act*.

[4] *See* 18 CFR 35.24(d)(2) (2018).

[5] *Tax Normalization for Certain Items Reflecting Timing Differences in the Recognition of Expenses or Revenues for Ratemaking and Income Tax*

Continued

noted above, timing differences may exist between the method of computing taxable income for reporting to the IRS and the method of computing income for regulatory accounting and ratemaking purposes. The tax effects of these differences are placed in a deferred tax account to be used in later periods when the differences reverse.[6]

5. The Commission established this policy of tax normalization in Order No. 144 where it required use of ''the provision for deferred taxes [(*i.e.,* ADIT)] as a mechanism for setting the tax allowance at the level of current tax cost.'' [7] In keeping with this normalization policy, and as relevant to the Tax Cuts and Jobs Act's reduction of the federal corporate income tax rate, the Commission in Order No. 144 also required adjustments in the ADIT of public utilities' cost of service when excessive or deficient ADIT has been created as a result of changes in tax rates.[8] Furthermore, the Commission required ''a rate applicant to compute the income tax component in its cost of service by making provision for any excess or deficiency in its deferred tax reserves resulting . . . from tax rate changes.'' [9] The Commission required that such provision be consistent with a Commission-approved ratemaking method made specifically applicable to the rate applicant.[10] Where no ratemaking method has been made specifically applicable, the Commission required the rate applicant to advance some method in its next rate case.[11] The Commission stated that it would determine the appropriateness of any proposed method on a case-by-case basis, but as the issue is resolved in a number of cases, a method with wide applicability may be adopted.[12] The Commission codified the requirements of Order No. 144 in its regulations in 18 CFR 35.24.[13]

1. Public Utilities—18 CFR 35.24

6. Originally promulgated in Order No. 144, the Commission's regulations in 18 CFR 35.24 provide requirements for the proper ratemaking treatment of the tax effects of all transactions for which there are timing differences.[14] Under this section, a public utility must account for excess or deficient ADIT when computing the income tax component of its cost of service.[15] Additionally, in accounting for this excess or deficient ADIT, a public utility is required to apply the ratemaking method that has been specifically approved by the Commission for that public utility.[16] Where no such ratemaking method exists, a public utility may choose which ratemaking method to apply and the reasonableness of that ratemaking method will be determined on a case-by-case basis by the Commission.[17]

2. Natural Gas Pipelines—18 CFR 154.305

7. Order No. 144 also promulgated the Commission's regulations regarding tax normalization for natural gas pipelines which were originally located in part 2 of the regulations as section 2.202.[18] Order No. 144–A redesignated the tax normalization regulations for natural gas pipelines by removing them from part 2 of the Commission's regulations and placing them in part 154.[19] Subsequently, Order No. 582 redesignated the regulatory text in that part with respect to natural gas pipelines to its current designation in section 154.305, and made various revisions in that section.[20] The section requires a natural gas pipeline making a rate filing under the Natural Gas Act to compute the income tax component of its cost of service by using tax normalization for all transactions.[21] More specifically, the section requires natural gas pipelines to reduce rate base by the balances that are properly recordable in USofA Account 281 (Accumulated deferred income taxes—accelerated amortization property), Account 282 (Accumulated deferred income taxes—other property), and Account 283 (Accumulated deferred income taxes—other).[22] Conversely, rate base must be increased by balances that are properly recordable in Account 190 (Accumulated deferred income taxes).[23] The section also requires natural gas pipelines to compute the income tax component in its cost of service by including a provision for amortizing excess or deficiency in deferred taxes. This is done by applying a Commission-approved ratemaking method made specifically applicable to the natural gas pipeline for determining the cost-of-service provision: (1) If the natural gas pipeline has not provided deferred taxes in the same amount that would have accrued had tax normalization always been applied or (2) if, as a result of changes in tax rates, the accumulated provision for deferred taxes becomes deficient in, or in excess of, amounts necessary to meet future tax liabilities.[24] Similar to the tax normalization regulations for public utilities, if the Commission has not approved a specific ratemaking method specifically applicable to the natural gas pipeline, then the natural gas pipeline must use a previously approved ratemaking method.[25] The Commission will determine whether such method is appropriate on a case-by-case basis.[26]

3. Oil Pipelines

8. Unlike the Commission's regulations applicable to public utilities and natural gas pipelines, there is no tax normalization section under the Commission's regulations for oil pipelines. Instead, the Commission's regulations for oil pipelines under the USofA General Instructions, 1–12 *Accounting for Income Taxes,* require that when income tax rates are changed, oil pipelines reduce or increase their ADIT balances immediately by the full amount of the excess or deficient tax reserve.[27] Specifically, section (b) requires oil pipelines to apply the

Purposes, Order No. 144, FERC Stats. & Regs. ¶ 30,254 at 31,522, 31,530 (1981), *order on reh'g,* Order No. 144–A, FERC Stats. & Regs. ¶ 30,340 (1982).

[6] Order No. 144, FERC Stats. & Regs. ¶ 30,254 at 31,554.

[7] *Id.* at 31,530.

[8] *Id.* at 31,519.

[9] Order No. 144, FERC Stats. & Regs. ¶ 30,254 at 31,560. *See also* 18 CFR 35.24(c)(1)(ii); 18 CFR 35.24(c)(2).

[10] Order No. 144, FERC Stats. & Regs. ¶ 30,254 at 31,560. *See also* 18 CFR 35.24(c)(3).

[11] Order No. 144, FERC Stats. & Regs. ¶ 30,254 at 31,560.

[12] *Id. See also* 18 CFR 35.24(c)(3).

[13] Originally promulgated as part of Order No. 144, the regulatory text was redesignated as 18 CFR 35.25 in Order No. 144–A. *See* Order No. 144–A, FERC Stats. & Regs. ¶ 30,340 at 30,140. In Order No. 545, the Commission again redesignated the regulatory text to its present designation as 18 CFR 35.24. *See Streamlining Electric Power Regulation,* Order No. 545, FERC Stats. & Regs. ¶ 30,955, at 30,713 (1992) (cross-referenced at 61 FERC ¶61,207).

[14] *See id.*

[15] *See* 18 CFR 35.24(c)(1)(ii), (c)(2).

[16] *See* 18 CFR 35.24(c)(3).

[17] *See id.*

[18] Order No. 144, FERC Stats. & Regs. ¶ 30,254.

[19] Order No. 144–A, FERC Stats. & Regs.¶ 30,340 at 30,140. The Commission deemed part 154 a more appropriate location because tax normalization is required to be used by natural gas pipelines in filing their rate applications and the regulations that govern the filing of such rate applications are located in part 154. *Id.*

[20] 18 CFR 154.305 (2018). *See* Order No. 582, *Filing and Reporting Requirements for Interstate Natural Gas Company Rate Schedules and Tariffs,* FERC Stats. & Regs. ¶ 31,025 (1995), *order on reh'g,* Order No. 582–A, FERC Stats. & Regs. ¶ 31,043 (1996), *order on clarification,* FERC Stats. & Regs. ¶ 31,037 (1996). The tax normalization regulations were moved from 18 CFR 154.63a to 154.305.

[21] 18 CFR 154.305.

[22] 18 CFR 154.305(c)(1).

[23] *Id.*

[24] 18 CFR 154.305(d). Such amounts must be included as an addition or reduction to rate base until the deficiency or excess is fully amortized using the Commission approved ratemaking method. *Id.*

[25] 18 CFR 154.305(d)(3).

[26] *Id.*

[27] 18 CFR part 352, General Instructions 1–12, Accounting for Income Taxes.

enacted tax rate in determining the amount of deferred taxes and adjust their deferred tax liabilities and assets for the effect of the change in tax law or rates in the period that the change is enacted.[28] The section further requires the adjustment to be recorded in the appropriate deferred tax balance sheet accounts based on the nature of the temporary difference and the related classification requirements of the account.[29]

4. Prior Accounting Guidance for Public Utilities and Natural Gas Pipelines

9. In Docket No. AI93–5–000, the Chief Accountant issued accounting guidance on the proper accounting for income taxes.[30] Among other matters, the accounting guidance directed public utilities and natural gas companies to adjust their deferred tax liabilities and assets for the effect of the change in tax law or rates in the period that the change is enacted.[31] The guidance stated that adjustments should be recorded in the appropriate deferred tax balance sheet accounts (Accounts 190, 281, 282 and 283) based on the nature of the temporary difference and the related classification requirements of the accounts.[32] Further, if as a result of action by a regulator, it is probable that the future increase or decrease in taxes payable due to the change in tax law or rates will be recovered from or returned to customers through future rates, an asset or liability should be recognized in Account 182.3 (Other Regulatory Assets), or Account 254 (Other Regulatory Liabilities), as appropriate, for that probable future revenue or reduction in future revenue.[33]

C. Notice of Inquiry

10. Following the enactment of the Tax Cuts and Jobs Act, the Commission issued a Notice of Inquiry seeking comments on, among other things, whether, and if so, how, the Commission should address the effects on ADIT of the Tax Cuts and Jobs Act.[34] The Commission noted that the Tax Cuts and Jobs Act's reduction to the federal corporate income tax rate would potentially create excess or deficient ADIT on the books of public utilities.[35] As relevant to the guidance provided in this Policy Statement, the Commission sought comments on the treatment of ADIT for assets sold or retired after December 31, 2017, and the amortization of excess and deficient ADIT.[36]

II. Discussion

11. This Policy Statement states our requirements regarding the treatment of ADIT in light of the tax rate reduction implemented in the Tax Cuts and Jobs Act. Specifically, we provide guidance regarding: (1) The accounts in which public utilities, natural gas pipelines, and oil companies should record the amortization of excess and/or deficient ADIT for accounting purposes and ratemaking purposes and (2) whether, and if so how, such entities should address excess and/or deficient ADIT that is recorded on the books of public utilities, natural gas pipelines, and oil companies after December 31, 2017, as a result of assets being sold or retired for both accounting and ratemaking purposes.

12. First, we clarify that for both accounting purposes and ratemaking purposes, public utilities and natural gas companies should record the amortization of the excess and/or deficient ADIT recorded in Account 254 (Other Regulatory Liabilities) and/or Account 182.3 (Other Regulatory Assets) by recording the offsetting entries to Account 410.1 (Provision for Deferred Income Taxes, Utility Operating Income) or Account 411.1 (Provision for Deferred Income Taxes—Credit, Utility Operating Income), as required by the USofA. We further clarify that for accounting purposes oil pipelines should adjust their ADIT balances to reflect the change in federal income tax rates with offsetting entries to the appropriate income statement account, as required by the USofA. Accordingly, oil pipeline companies will not record excess or deficient ADIT for accounting purposes. As detailed below, we also clarify that oil pipelines should provide additional disclosures in the Notes that accompany their FERC Form No. 6, Annual Report of Oil Pipeline Companies (Form No. 6).

13. Second, for accounting purposes, we reiterate that public utilities and natural gas pipelines must continue to follow the accounting guidance issued by the Chief Accountant in Docket No. AI93–5–000 with respect to changes in tax law or rates. To ensure transparency in the accounting adjustments to the deferred tax accounts, we clarify that entities should provide additional disclosures in their 2018 FERC annual financial filing within the Notes to the Financial Statements as detailed below.

14. With respect to ratemaking, for a public utility or natural gas pipeline that continues to have an income tax allowance, any excess or deficient ADIT associated with an asset must continue to be amortized in rates even after the sale or retirement of that asset. This excess or deficient ADIT will continue to be refunded to or recovered from ratepayers based on the schedule that was initially established. Similarly, for ratemaking purposes oil pipelines should keep records of excess and deficient ADIT.

A. In Which Accounts Should Companies Record Amortization of Excess and Deficient ADIT

15. In the NOI, the Commission sought comment on whether a public utility or natural gas pipeline should record the amortization by recording a reduction to the regulatory asset or regulatory liability account and recording an offsetting entry to Account 407.3 (Regulatory Debits) or Account 407.4 (Regulatory Credits).[37] For oil pipelines, the Commission sought comment on whether this information should be recorded in Account 665 (Unusual or Infrequent Items (Debit)) or Account 645 (Unusual or Infrequent Items (Credit)).[38]

1. Comment Summary

16. Ameren takes issue with the premise of the Commission's question that a separate regulatory liability or asset account is necessary to record excess or deficient ADIT, respectively, arguing that the excess or deficient ADIT should remain in the accounts where they were originally recorded.[39] APPA and AMP, along with Indicated Customers, argue that it would be both appropriate and transparent to record the excess ADIT in the same ADIT accounts (*e.g.,* Accounts 190, 282 and 283) where the original entries for the ADIT assets and ADIT liabilities were established, but believe separate regulatory liability and/or asset accounts would also be appropriate.[40]

[28] *Id.*

[29] *Id.*

[30] *See Accounting for Income Taxes,* Docket No. AI93–5–000, at Item 8 (Apr. 23, 1993).

[31] *Id.*

[32] *Id.*

[33] *Id.*

[34] *Inquiry Regarding the Effect of the Tax Cuts and Jobs Act on Commission-Jurisdictional Rates,* FERC Stats. & Regs. ¶ 35,582 (2018) (NOI). In this Policy Statement, we refer to the comments filed in response to the NOI. A list of commenters in that proceeding and the abbreviated names used in this Policy Statement appears in Appendix A.

[35] NOI, FERC Stats. & Regs. ¶ 35,582 at P 13.

[36] *Id.* PP 20–22.

[37] NOI, FERC Stats. & Regs. ¶ 35,582 at P 22.

[38] *Id.*

[39] Ameren, Comments to NOI, Docket No. RM18–12–000, at 16 (filed May 21, 2018) (Ameren NOI Comments).

[40] APPA and AMP, Comments to NOI, Docket No. RM18–12–000, at 16 (filed May 22, 2018) (APPA and AMP NOI Comments); Indicated Customers, Comments to NOI, Docket No. RM18–12–000, at 14 (filed May 21, 2018) (Indicated Customers NOI Comments).

17. When separate regulatory liability or assets are used, commenters' viewpoints diverge on the appropriate account to record the offsetting entry. Certain commenters agree with the Commission's initial suggestion.[41] PSEG states that Accounts 407.3 and 407.4 correspond to the appropriate balance sheet account where the excess deferred taxes reside.[42] Regarding natural gas pipelines, Berkshire asserts that recording the amounts in Account 407.3 or 407.4 will be easier for FERC Form No. 2 users to understand because it will result in similar treatment to other IRS schedule M items and above the line accounting while avoiding the requirement to spread the total year's amortization over each month using the FASB Interpretation No. 18 method.[43]

18. Other commenters believe that either Accounts 407.3 and 407.4 or 410.1 (Provision for deferred income taxes, utility operating income) and 411.1 (Provision for deferred income taxes) are appropriate. Avangrid asserts that Account 407 is consistent with the fact that the excess deferred tax obligation ceased upon tax reform enactment and that the utilities will prospectively amortize a regulatory deferral, rather than a deferred tax liability; however, use of Account 411 is consistent with USofA requirements.[44] EEI and INGAA state that their members' opinions are split between the two accounting options and request that the Commission recognize that both approaches may be appropriate.[45]

19. Many other commenters believe that only Accounts 410.1 and 411.1 are appropriate.[46] New York Transco notes that those accounts were originally used when the regulatory asset or regulatory liability was established.[47]

20. Regarding oil pipelines, AOPL states with respect to regulatory accounting under the USofA, any excess ADIT is eliminated when tax rates change consistent with generally accepted accounting principles, rather than being reduced over time through amortization. AOPL states there is no reason to change either the Commission's accounting rules or current oil pipeline accounting practices; the Commission's ratemaking precedent controls rather than accounting rules for purposes of setting cost-of-service rates.[48]

2. Determination

a. Accounting Guidance

21. We clarify that public utilities and natural gas pipelines should record the amortization of the excess and/or deficient ADIT recorded in Account 254 (Other Regulatory Assets) and/or Account 182.3 (Other Regulatory Assets) by recording the offsetting entries to Account 410.1 (Provision for Deferred Income Taxes, Utility Operating Income) or Account 411.1 (Provision for Deferred Income Taxes—Credit, Utility Operating Income), as appropriate. As explained below, recording the amortization in Account 410.1 and Account 411.1 is consistent with the instructions for those accounts as detailed in the Commission's regulations and provides more transparency as compared with recording the amounts in Account 407.3 and Account 407.4 because the specific source of the regulatory asset or regulatory liability will be known.

22. The Commission's instructions for Account 182.3 provide in part ''[w]hen specific identification of the particular source of a regulatory asset cannot be made . . . account 407.4, regulatory credits, shall be credited.'' [49] Similarly, the Commission's instructions for Account 254 state in part ''[w]hen specific identification of the particular source of the regulatory liability cannot be made . . . account 407.3, regulatory debits, shall be debited.'' [50]

23. In contrast, Account 410.1 and Account 411.1 are specifically designated for the recordation of ADIT.[51] In this situation where, as a result of a change in tax law or rates, excess and/or deficient ADIT have been reclassified to Account 254 and/or Account 182.3, in accordance with the Commission's prior guidance,[52] specific identification of the source of the regulatory liability and/or regulatory asset can be made. Accordingly, the Commission's existing regulations support amortizing the excess and/or deficient ADIT recorded in Account 254 and/or Account 182.3 to Account 410.1 or Account 411.1, as appropriate and consistent with the manner such amounts are reflected in rates.

24. With respect to oil pipelines, deferred tax balances should be adjusted for the effect of changes in tax law or rates in the period the change is enacted in accordance with the USofA for oil pipelines.[53] Specifically, upon the enactment of the Tax Cuts and Jobs Act, oil pipelines should have reduced their ADIT balances to reflect the 21 percent federal income tax rate with offsetting entries to the appropriate income statement account.[54] We believe the current guidance set forth in the USofA is appropriate and will not require oil pipelines to account for excess or deficient ADIT or record the amortization of such amounts. However, to ensure transparency with respect to these ADIT adjustments, oil pipelines should disclose in the Notes to their Form No. 6 financial statements, the amounts of their ADIT adjustments resulting from the change in the federal corporate income tax rate, supported by

[41] Berkshire, Comments to NOI, Docket No. RM18–12–000, at 5–6 (filed May 22, 2018) (Berkshire NOI Comments); Consumer Advocates, Comments to NOI, Docket No. RM18–12–000, at 8–10 (filed May 21, 2018) (Consumer Advocates NOI Comments); DEMEC, Comments to NOI, Docket No. RM18–12–000, at 16 (filed May 21, 2018) (DEMEC NOI Comments); PSEG, Comments to NOI, Docket No. RM18–12–000, at 10–11 (filed May 22, 2018) (PSEG NOI Comments); TransCanada, Comments to NOI, Docket No. RM18–12–000, at 25 (filed May 21, 2018) (TransCanada NOI Comments).

[42] PSEG NOI Comments at 10–11.

[43] Berkshire NOI Comments at 5–6.

[44] Avangrid, Comments to NOI, Docket No. RM18–12–000, at 12–13 (May 22, 2018) (Avangrid NOI Comments).

[45] EEI, Comments to NOI, Docket No. RM18–12–000, at 19–20 (filed May 22, 2018) (EEI NOI Comments); INGAA, Comments to NOI, Docket No. RM18–12–000, at 12 (filed June 5, 2018) (INGAA NOI Comments).

[46] Ameren NOI Comments at 16; APPA and AMP NOI Comments at 16; Dominion Energy Gas Pipelines, Comments to NOI, Docket No. RM18–12–000, at 14–15 (filed May 21, 2018) (Dominion Energy Gas Pipelines NOI Comments); Enable Interstate Pipelines, Comments to NOI, Docket No. RM18–12–000, at 39–40 (filed May 21, 2018) (Enable Interstate Pipelines NOI Comments); Indicated Customers, Comments to NOI, Docket No. RM18–12–000, at 10 (filed May 21, 2018) (Indicated Customers NOI Comments); Indicated Local Distribution Companies, Comments to NOI, Docket No. RM18–12–000, at 11 (filed May 22, 2018) (Indicated Local Distribution Companies NOI Comments); New York Transco, Comments to NOI, Docket No. RM18–12–000, at 10 (filed May 22, 2018) (New York Transco NOI Comments).

[47] New York Transco NOI Comments at 10.

[48] AOPL, Comments to NOI, Docket No. RM18–12–000, at 16 (filed May 22, 2018) (AOPL NOI Comments).

[49] *See* Definition of Account 182.3, 18 CFR part 101, *Uniform System of Accounts Prescribed for Public Utilities and Licensees Subject to the Provisions of the Federal Power Act;* Definition of Account 182.3, 18 CFR part 201, *Uniform System of Accounts Prescribed for Natural Gas Companies Subject to the Provisions of the Natural Gas Act.*

[50] *See* Definition of Account 254, 18 CFR part 101, *Uniform System of Accounts Prescribed for Public Utilities and Licensees Subject to the Provisions of the Federal Power Act;* Definition of Account 254, 18 CFR part 201, *Uniform System of Accounts Prescribed for Natural Gas Companies Subject to the Provisions of the Natural Gas Act.*

[51] *See* Definition of Account 410.1 and 411.1, 18 CFR part 101, *Uniform System of Accounts Prescribed for Public Utilities and Licensees Subject to the Provisions of the Federal Power Act;* Definition of Account 410.1 and 411.1, 18 CFR part 201, *Uniform System of Accounts Prescribed for Natural Gas Companies Subject to the Provisions of the Natural Gas Act.*

[52] *See Accounting for Income Taxes,* Docket No. AI93–5–000, at Item 8 (Apr. 23, 1993).

[53] *See* 18 CFR part 352, General Instructions 1–12(b), Accounting for Income Taxes. *See also,* 18 CFR part 352, Instructions for Balance Sheet Accounts, 19–5 Current Deferred Income Tax Assets, 45 Accumulated Deferred Income Tax Assets, 59 Deferred Income Tax Liabilities, and 64 Accumulated Deferred Income Tax Liabilities.

[54] *Id.*

a schedule that illustrates the calculation of the revised balances. Because the accounting for the excess and/or deficient ADIT may create differences between oil pipelines' accounting and ratemaking, such differences should also be disclosed in the Notes to their Form No. 6 financial statements, Form No. 6 Page 230, Analysis of Federal Income and Other Taxes Deferred, and Page 700, Annual Cost of Service Based Analysis Schedule.

b. Ratemaking Guidance

25. With respect to public utilities, the appropriate ratemaking treatment will be addressed in the Notice of Proposed Rulemaking (NOPR) we are issuing concurrent with this Policy Statement. In the NOPR, we are proposing to require all public utility transmission providers with transmission rates under an Open Access Transmission Tariff (OATT), a transmission owner tariff, or a rate schedule to revise those rates to account for changes caused by the Tax Cuts and Jobs Act. Natural gas pipelines should continue to file for changes in rates consistent with sections 154.305, 154.312, and 154.313 of the Commission's regulations.[55]

26. For oil pipelines, the current regulatory treatment of excess and/or deficient ADIT amounts is to maintain such amounts separately for rate making purposes only and to amortize them by removing the annual amortization amount from the cost of service in the process of determining an income tax allowance. We will continue the practice of amortizing and removing the excess and or deficiency by reducing the allowed return before it is grossed up for income taxes.

B. Whether, and If So How, To Address Excess ADIT That Is Removed From the Books of Public Utilities, Natural Gas Pipelines, and Oil Pipelines After December 31, 2017, as a Result of Assets Being Sold or Retired

27. In the NOI, the Commission sought comment on whether, and if so how, it should address excess ADIT that is removed from the books of public utilities, natural gas pipelines, and oil pipelines after December 31, 2017, as a result of assets being sold or retired.[56]

1. Comment Summary

28. Both public utility and natural gas pipeline commenters note that, to date and in response to the last time Congress changed the federal corporate income tax rate, the IRS only has issued guidance on the disposition of excess ADIT in the context of extraordinary retirements.[57] They suggest that the Commission defer addressing excess ADIT that is removed from the books as a result of assets being sold or retired unless and until the IRS has had an opportunity to weigh in on this issue.[58]

29. Certain public utilities argue that, for companies that properly reflect Average Rate Assumption or the Reverse South Georgia Method and have formula rates that reflect ADIT balances and adjustments thereto, there is no need for the Commission to address excess ADIT that is removed from the books after December 2017 as a result of assets being sold or retired.[59]

30. Similarly, several natural gas pipelines contend that Commission precedent is clear that when assets are sold or transferred as part of a taxable event, the ADIT balance associated with those assets is extinguished; similarly, deferred liabilities resulting from excess ADIT are also extinguished following the retirement of an asset. These pipelines believe that the Commission has provided no basis for departing from these clear rules.[60] These pipelines note that the Commission has stated that ''ADIT balances consist of deferred taxes that are intended to be paid at a future time—when the taxes become due. When a taxable event occurs such as the sale of assets . . . taxes are due and the ADIT balances are reduced to zero;'' thus, the ''ADIT balances that existed prior to the sale no longer exist and are no longer an offset against rate base.'' [61] These pipelines state the NOI explained that any ADIT associated with assets that are sold are removed from the regulated entity's ''books because any previously deferred tax effects related to the assets are now triggered as part of the computation of gains or losses associated with the sale (*i.e.,* the deferred taxes are now payable to the IRS).'' [62]

31. Eversource and Exelon submit that treatment of ADIT balances is best addressed on a company-specific basis and that companies should be able to either remove the ADIT associated with assets removed from their books or continue to amortize those balances over the remaining amortization period.[63] Indicated Local Distribution Companies suggest that any future sale or retirement event should be decided as part of a pipeline's general rate proceeding.[64]

32. Other commenters urge the Commission to require regulated entities to return any excess ADIT associated with any sold or retired assets. They argue that the Commission should be guided by the principle that all excess ADIT balances were provided by customers and thus customers should be credited with such balances through the combination of a credit to amortization expense and the continued offset to rate base. In support, they assert that when a public utility sells a jurisdictional asset, it will remove from its books the entire ADIT associated with a sold asset, which does not transfer with the asset to the new owner, and retain the entire ADIT for investors. Thus, customers are never credited with the excess or any other part of the ADIT that they have been paying during the useful life of the asset prior to its sale.[65]

33. Indicated Customers note that with regard to the sale of public utility assets for which there is an excess ADIT balance remaining on the books, the 2006 IRS Private Letter Ruling No. PLR–168537–02 prohibits the return to ratepayers of that ADIT and excess ADIT related to the asset that is being sold, because any ADIT and excess ADIT amounts that are on the books for that asset cease to exist as of the date of sale.[66] Notwithstanding, Indicated

[55] 18 CFR 154.305, 154.312, 154.313 (2018). Section 154.313 should be used if the filing requests a minor rate change.

[56] NOI, FERC Stats. & Regs. ¶ 35,582 at P 20.

[57] *See* Treas. Reg. 26 CFR 1.168(i)–3, Treatment of Excess Deferred Income Tax Reserve Upon Disposition of Deregulated Public Utility Property.

[58] Avangrid NOI Comments at 11; EEI NOI Comments at 19; Ameren NOI Comments at 15; EQT Midstream, Comments to NOI, Docket No. RM18–12–000, at 14 (filed May 21, 2018) (EQT Midstream NOI Comments); Indicated Transmission Owners, Comments to NOI, Docket No. RM18–12–000, at 10 (filed May 22, 2018); Dominion Energy Gas Pipelines NOI Comments at 13.

[59] Ameren NOI Comments at 14, MISO Transmission Owners, Comments to NOI, Docket No. RM18–12–000, at 14 (filed May 21, 2018).

[60] EQT Midstream NOI Comments at 14; INGAA NOI Comments at 11–12; Tallgrass, Comments to NOI, Docket No. RM18–12–000, at 12–13 (filed May 21, 2018); AOPL NOI Comments at 14–15; Enable Interstate Pipelines, Comments to NOI, Docket No. RM18–12–000, at 40 (filed on May 21, 2018).

[61] *Id.* (citing *Enbridge Pipeline (KPC),* 102 FERC ¶ 61,310, at PP 5, 68 (2003)).

[62] *Id.* (citing NOI, FERC Stats. & Regs. ¶ 35,582 at P 20).

[63] Eversource, Comments to NOI, Docket No. RM18–12–000, at 10 (filed May 22, 2018); Exelon, Comments to NOI, Docket No. RM18–12–000, at 14 (filed May 22, 2018).

[64] Indicated Local Distribution Companies NOI Comments at 9.

[65] Consumer Advocates NOI Comments at 8; Indicated Customers NOI Comments at 10–11; DEMEC NOI Comments, Kumar Test. at P 14.

[66] I.R.S. P.L.R., 168537–02 at 9 (May 25, 2006) (''Because [t]axpayer has sold the assets that generated the [accumulated deferred investment tax credit] ADITC, the asset for which regulated depreciation expense is computed is no longer available. Consequently, no portion of the related unamortized ADITC remaining at the date of sale may be returned to ratepayers by amortizing those ADITC amounts over the period [t]axpayer recovers stranded costs from its ratepayers or by decreasing the net loss from the sale of the nuclear generating

Continued

Customers, and APPA and AMP argue that the impact of not returning both the ADIT and excess ADIT, prior to the sale, and the consequent appropriation of customer-provided capital, should be given consideration in the Commission's evaluation of the application seeking approval of the asset transfer. If the ADIT and excess ADIT are not considered in the transfer transaction, they contend that the selling entity would receive a windfall to the detriment of ratepayers. Further, the acquiring utility could have no offsetting ADIT in its rate base related to the purchased assets, thereby causing an increase in rates to customers, in addition to the customers' loss of capital advanced to the selling utility.[67]

34. Commenters that believe that the Commission should require ADIT balances be returned to the customers offer several suggestions. APPA and AMP suggest that in the case of a sale or early retirement of public utility assets, the flowback should occur immediately in the formula rate update after the event; otherwise, the flowback should be in the form of a lump-sum payment or credit.[68] Indicated Customers suggest that the Commission should consider deploying remedies it has used in proceedings under FPA section 203, such as establishing an open season for customers to terminate their contracts, a commitment by applicants to protect customers from any adverse rate impacts, rate moratorium or rate reduction.[69] Natural Gas Indicated Shippers suggest that the excess ADIT associated with sold or retired assets should be amortized and returned to the customers in the same manner a pipeline proposes to return excess ADIT due to tax cost changes.[70]

2. Determination

a. Accounting Guidance

35. As discussed above, in 1993, the Chief Accountant issued guidance on how entities must account for the effect of a change in tax law or rates by adjusting its deferred tax liabilities and assets.[71] This guidance remains unchanged, and requires an entity to adjust its deferred tax liabilities and assets for the effect of the change in tax law or rates in the period that the change is enacted.[72] If as a result of action by a regulator, it is probable that the future increase or decrease in taxes payable due to a change in tax law or rates will be recovered from or returned to customers through future rates, an asset or liability shall be recognized in Account 182.3 (Other Regulatory Assets) for deficient ADIT, or Account 254 (Other Regulatory Liabilities) for excess ADIT, as appropriate.[73] Because these deficient ADIT and excess ADIT balances can no longer be characterized as deferred tax amounts to be settled with the IRS, the sale or retirement of any assets as of January 1, 2018 would not automatically reverse these balances as tax timing differences.

36. Accordingly, for public utilities and natural gas pipelines, the excess and/or deficient ADIT recorded in Account 254 and/or Account 182.3 should continue to be recorded in those accounts and amortized to Accounts 410.1 and/or Account 411.1, if those balances are still deemed to be either refundable to or recoverable from ratepayers. If the rate treatment of those balances is instead disallowed, then those amounts shall be written off to Account 421 (Miscellaneous Non-Operating Income) or Account 426.5 (Other Deductions), as appropriate, in the year of the disallowance.[74]

37. We clarify that, for public utilities and natural gas pipelines, the balances of excess and deficient ADIT recorded in Account 254 and Account 182.3, respectively, continue to exist as regulatory liabilities and assets after an asset sale, in cases for which the excess and deficient ADIT do not transfer to the purchaser of the plant asset. Similarly, we clarify that public utilities and natural gas companies should continue to account for excess and deficient ADIT related to retirements as regulatory liabilities and assets.

38. We acknowledge that numerous current and deferred tax accounts as well as other accounts may be affected by reversals of ADIT account balances recorded on the books of public utilities and natural gas companies subject to the Commission's jurisdiction. Thus, in order to provide transparency regarding the accounting and rate treatment of amounts removed from the ADIT accounts, we clarify that public utilities and natural gas pipelines should disclose in their FERC annual financial filings within the Notes to the Financial Statements: (1) The FERC accounts affected; (2) how any ADIT accounts were re-measured in the determination of the excess or deficient ADIT amounts in Accounts 182.3 and 254; (3) the related amounts associated with the reversal and elimination of ADIT balances in those accounts; (4) the amount of excess and deficient ADIT that is protected and unprotected; (5) the accounts to which the excess or deficient ADIT will be amortized; and (6) the amortization period of the excess and deficient ADIT to be returned or recovered through rates for both protected and unprotected ADIT.[75] Disclosures should also summarize the manner by which excess and deficient will be included in rates by rate jurisdiction.

39. As for oil pipelines, as discussed above, ADIT balances will be reduced immediately by the full amount of the excess or deficient tax reserve in line with the USofA for oil pipelines outlined in General Instruction 1–12.[76]

b. Ratemaking Guidance

40. The Commission has previously found that the sale or retirement of an asset with an ADIT balance is usually deemed a taxable event under IRS rules, and, as such, the ADIT balance is extinguished as the deferred taxes then become payable to the appropriate government authorities, and there is no longer an ADIT balance to ''return'' to customers.[77] However, we believe that

assets by those ADITC amounts. Additionally, the unamortized [accumulated deferred investment tax credit] and [excess deferred federal income taxes] associated with the sold generating assets ceases to exist at the date of sale.''). APPA and AMP argue that this Private Letter Ruling can be read to have no bearing on the flowback of unprotected ADIT balances. APPA and AMP NOI Comments at n. 8.

[67] Indicated Customers NOI Comments at 10–11; APPA and AMP NOI Comments at 13–14.

[68] APPA and AMP NOI Comments at 13–14.

[69] Indicated Customers NOI Comments at 11–12 (citing *Inquiry Concerning the Commission's Merger Policy Under the Federal Power Act: Policy Statement,* Order No. 592, FERC Stats. & Regs. ¶ 31,044 (1996), *order on reconsideration,* 79 FERC ¶ 61,321 (1997)).

[70] Tallgrass Pipelines, Comments to NOI, Docket No. RM18–12–000, at 18 (filed May 22, 2018).

[71] *See Accounting for Income Taxes,* Docket No. AI93–5–000, at Item 8 (Apr. 23, 1993).

[72] *Id.*

[73] *Id.*

[74] *See* Definitions of Account 182.3 and Account 254, 18 CFR part 101, *Uniform System of Accounts Prescribed for Public Utilities and Licensees Subject to the Provisions of the Federal Power Act;* Definitions of Account 182.3 and Account 254, 18 CFR part 201, *Uniform System of Accounts Prescribed for Natural Gas Companies Subject to the Provisions of the Natural Gas Act.*

[75] Public utilities should include this information in FERC Form No. 1 or 1–A and natural gas pipelines should include this information in FERC Form No. 2 or 2–A.

[76] General Instructions 1–12, *Accounting for Income Taxes,* 18 CFR part 352.

[77] The Commission has found that master limited partnerships that were no longer entitled to an income tax allowance were not required to return any remaining ADIT balances. *Inquiry Regarding the Commission's Policy for Recovery of Income Tax Costs,* 162 FERC ¶ 61,227, *order on reh'g,* 164 FERC ¶ 61,030 (2018) (Revised Income Tax Policy Statement Order on Rehearing). However, as relevant here, the Commission found that ''[t]here is a critical distinction between adjustments to amortize excess or deficient ADIT to be included in future rates to account for changes in income tax rates, as opposed to a complete elimination of the income tax allowance. When income tax rates are merely reduced and an income tax allowance remains in *future* cost of service, it is appropriate to credit any excess in ADIT in the *future* cost of service.'' Revised Income Tax Policy Statement

excess or deficient ADIT associated with post-December 31, 2017, asset dispositions and retirements should be treated differently for ratemaking purposes. For these assets, there are two associated balances: (1) The ADIT balance based on the 21 percent tax rate that will be owed to the IRS and (2) deficient ADIT or excess ADIT balances resulting from the reduced tax liability that will not be payable to the IRS upon the sale or retirement of the asset. While the ADIT balance that needs to be settled with the IRS would be extinguished following a sale, the deficient ADIT or excess ADIT balances is more reflective of a regulatory liability or asset, and no longer reflects deferred taxes that are still to be settled with the IRS and need not be extinguished.

41. Additionally, we note that the rationale for continuing to amortize deficient ADIT or excess ADIT balances in rates upon sales or retirements of assets is substantively similar to the rationale for amortizing excess ADIT in rates for assets that have not been sold or retired. The difference is that for a sale or retirement, ADIT based on a 21 percent tax rate will be settled with the IRS immediately, while for an asset that is not sold or retired, the ADIT will be settled with the IRS over the remaining life of the asset as it depreciates. In other words, the difference between the ADIT for assets that are sold or retired and ADIT for assets that are not sold or retired is the timing of when companies will settle the 21 percent of ADIT with the IRS. In both scenarios, there is excess ADIT based on the 14 percent previously collected from the customers that will no longer be payable to the IRS.

42. While some commenters suggest that continuing to amortize excess or deficient ADIT following a sale or retirement would constitute a normalization violation based on certain IRS private letter rulings, the Commission notes that the IRS established a rulemaking proceeding and reversed its positions made in the PLR referenced by the commenters.[78] Current IRS regulations speak specifically to the normalization requirements for sales and retirements as a result of the Tax Reform Act of 1986.[79] These regulations permit the amortization of protected excess and/or deficient ADIT even in the event that the underlying asset associated with the ADIT has been sold or retired.[80] That is, the selling jurisdictional entity can continue to amortize excess ADIT in rates after the sale without violating the IRS' normalization requirements. The only limitation imposed by the IRS is that the timing of the amortization must be similar to protected excess and/or deficient ADIT for which the underlying asset has not been sold or retired.[81]

43. Consistent with the above discussion, oil pipelines should continue maintaining excess and/or deficient ADIT within the appropriate ADIT accounts for ratemaking purposes. When jurisdictional assets are retired or sold the oil pipeline should continue to amortize any excess and/or deficient amounts associated with those assets as part of the process of determining an income tax allowance within the rate making process, or seek prior Commission approval to do otherwise.

C. Conclusion

44. We adopt the policies set forth herein regarding the treatment of ADIT for public utilities, natural gas pipelines and oil pipelines. Above, we state our policy regarding the treatment of ADIT for both accounting and ratemaking purposes as to Commission-jurisdictional public utilities, natural gas pipelines and oil pipelines, in light of the Tax Cuts and Jobs Act of 2017 and also address the accounting and ratemaking treatment of ADIT following the sale or retirement of an asset. We expect such regulated entities to follow these policies absent prior Commission approval to use a different treatment. We further note that if a regulated entity determines that its unique circumstances merit a different treatment of ADIT, such an entity is free to request such treatment at any time.

III. Document Availability

48. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through FERC's Home Page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE, Room 2A, Washington, DC 20426.

49. From FERC's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

50. User assistance is available for eLibrary and the FERC's website during normal business hours from FERC Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov*.

IV. Applicability Date

51. This Policy Statement will become applicable November 23, 2018.

By the Commission. Commissioner McIntyre is not voting on this order.

Issued: November 15, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

Note: Appendix A will not be published in the Code of Federal Regulations.

Appendix

A—List of Commenters to NOI TABLE

Short name	Commenter
AEP	American Electric Power Service Corporation.
Ameren	Ameren Services Company on behalf of Union Electric Company d/b/a Ameren Missouri, Ameren Illinois Company d/b/a Ameren Illinois, and Ameren Transmission Company of Illinois.
AOPL	Association of Oil Pipe Lines.

Order on Rehearing, 164 FERC ¶ 61,030 at P 20. Thus, in the case of retired or sold assets of regulated entities that continue to have an income tax allowance (and in the case of all regulated entities with excess and deficient ADIT), it is appropriate to credit any excess in ADIT in the future cost of service.

[78] *See Application of Normalization Accounting Rules to Balances of Excess Deferred Income Taxes and Accumulated Deferred Investment Tax Credits of Public Utilities Whose Assets Cease To Be Public Utility Property,* 73 FR 14,934 (Mar. 20, 2008); *Application of Normalization Accounting Rules to Balances of Excess Deferred Income Taxes and Accumulated Deferred Investment Tax Credits of Public Utilities Whose Assets Cease to Be Public Utility Property,* 70 FR 75,762 (Dec. 21, 2005) (notice of proposed rulemaking, notice of public hearing, and withdrawal of previous proposed regulations).

[79] 26 CFR 1.168(i)–3 (2018). This section of the IRS code does not apply to ordinary retirements within the meaning of 26 CFR 1.167(a)–11(d)(3)(ii) of the internal revenue regulations, and such retirements are excluded from this policy statement.

[80] *Id.*

[81] *Id.*

Short name	Commenter
APGA	American Public Gas Association.
APPA and AMP	American Public Power Association and American Municipal Power, Inc.
Avangrid	Avangrid Networks, Inc.
Berkshire	Berkshire Hathaway Energy Pipeline Group.
Boardwalk	Boardwalk Pipeline Partners LP.
CAPP	Canadian Association of Petroleum Producers.
Consumer Advocates	Office of the Attorney General of the Commonwealth of Massachusetts; the Ohio Consumers' Counsel; the Maryland Office of People's Counsel; the Nevada Bureau of Consumer Protection; the Delaware Division of the Public Advocate; the Pennsylvania Office of Consumer Advocate; the Citizens Utility Board of Wisconsin; and the Indiana Office of Utility Consumer Counselor.
DEMEC	Delaware Municipal Electric Corporation, Inc.
Dominion Energy Gas Pipelines	Dominion Energy Transmission, Inc.; Dominion Energy Carolina Gas Transmission, LLC; Dominion Energy Quester Pipeline, LLC; Dominion Energy Overthrust Pipeline, LLC; and Questar Southern Trails Pipeline Company.
EEI	Edison Electric Institute.
Enable Interstate Pipelines	Enable Mississippi River Transmission, LLC and Enable Gas Transmission, LLC.
Enbridge and Spectra	Enbridge Energy Partners, L.P. and Spectra Energy Partners, LP.
EQT Midstream	EQT Midstream Partners, LP.
Eversource	Eversource Energy Service Company.
Exelon	Exelon Corporation.
Indicated Customers	Central Electric Power Cooperative, Inc., North Carolina Electric Membership Corporation, Southern Maryland Electric Cooperative, Inc., and the New Jersey Division of Rate Counsel.
Indicated Local Distribution Companies.	Atmos Energy Corporation; the City of Charlottesville, Virginia; the City of Richmond, Virginia; the Easton Utilities Commission; Exelon Corporation; and Washington Gas Light Company.
Indicated Transmission Owners	American Electric Power Service Corporation; Dominion Energy Services, Inc., on behalf of Virginia Electric and Power Company d/b/a Dominion Energy Virginia; Duquesne Light Company; Exelon Corporation; FirstEnergy Service Company, on behalf of American Transmission Systems, Incorporated; Jersey Central Power & Light Company; Mid-Atlantic Interstate Transmission, LLC; West Penn Power Company; The Potomac Edison Company; Monongahela Power Company; and PPL Electric Utilities Corp.
INGAA	Interstate Natural Gas Association of America.
ITC Great Plains	ITC Great Plains, LLC.
Kentucky Municipals	Frankfort Plant Board of Frankfort, Kentucky; Barbourville Utility Commission of the City of Barbourville, City; Utilities Commission of the City of Corbin; and the Cities of Bardwell, Berea, Falmouth, Madisonville, and Providence, Kentucky.
Kinder Morgan Entities	Natural Gas Pipeline Company of America LLC; Tennessee Gas Pipeline Company, L.L.C.; Southern Natural Gas Company, L.L.C.; Colorado Interstate Gas Company, L.L.C.; Wyoming Interstate Company, L.L.C.; El Paso Natural Gas Company, L.L.C.; Mojave Pipeline Company, L.L.C.; Bear Creek Storage Company, L.L.C.; Cheyenne Plains Gas Pipeline Company, L.L.C.; Elba Express Company, L.L.C.; Kinder Morgan Louisiana Pipeline LLC; Southern LNG Company, L.L.C.; and TransColorado Gas Transmission Company LLC.
Kinder Morgan Subsidiaries	SFPP, L.P.; Calnev Pipe Line, LLC; and Kinder Morgan Cochin, LLC.
MISO Transmission Owners	Ameren Services Company, as agent for Union Electric Company d/b/a Ameren Missouri, Ameren Illinois Company d/b/a Ameren Illinois and Ameren Transmission Company of Illinois; American Transmission Company LLC; Central Minnesota Municipal Power Agency; City Water, Light & Power (Springfield, IL); Cleco Power LLC; Cooperative Energy; Dairyland Power Cooperative; Duke Energy Business Services, LLC for Duke Energy Indiana, LLC; East Texas Electric Cooperative; Entergy Arkansas, Inc.; Entergy Louisiana, LLC; Entergy Mississippi, Inc.; Entergy New Orleans, LLC; Entergy Texas, Inc.; Great River Energy; Indiana Municipal Power Agency; Indianapolis Power & Light Company; International Transmission Company d/b/a ITC*Transmission;* ITC Midwest LLC; Lafayette Utilities System; Michigan Electric Transmission Company, LLC; MidAmerican Energy Company; Minnesota Power (and its subsidiary Superior Water, L&P); Missouri River Energy Services; Montana-Dakota Utilities Co.; Northern Indiana Public Service Company LLC; Northern States Power Company, a Minnesota corporation, and Northern States Power Company, a Wisconsin corporation, subsidiaries of Xcel Energy Inc.; Northwestern Wisconsin Electric Company; Otter Tail Power Company; Prairie Power Inc.; Southern Indiana Gas & Electric Company (d/b/a Vectren Energy Delivery of Indiana); Southern Minnesota Municipal Power Agency; Wabash Valley Power Association, Inc.; and Wolverine Power Supply Cooperative, Inc.
National Grid	National Grid USA.
Natural Gas Indicated Shippers	Aera Energy, LLC; Anadarko Energy Services Company; Apache Corporation; BP Energy Company; ConocoPhillips Company; Hess Corporation; Occidental Energy Marketing, Inc.; Petrohawk Energy Corporation; and XTO Energy, Inc.
New York Transco	New York Transco LLC.
Oklahoma Attorney General	Mike Hunter, Oklahoma Attorney General.
PJM	PJM Interconnection, L.L.C.
Plains	Plains Pipeline, L.P.
Process Gas and American Forest and Paper.	Process Gas Consumers Group and American Forest and Paper Association.
PSEG	Public Service Electric and Gas Company.
Tallgrass Pipelines	Trailblazer Pipeline Company LLC; Tallgrass Interstate Gas Transmission, LLC; and Rockies Express Pipeline LLC.
TAPS	Transmission Access Policy Study Group.
TransCanada	TransCanada Corporation.

Short name	Commenter
United Airlines Petitioners	United Airlines, Inc.; American Airlines, Inc.; Delta Air Lines, Inc.; Southwest Airlines, Co.; BP West Coast Products LLC; ExxonMobil Oil Corporation; Chevron Products Company; HollyFrontier Refining & Marketing LLC; Valero Marketing and Supply Company; Airlines for America; and the National Propane Gas Association.
Williams	Williams Companies, Inc.

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BILLING CODE 6717–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 221

[Docket ID: DOD–2015–OS–0054]

RIN 0790–AJ36

DoD Identity Management

AGENCY: Under Secretary of Defense for Personnel and Readiness (USD(P&R)), DoD.

ACTION: Final rule.

SUMMARY: This rulemaking establishes implementation guidelines for DoD Self-Service (DS) Logon to provide a secure means of authentication to applications containing personally identifiable information (PII) and personal health information (PHI). This will allow beneficiaries and other individuals with a continuing affiliation with DoD to update pay or health-care information in a secure environment. This service can be accessed by active duty, National Guard and Reserve, and Commissioned Corps members of the uniformed services when separating from active duty or from the uniformed service.

DATES: This rule is effective on December 24, 2018.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Eves, Defense Human Resources Activity, 571–372–1956.

SUPPLEMENTARY INFORMATION:

Public Comments and Responses

On Thursday, November 3, 2016 (81 FR 76325–76330), the Department of Defense (DoD) published a proposed rule titled, ''DoD Identity Management'' for a 60-day public comment period. When the comment period ended on January 3, 2017, no comments were received.

Discussion of Changes Made Based on Internal Review

While in final internal review, it was discovered, based on existing DoD instructions, that only certain retired DoD civilians should be included among the populations eligible for the DS Logon credential as identified in DoD Instruction 1330.17, ''DoD Commissary Program,'' and DoD Instruction 1330.21, ''Armed Services Exchange Regulations.'' Only those retired DoD civilians who are eligible for DoD commissary and exchange benefits are eligible for the DS Logon credential. Compliance with existing DoD policy and current instructions required modification of § 221.6(b)(1)(ii) of the final rule, which was amended to read ''Eligible retired DoD civilian employees in accordance with DoD Instruction 1330.17, ''DoD Commissary Program'' (available at *http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/133017p.pdf*) and DoD Instruction 1330.21, ''Armed Services Exchange Regulations'' (available at *http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/133021p.pdf*).'' This amendment was made to reflect current Department policy and clarifies that only certain retired DoD civilians (not all retired DoD civlians) are eligible for access to these programs.

Background

This final rule establishes implementation guidelines for DS Logon and describes procedures for obtaining a DS Logon credential. All active duty, National Guard and Reserve, and Commissioned Corps members of the uniformed services must obtain a DS Logon credential when separating from active duty or from the uniformed service. The DS Logon credential is also available to all beneficiaries that are eligible for DoD-related benefits or entitlements to facilitate secure authentication to critical websites, to include members of the uniformed services, veterans with a continuing affiliation to the DoD, spouses, dependent children aged 18 and over, certain retired DoD civilians, surrogates and other eligible individuals. It discusses how credential holders may maintain and update their credentials and manage their personal settings. Finally, it discusses the permissions credential holders have to access their information, who has access to view and edit their information, and who is eligible to act on their behalf.

DoD collects and maintains information on Service members, beneficiaries, DoD employees, and other individuals affiliated with the DoD in order to issue DoD identification (ID) cards that facilitate access to DoD benefits, DoD installations, and DoD information systems. This action formally establishes DoD policy requirements for DS Logon credentials that are used to facilitate logical access to self-service websites. This regulatory action will update the CFR for DoD Manual (DoDM) 1341.02, Volume 1, ''DoD Identity Management: DoD Self-Service (DS) Logon Program and Credential.''

Authorities

The DoD Personal Identity Protection (PIP) Program uses emerging technologies to support the protection of individual identity and to assist with safeguarding DoD physical assets, networks, and systems from unauthorized access based on fraudulent or fraudulently obtained credentials. DEERS is the authoritative data source for identity and verification of affiliation with the DoD in accordance with the DoD PIP Program. Specific authorities are listed below.

- Title 10 U.S.C. 1044a. This section establishes the authority for a Judge Advocate, other members of the armed forces designated by law and regulations, or other eligible persons to have the powers to act as a notary. The persons identified in Title 10 U.S.C. 1044a subsection (b) have the general power of a notary and may notarize a completed and signed DD Form 3005, ''Application for Surrogate Association for DoD Self-Service (DS) Logon.''
- DoD Instruction 1000.25, ''DoD Personnel Identity Protection (PIP) Program'' (available at *http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/100025p.pdf*). This issuance establishes minimum acceptable criteria for the establishment and confirmation of personal identity and for the issuance of DoD personnel identity verification credentials.
- DoD Instruction 1341.2, ''Defense Enrollment Eligibility Reporting System (DEERS) Procedures'' (available at *http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/134102p.pdf*). This issuance establishes DEERS as the authoritative data source for identity and verification of affiliation

with the DoD, and benefit eligibility to include medical, dental, and pharmacy.

• Office of Management and Budget M–04–04, ''E-Authentication Guidance for Federal Agencies'' (available at *https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy04/m04-04.pdf*). This memorandum requires agencies to review new and existing electronic transactions to ensure that authentication processes provide the appropriate level of assurance, establishing and describing four levels of identity assurance for electronic transactions requiring authentication.

• 32 CFR part 310. This CFR part established the DoD Privacy Program in accordance with the provisions of the Privacy Act of 1974, and prescribes uniform procedures for the implementation of and compliance with the DoD Privacy Program.

Expected Impact of the Final Rule

The annual operating costs for the DS Logon program are approximately $1,700,000.00. Based on 6.8 million active users, the cost to the Department per user is about $0.25. This rule is not anticipated to change the population of individuals able to receive a DS Logon account. As part of the proposed rule, DoD requested comments on a new information collection request for this program. No public comment was received. Additional information on the collection can be found in the Paperwork Reduction Act section of this rule.

Regulatory Procedures

Executive Order 12866, ''Regulatory Planning and Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. It has been determined that this rule is not a significant regulatory action. The rule does not: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in these Executive Orders.

Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs''

This final rule is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

Section 202, Public Law 104–4, ''Unfunded Mandates Reform Act''

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) requires agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately $141 million. This final rule would not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. 601)

The Department of Defense certifies that this final rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)

It has been certified that 32 CFR part 221 does impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995. These requirements have been approved by OMB and assigned OMB Control Number 0704–0559, Application for Surrogate Association for DoD Self-Service (DS) Logon.

Executive Order 13132, ''Federalism''

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct effects on the States, the relationship between the National Government and the states, or the distribution of power and responsibilities among the various levels of government. This final rule will not impose such substantial direct effects.

List of Subjects in 32 CFR Part 221

Identity management, Identification cards, Logon credentials.

■ Accordingly, 32 CFR part 221 is added to read as follows:

PART 221—DOD IDENTITY MANAGEMENT

Sec.

Authority: 10 U.S.C. 1044a.

§ 221.1 Purpose.

(a) The purpose of the overall part is to implement policy, assign responsibilities, and provide procedures for DoD personnel identification.

(b) This part establishes implementation guidelines for DoD Self-Service (DS) Logon Program.

§ 221.2 Applicability.

This part applies to:

(a) The Office of the Secretary of Defense, the Military Departments (including the Coast Guard at all times, including when it is a Service in the Department of Homeland Security, by agreement with that Department), the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this part as the ''DoD Components'').

(b) The Commissioned Corps of the U.S. Public Health Service (USPHS), under agreement with the Department of Health and Human Services, and the National Oceanic and Atmospheric Administration (NOAA), under agreement with the Department of Commerce.

§ 221.3 Definitions.

Unless otherwise noted, the following terms and their definitions are for the purposes of this part:

Beneficiary. Individuals affiliated with the DoD and any of the uniformed Services identified in § 221.2 Applicability, that may be eligible for benefits or entitlements.

Certified copy. A copy of a document that is certified as a true original and:

(1) Conveys the appropriate seal or markings of the issuer;

(2) Has a means to validate the authenticity of the document by a reference or source number;

(3) Is a notarized legal document or other document approved by a judge advocate, member of any of the armed forces, or other eligible person in accordance with 10 U.S.C. 1044a; or

(4) Has the appropriate certificate of authentication by a U.S. Consular Officer in the foreign country of issuance which attests to the authenticity of the signature and seal.

DoD beneficiary (DB). Beneficiaries who qualify for DoD benefits or entitlements who may be credentialed in accordance with National Institute of Science and Technology Special Publication 800–63–2, ''Electronic Authentication Guideline'' (available at *http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-63-2.pdf*). This population may include widows, widowers, and eligible former spouses.

Dependent. An individual whose relationship to the sponsor leads to entitlement to benefits and privileges.

DS Logon credential. A username and password to allow Service members, beneficiaries, and other individuals affiliated with the DoD secure access to self-service websites.

DS Logon credential holder. A Service member, beneficiary, and other individual affiliated with the DoD who has applied for and received a DS Logon credential.

Former member. An individual who is eligible for, or entitled to, retired pay for non-regular service in accordance with 31 U.S.C. chapter 1223, but who has been discharged from the Service and who maintains no military affiliation.

Former spouse. An individual who was married to a uniformed services member for at least 20 years, and the member had at least 20 years of service creditable toward retirement, and the marriage overlapped as follows:

(1) Twenty years marriage, 20 years creditable service for retirement, and 20 years overlap between the marriage and the service (referred to as 20/20/20). The benefits eligibility begins on the date of divorce;

(2) Twenty years marriage, 20 years creditable service for retirement, and 15 years overlap between the marriage and the service (referred to as 20/20/15). The benefits eligibility begins on the date of divorce; or

(3) A spouse whose marriage was terminated from a uniformed Service member who has their eligibility to receive retired pay terminated as a result of misconduct based on Service-documented abuse of the spouse and has 10 years of marriage, 20 years of creditable service for retirement, 10 years of overlap between the marriage and the service (referred to as 10/20/10). The benefits eligibility begins on the date of divorce.

Legal guardian (LG). The terms ''guardian'' and ''conservator'' are used synonymously. Some States may limit the authority of a guardian to specific types of health care decisions; a court may also impose limitations on the health care decisions.

Surrogate. A person who has been delegated authority, either by an eligible individual who is at least 18 years of age and mentally competent to consent or by a court of competent jurisdiction in the United States (or possession of the United States), to act on behalf of the eligible individual in a specific role.

Widow. The female spouse of a deceased member of the uniformed services.

Widower. The male spouse of a deceased member of the uniformed services.

§ 221.4 Policy.

In accordance with DoD Instruction 1000.25, ''DoD Personnel Identity Protection (PIP) Program'' (available at *http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/100025p.pdf*), DoD Instruction 1341.02, ''Defense Enrollment Eligibility Reporting System (DEERS) Procedures'' (available at *http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/134102p.pdf*), Office of Management and Budget M–04–04, ''E-Authentication Guidance for Federal Agencies'' (available at *www.whitehouse.gov/sites/default/files/omb/memoranda/fy04/m04-04.pdf*) and 32 CFR part 310, it is DoD policy that DoD will provide a secure means of authentication to PII and personal health information (PHI) for all beneficiaries and other individuals with a continuing affiliation with DoD.

§ 221.5 Responsibilities.

(a) The Under Secretary of Defense for Personnel and Readiness (USD(P&R)) oversees implementation of the procedures within this part.

(b) Under the authority, direction, and control of the USD(P&R), and in addition to the responsibilities in paragraph (c) of this section, the Director, DoDHRA, through the Director, DMDC:

(1) Approves the addition or elimination of population categories for DS Logon eligibility.

(2) Develops and fields the required Defense Enrollment Eligibility Reporting System (DEERS) and RAPIDS infrastructure and all elements of field support required to support the management of the DS Logon credential including, but not limited to, issuance, storage, maintenance, and customer service.

(3) Obtains and distributes DS Logon credentials, and provides a secure means for delivery.

(c) The DoD Component heads:

(1) Comply with this part and distribute this guidance to applicable stakeholders.

(2) Provide manpower for issuance of DS Logon credentials and instruction for use to all eligible individuals who are requesting a DS Logon credential in conjunction with the issuance of a DoD identification (ID) card or who are applying for a DS Logon credential as a surrogate, when responsible for a DoD ID card site(s).

(d) The Secretaries of the Military Departments, in addition to the responsibilities in paragraph (c) of this section, and the heads of the non-DoD uniformed services:

(1) Comply with this part and distribute this guidance to applicable stakeholders.

(2) Provide manpower for issuance of DS Logon credentials and instruction for use to all eligible individuals who are requesting a DS Logon credential in conjunction with the issuance of a DoD ID card or who are applying for a DS Logon credential as a surrogate.

(3) Ensure all Active Duty, National Guard and Reserve, and Commissioned Corps members of their uniformed services obtain a DS Logon credential when separating from active duty or from the uniformed service.

§ 221.6 Procedures.

(a) *General.* A DS Logon credential will be made available to all beneficiaries that are eligible for DoD-related benefits or entitlements to facilitate secure authentication to critical websites. This includes members of the uniformed services, veterans with a continuing affiliation to the DoD, spouses, dependent children aged 18 and over, and other eligible individuals identified in paragraph (b) of this section.

(b) *Overview.* Only one DS Logon credential may exist for an individual, regardless of the number of affiliations an individual may have to the DoD.

(1) *Eligibility.* Beneficiaries of DoD-related benefits or entitlements and other individuals with a continuing affiliation with the DoD may be eligible for a DS Logon credential. Eligible populations include:

(i) Veterans, including former members, retirees, Medal of Honor

recipients, disabled American veterans, and other veterans with a continuing affiliation to the DoD.

(ii) Eligible retired DoD civilian employees in accordance with DoD Instruction 1330.17, ''DoD Commissary Program'' (available at *http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/133017p.pdf*), and DoD Instruction 1330.21, ''Armed Services Exchange Regulations'' (available at *http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/133021p.pdf*).

(iii) Eligible dependents in accordance with Volume 2 of DoD Manual 1000.13, ''DoD Identification (ID) Cards: Benefits for Members of the Uniformed Services, Their Dependents, and Other Eligible Individuals'' (available at *http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodm/100013_vol2.pdf*), including spouses, dependent children aged 18 or older, and dependent parents.

(iv) DBs, including eligible widows, widowers, and former spouses, in accordance with Volume 2 of DoD Manual 1000.13.

(v) Surrogates, as described in paragraph (d) of this section.

(vi) Other populations as determined by the Director, DMDC.

(2) [Reserved].

(c) *Lifecycle*—(1) *Application.* Eligible individuals, as identified in paragraph (b)(1) of this section, may apply for a DS Logon credential:

(i) *Online.* Individuals with internet access may apply for a sponsor or dependent DS Logon by submitting a:

(A) *My Access Center website request.* This type of request supports the provisioning of a Basic DS Logon credential. The My Access Center website can be accessed at *https://myaccess.dmdc.osd.mil/*.

(B) *CAC request.* Individuals with a CAC, a computer with internet access and a CAC reader may apply for either a sponsor or a dependent DS Logon credential via the My Access Center website or any application that has implemented DS Logon.

(*1*) A sponsor DS Logon credential is provisioned immediately upon request. This type of request supports the provisioning of a Premium DS Logon credential.

(*2*) A request for a DS Logon credential on behalf of a dependent generates an activation letter with an activation code that is mailed to the sponsor at his or her home address in DEERS. Once complete, this type of request supports the provisioning of a Premium DS Logon credential.

(C) *Request using a Defense Finance and Accounting Services (DFAS) myPay account.* Eligible individuals may apply for a sponsor or dependent DS Logon credential using a DFAS myPay personal identification number via the My Access Center website. A request for a DS Logon credential generates an activation letter with an activation code that is mailed to the sponsor at his or her home address in DEERS. Once complete, this type of request supports the provisioning of a Premium DS Logon credential.

(ii) *Via remote proofing.* Eligible individuals with an existing DEERS record may apply for a sponsor or dependent DS Logon credential using remote proofing via the My Access Center website. Individuals requesting a DS Logon credential via remote proofing must correctly answer a number of system-generated questions. Once remote proofing is completed, a Premium DS Logon credential is provisioned immediately.

(iii) *Via in-person proofing.* Eligible individuals may apply for a sponsor or dependent DS Logon credential using in-person proofing. In-person proofing is performed at Department of Veterans Affairs regional offices where the DS access station application is implemented, and at DoD ID card sites when a DS Logon credential is requested either in conjunction with DoD ID card issuance or during initial enrollment of a surrogate. Once in-person proofing is completed, a Premium DS Logon credential is provisioned immediately. Individuals requesting a DS Logon credential via in-person proofing must present:

(A) *Identity documents.* DS Logon credential applicants must satisfy the identity verification criteria in paragraph 4a of Volume 1 of DoD Manual 1000.13, ''DoD Identification (ID) Cards: ID Card Life-Cycle'' (available at *http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodm/100013_vol1.pdf*), by presenting two forms of government-issued ID, one of which must contain a photograph. The requirement for the primary ID to have a photo cannot be waived. Identity documents must be original or a certified copy. All documentation not in English must have a certified English translation.

(B) *Proof of address.* DS Logon credential applicants must present proof of address, if address on the presented ID is different than the address in DEERS.

(C) *DD Form 214, ''Certificate of Release or Discharge from Active Duty.''* DS Logon credential applicants must present a DD Form 214 if a veteran who was separated before 1982. If separated from the Reserve Component, a DS Logon credential applicant may present a Reserve Component separation document in lieu of a DD Form 214.

(2) *Use.* DS Logon credential holders may use their DS Logon credential at the My Access Center website and any other DoD self-service website that accepts DS Logon.

(3) *Maintenance.* DS Logon credential holders may use the My Access Center website to maintain and update their DS Logon credential and manage their personal settings. The DS Logon credential holder may:

(i) Activate or deactivate an account.

(ii) Reset password.

(iii) Update challenge questions and answers.

(iv) Upgrade from a Basic DS Logon to a Premium DS Logon credential.

(v) Select or update preferred sponsor, if a dependent of two sponsors.

(vi) Manage personal and advanced security settings.

(vii) Manage contact information.

(viii) Manage relationships and access granting.

(ix) Manage the DS Logon credential using additional capabilities as implemented by the Director, DMDC.

(4) *Decommissioning.* DS Logon credentials may be decommissioned by the DS Logon credential holder, via self-service; by an operator, at the request of the DS Logon credential holder; or by the system, when the credential holder no longer has an affiliation to the DoD or is identified as deceased in DEERS.

(5) *Reactivation.* DS Logon credentials may be reactivated if the person is living and still eligible for the credential.

(d) *Associations.* DS Logon supports several types of associations, including DEERS-identified family relationships and operator-initiated and -approved surrogates.

(1) *Family.* Individuals are connected to one another based on their family relationship information in DEERS. A family relationship must exist in DEERS before the relationship can exist in DS Logon.

(i) *Multiple sponsors.* An individual has only one DS Logon credential, regardless of the number of sponsors the individual has (*e.g.,* a dependent child whose parents are both Service members).

(ii) *Transferring families.* If an individual has a second family in DEERS, the individual can move their DS Logon credential to the second family. This changes the assignment of the DS Logon credential from the first family to the second family and removes any granted permissions from the first family.

(2) *Surrogacy.* Surrogacy is a feature that allows an individual who may not be affiliated with the DoD and who may not be related to the DS Logon credential holder or eligible individual by a DoD-recognized family relationship to be granted access to a DS Logon credential holder's or an eligible individual's information. A surrogate may be established as the custodian of a deceased Service member's unmarried minor child(ren) who is under 18, who is at least 18 but under 23 and attending school full-time, or who is incapacitated. A surrogate may also be established as the agent of an incapacitated dependent (*e.g.,* spouse, parent) or of a wounded, ill, or incapacitated Service member.

(i) *Eligibility.* An operator must first establish an identity in DEERS before establishing the surrogacy association in DS Logon. To establish a surrogate association, the surrogate must present to an operator for approval:

(A) A completed and signed DD Form 3005, ''Application for Surrogate Association for DoD Self-Service (DS) Logon.''

(B) Any additional eligibility documents required by the DD Form 3005 which describe the scope of the surrogate's authority.

(C) Proof of identity, in accordance with the requirements for in-person proofing in paragraph (c)(1)(iii) of this section.

(ii) *Types of surrogates*—(A) *Financial agent (FA).* An eligible individual names an FA to assist with specific financial matters.

(B) *Legal agent (LA).* An eligible individual names an LA to assist with legal matters.

(C) *Caregiver (CG).* An eligible individual names a CG to assist with general health care requirements (example, viewing general health-care related information, scheduling appointments, refilling prescriptions, and tracking medical expenses), but does not make health care decisions.

(D) *Health care agent (HA).* An eligible individual (the patient) names an HA in a durable power of attorney for health care documents to make health care decisions.

(E) *Legal guardian (LG).* An LG is appointed by a court of competent jurisdiction in the United States (or jurisdiction of the United States) to make legal decisions for an eligible individual.

(F) *Special guardian (SG).* An SG is appointed by a court of competent jurisdiction in the United States (or jurisdiction of the United States) for the specific purpose of making health care-related decisions for an eligible individual.

(e) *Permissions.* A sponsor, a sponsor's spouse, and a sponsor's dependent over the age of 18 can manage who has access to their information (*i.e.,* who has access to view and edit their information and who is eligible to act on their behalf). The provisions of this section may be superseded by order of a court of competent jurisdiction.

(1) *Sponsor access.* Sponsors will automatically have access to the information of all dependents under the age of 18.

(2) *Spousal access*—(i) *Automatic.* A sponsor's spouse will automatically have access to the information of all dependent children under the age of 18 whose relationship to the sponsor began on or after the date of marriage of the sponsor and sponsor's spouse.

(ii) *Sponsor-granted.* The sponsor may grant the sponsor's spouse access to the information of dependent children under the age of 18 whose relationship to the sponsor began before the date of marriage of the sponsor and the sponsor's spouse.

(3) *Granted access.* A sponsor, a sponsor's spouse, and a sponsor's dependent over the age of 18 may grant access to their information via the My Access Center website in accordance with paragraph (c)(3) of this section. Surrogate access to the information of a sponsor, a sponsor's spouse, and a sponsor's dependent (regardless of age) must be granted via in-person proofing, including the submission of eligibility documents to an operator for approval in accordance with paragraph (d)(2) of this section.

(i) *Access granting by a sponsor.* Sponsors may grant their spouse access to the sponsor's information and the information of any sponsor's dependents under the age of 18. Access to the sponsor's information and the information of any sponsor's dependents under the age of 18 may not be granted to any other sponsor's dependent, unless that dependent has been identified as a surrogate.

(ii) *Access granting by a spouse.* Spouses may grant the sponsor access to the spouse's information. Access to the spouse's information may not be granted to any other sponsor's dependent, unless that sponsor's dependent has been identified as a surrogate.

(iii) *Access granting by a dependent over 18.* A sponsor's dependent over the age of 18 may grant the sponsor and the sponsor's spouse access to the dependent's information. Access to the information of a sponsor's dependent over the age of 18 may not be granted to any other sponsor's dependent, unless that sponsor's dependent has been identified as a surrogate.

Dated: November 19, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0257]

RIN 1625–AA09

Drawbridge Operation Regulation; Delaware River, Pennsauken Township, NJ

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is modifying the operating regulation that governs the DELAIR Memorial Railroad Bridge across the Delaware River, mile 104.6, at Pennsauken Township, NJ. This modified regulation will allow the bridge to be remotely operated from the Conrail South Jersey dispatch center in Mount Laurel, NJ, instead of being operated by an on-site bridge tender. This regulation will not change the operating schedule of the bridge.

DATES: This rule is effective December 24, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov*. Type USCG–2016–0257 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Hal R. Pitts, Fifth Coast Guard District (dpb); telephone (757) 398–6222, email *Hal.R.Pitts@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
OMB Office of Management and Budget
NPRM Notice of Proposed Rulemaking (Advance, Supplemental)
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On April 12, 2017, we published a document in the **Federal Register** entitled, ''Drawbridge Operation Regulation; Delaware River, Pennsauken Township, NJ'' announcing a temporary deviation from the regulations, with request for comments (see 82 FR 17562). This temporary deviation commenced at 8 a.m. on April 24, 2017, and concluded at 7:59 a.m. on October 21, 2017. The comment period closed on August 17, 2017. The purpose of the deviation was to test the newly installed remote operation system of the DELAIR Memorial Railroad Bridge across the Delaware River, mile 104.6, at Pennsauken Township, NJ, owned and operated by Conrail Shared Assets. The installation of the remote operation system did not change the operational schedule of the bridge.

On June 30, 2017, we published a notice of proposed rulemaking (NPRM) entitled, ''Drawbridge Operation Regulation; Delaware River, Pennsauken Township, NJ'' (see 82 FR 29800). This proposed regulation would allow the bridge to be remotely operated from the Conrail South Jersey dispatch center in Mount Laurel, NJ, instead of being operated by an on-site bridge tender. This proposed regulation would not change the operating schedule of the bridge. The original comment period closed on August 18, 2017.

During the initial temporary deviation performed from 8 a.m. on April 24, 2017, through 7:59 a.m. on October 21, 2017, the bridge owner identified deficiencies in the remote operation center procedures, bridge to vessel communications, and equipment redundancy. Comments concerning these deficiencies were submitted to the docket and provided to the Coast Guard and bridge owner by representatives from the Mariners' Advisory Committee for the Bay and River Delaware.

On October 18, 2017, we published a document in the **Federal Register** entitled, ''Drawbridge Operation Regulation; Delaware River, Pennsauken Township, NJ'' announcing a second temporary deviation from the regulations, with request for comments (see 82 FR 48419). This temporary deviation commenced at 8 a.m. on October 21, 2017, and concluded at 7:59 a.m. on April 19, 2018. This document included a request for comments and related material to reach the Coast Guard on or before January 15, 2018.

On December 6, 2017, we published a notice of proposed rulemaking; reopening of comment period; entitled ''Drawbridge Operation Regulation; Delaware River, Pennsauken Township, NJ'' in the **Federal Register** (see 82 FR 57561). This document included a request for comments and related material to reach the Coast Guard on or before January 15, 2018.

On January 22, 2018, we published a notice of temporary deviation from regulations; reopening comment period; entitled ''Drawbridge Operation Regulation; Delaware River, Pennsauken Township, NJ'' in the **Federal Register** (see 83 FR 2909). This document included a request for comments and related material to reach the Coast Guard on or before March 2, 2018.

On February 15, 2018, we published a notice of proposed rulemaking; reopening comment period; entitled ''Drawbridge Operation Regulation; Delaware River, Pennsauken Township, NJ'' in the **Federal Register** (see 83 FR 6821). This document included a request for comments and related material to reach the Coast Guard on or before March 2, 2018.

The Coast Guard reviewed 26 comments posted to the docket and six reports with supporting documentation submitted by the bridge owner during the initial and second temporary deviation periods concerning the remote operation system of the DELAIR Memorial Railroad Bridge. Through this review, the Coast Guard found that further testing and evaluation of the remote operation system of the bridge was necessary before making a decision on the proposed regulation.

On April 26, 2018, we published a document in the **Federal Register** entitled, ''Drawbridge Operation Regulation; Delaware River, Pennsauken Township, NJ'' announcing a third temporary deviation from the regulations, with request for comments (see 83 FR 18226). This temporary deviation commenced at 8 a.m. on April 19, 2018, and concluded at 7:59 a.m. on October 16, 2018. This document included a request for comments and related material to reach the Coast Guard on or before August 17, 2018.

On May 4, 2018, we published a notice of proposed rulemaking; reopening comment period; entitled ''Drawbridge Operation Regulation; Delaware River, Pennsauken Township, NJ'' in the **Federal Register** (see 83 FR 19659). This document included a request for comments and related material to reach the Coast Guard on or before August 17, 2018.

On October 17, 2018, we published a document in the **Federal Register** entitled, ''Drawbridge Operation Regulation; Delaware River, Pennsauken Township, NJ'' announcing a temporary deviation from the regulations (see 83 FR 52319). This document was published to allow the DELAIR Memorial Railroad Bridge across the Delaware River, mile 104.6, at Pennsauken Township, NJ, to continue to be remotely operated from the Conrail South Jersey dispatch center in Mount Laurel, NJ, instead of being operated by an on-site bridge tender, to allow sufficient time for the Coast Guard to conduct an evaluation of the proposed rulemaking. This temporary deviation commenced at 8 a.m. on October 16, 2018, and is scheduled to conclude at 7:59 a.m. on December 15, 2018.

In total the Coast Guard received 26 comments posted to the docket and eight reports with supporting documentation submitted by the bridge owner on this rule. No comments were received during the third temporary deviation between April 19, 2018, and October 16, 2018.

III. Legal Authority and Need for Rule

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

The DELAIR Memorial Railroad Bridge across the Delaware River, mile 104.6, at Pennsauken Township, NJ, owned and operated by Conrail Shared Assets, has a vertical clearance of 49 feet above mean high water in the closed-to-navigation position. There is a daily average of 28 New Jersey Transit trains and eight Conrail freight trains that cross the bridge and a daily average of three bridge openings that allow one or more vessels to transit through the bridge during each opening. The bridge is normally maintained in the closed position due to the average daily number of trains crossing the bridge. The operating schedule is published in 33 CFR 117.716. This current operating schedule has been in effect since 1984 and will not change with the implementation of remote operation of the bridge. However, within this modified operating regulation, section 117.716 has been restructured to clearly distinguish the remote operation of the DELAIR Memorial Railroad Bridge. This modified operating regulation allows the bridge to be operated remotely from the bridge owner's South Jersey dispatch center in Mount Laurel, NJ.

The Delaware River is used by a variety of vessels, including deep draft commercial vessels, tug and barge traffic, recreational vessels, and public vessels, including military vessels of various sizes. The three-year average number of bridge openings and maximum number of bridge openings by month and overall for 2013 through 2015, as drawn from the data contained in the bridge tender logs, is presented below.

Month	Average openings	Maximum openings
January	73	88
February	54	56
March	80	94
April	55	68
May	60	67
June	60	71
July	122	162
August	112	138
September	143	201
October	109	117
November	100	116
December	100	122
Monthly	89	201
Daily	3	7

The bridge owner and the maritime community have been working together since 2013 in an effort to incorporate sensors and other technologies into the bridge and the Conrail South Jersey dispatch center to allow for the safe and effective remote operation of the bridge.

IV. Discussion of Comments and Changes to the Final Rule

During the initial and second temporary deviation periods between April 24, 2017, and April 19, 2018, 26 comments were received, including three duplicate comments, one process comment, and two comments not related to this rule. No comments were received during the third temporary deviation period between April 19, 2018, and October 16, 2018.

Comments were received from six professional mariners between December 7, 2017, and January 11, 2018, during the second temporary deviation period. These comments expressed concerns associated with the remote operation center's (1) failure to provide timely replies to mariner's requests for a bridge opening, (2) failure to follow established communications protocols, (3) unprofessional responses to mariner's requests and a perception of ineffectual management and a cultural bias against the needs of maritime transportation. These comments were in response to the deficiencies observed during the second temporary deviation period and were observed and reported during the first temporary deviation period, along with corrective actions taken by the bridge owner. Following a review of these comments, the bridge owner acknowledged the recurring deficiencies in the remote operation of the bridge related to human performance factors and management, and reported that additional corrective actions were taken. The Coast Guard found that the bridge owner's actions taken to address the comments received from professional mariners have been satisfactory, given the bridge was operated safely and effectively during the third temporary deviation, which included 681 bridge openings, without further comment from any mariners.

During the first temporary deviation period, comments were received from the Brotherhood of Maintenance of Way Employees Division of the International Brotherhood of Teamsters that: (1) Questioned the remote operation center's capability to safely and effectively operate the bridge, (2) indicated that bridge tenders were currently performing on-site bridge maintenance, inspection and repair functions that would no longer be performed at the required frequencies, and (3) reported multiple remote operation system failure conditions as defined in the notice of proposed rulemaking. The bridge owner advised the Coast Guard that on-site bridge tenders were not responsible for performing on-site bridge maintenance, inspection or repairs functions and that those functions would continue to be performed by qualified personnel. In reviewing the other two comments above in conjunction with the details concerning the remote operation of the bridge during the second and third temporary deviation periods, the Coast Guard has found that the remote operation center is capable of safely and effectively controlling the bridge and early remote operation system failures have been overcome by the bridge owner's corrective actions.

The Delaware Riverkeeper Network submitted comments during the first temporary deviation period indicating that: (1) They were opposed to the regulation based on increased potential for negative environmental impacts to local and regional communities, (2) human oversight via an on-site bridge tender should not be replaced by a remote device, (3) the provision for qualified personnel to return and operate the bridge within 60 minutes was not considered an adequate response time, and (4) they believed that the proposed rule was a significant regulatory action based on increased potential for negative environmental impacts. The Coast Guard reviewed these comments and found that there is no evidence to support that remote operation of the bridge increases the potential for negative environmental impacts and is not likely to have an adverse effect to the environment in a material way, therefore the proposed rule is not a significant regulatory action. The Coast Guard also found that the remote operation system does not replace human oversight, and the 60-minute response time was tested throughout the three temporary deviation periods resulting in effective restoration of the remote operation system of the bridge and no adverse impact on navigation.

12 comments expressed concerns associated with general safety and security of the bridge and the potential inability of remote operation center operators to safely operate the bridge. The Coast Guard found that: (1) Although the on-site bridge tender's duties only include operation of the bridge, the bridge owner's implementation of additional safety and security technologies, in conjunction with the remote operation center's capabilities in providing visibility of the bridge and waterway to the remote operation center operator, adequately addressed the general safety and security related comments. Additionally, the bridge operated safely and effectively during the three temporary deviation periods, which included 2,597 bridge openings.

The Coast Guard finds that the comments received do not require any changes in the regulatory text as presented in the NPRM.

V. Discussion of Final Rule

This operating regulation allows the bridge to be operated remotely from the bridge owner's South Jersey dispatch center in Mount Laurel, NJ. The remote operation system includes eight camera views (four marine and four rail), two forward-looking infrared equipped camera views (marine), marine radar, a dedicated telephone line for bridge operations, radio telephone on VHF–FM channels 13 and 16, and an automated identification system (AIS) transmitter to provide bridge status. The AIS transmitter is installed on the New Jersey side of the bridge at the bridge and land intersection in approximate position 39°58′50.52″ N (39.9807), 75°03′58.75″ W (−75.06632). The AIS transmitter is assigned maritime mobile service identity (MMSI) number 993663001 and provides the status of the bridge (open/closed/inoperative) via the name transmitted by the private aids to navigation as DELAIR BRG–OPEN (fully open and locked position, channel light green), DELAIR BRG–CLOSED (other than fully open, not inoperative), or DELAIR BRG–INOP (other than fully open, inoperative). The AIS transmitter transmits the bridge status every two minutes and upon a change in bridge status.

The remote operation system is designed to provide greater or equal visibility of the waterway and bridge and in signals (communications) via sound and visual signals and radio telephone (voice) via VHF–FM channels 13 and 16 compared to the on-site bridge tender. The remote operation system also incorporates real-time bridge status via AIS signal to aid mariners in voyage planning and navigational decision-making, a dedicated telephone line (856) 231–2301 for bridge operations, and push-to-talk (PTT) capability on VHF–FM channel 13.

The signals for the remote operation center or on-site bridge tender to respond to a sound signal for a bridge opening include: (1) When the draw can be opened immediately—a sound signal of one prolonged blast followed by one short blast and illumination of a fixed white light not more than 30 seconds after the requesting signal, and (2) when the draw cannot be opened immediately—five short blasts sounded in rapid succession and illumination of a fixed red light not more 30 seconds after the vessel's opening signal. The signals for the remote operation center or on-site bridge tender to respond to a visual signal for a bridge opening include: (1) When the draw can be opened immediately—illumination of a fixed white light not more than 30 seconds after the requesting signal, and (2) when the draw cannot be opened immediately—illumination of a fixed red light not more 30 seconds after the vessel's opening signal. The fixed white light will remain illuminated until the bridge reaches the fully open position. The fixed white and red lights will be positioned on the east (New Jersey) bridge abutment adjacent to the navigation span.

Vessels that require an opening shall continue to request an opening via the methods defined in 33 CFR 117.15(b) through (d) (sound or visual signals or radio telephone (VHF–FM) voice communications), via telephone at (856) 231–2301, or via push-to-talk (PTT) on VHF–FM channel 13. Vessels may push the PTT button five times while on VHF–FM channel 13 to request an opening.

The remote operation system will be considered in a failed condition and qualified personnel will return and operate the bridge within 60 minutes if any of the following conditions are found: (1) The remote operation system becomes incapable of safely and effectively operating the bridge from the remote operation center, (2) visibility of the waterway or bridge is degraded to less than equal that of an on-site bridge tender (all eight camera views are required), (3) signals (communications) via sound or visual signals or radio telephone (voice) via VHF–FM channels 13 or 16 become inoperative, or (4) AIS becomes inoperative.

VI. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the fact that the operating schedule published in 33 CFR 117.716 will not change with the remote operation of the bridge and the remote operation of the bridge is not likely to have an adverse effect to the environment.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

This rule calls for no new collection of information under the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Government

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule simply promulgates the operating regulations or procedures for drawbridges. This action is categorically excluded from further review, under figure 2–1, paragraph (32)(e), of the Instruction.

A Record of Environmental Consideration and a Memorandum for the Record are not required for this rule.

G. Protest Activities

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

List of Subjects in 33 CFR Part 117

Bridges.

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

PART 117—DRAWBRIDGE OPERATION REGULATIONS

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

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

■ 2. Revise § 117.716 to read as follows:

§ 117.716 Delaware River.

(a) The following apply to all drawbridges across the Delaware River:

(1) The draws of railroad bridges need not be opened when there is a train in the bridge block approaching the bridge with the intention of crossing or within five minutes of the known time of the passage of a scheduled passenger train.

(2) The opening of a bridge may not be delayed more than five minutes for a highway bridge or 10 minutes for a railroad bridge after the signal to open is given.

(3) The owners of drawbridges shall provide and keep in good legible condition two board gages painted white with black figures not less than six inches high to indicate the vertical clearance under the closed draw at all stages of the tide. The gages shall be so placed on the bridge that they are plainly visible to operators of vessels approaching the bridge either up or downstream.

(b) The draw of the Conrail Memorial Railroad Bridge, mile 104.6, at Pennsauken Township, NJ shall be operated as follows:

(1) The bridge will be remotely operated from the Conrail South Jersey dispatch center in Mount Laurel, NJ, unless the remote operation system is in a failed condition.

(2) An AIS transmitter has been installed on the New Jersey side of the bridge at the bridge and land intersection in approximate position 39°58′50.52″ N (39.9807), 75°03′58.75″ (−75.06632). The AIS transmitter is assigned maritime mobile service identity (MMSI) number 993663001. The status of the bridge (open/closed/inoperative) will be provided via the name transmitted by the AIS private aids to navigation as DELAIR BRG–OPEN (fully open and locked position, channel light green), DELAIR BRG–CLOSED (other than fully open, not inoperative), or DELAIR BRG–INOP (other than fully open, inoperative). The AIS transmitter will transmit the bridge status every two minutes and upon a change in the bridge status.

(3) The remote operation system will be considered in a failed condition and qualified personnel will return and operate the bridge within 60 minutes if any of the following conditions are found:

(i) The remote operation system becomes incapable of safely and effectively operating the bridge from the remote operation center; or

(ii) Visibility of the waterway or bridge is degraded to less than equal that of an on-site bridge tender; or

(iii) Signals (communications) via sound or visual signals or radio telephone (voice) via VHF–FM channels 13 or 16 become inoperative; or

(iv) AIS becomes inoperative.

(4) Vessels that require an opening shall continue to request an opening via the methods defined in § 117.15(b) through (d) (sound or visual signals or radio telephone (VHF–FM) voice communications), via telephone at (856) 231–2301, or via push-to-talk (PTT) on VHF–FM channel 13. Vessels may push the PTT button five times while on VHF–FM channel 13 to request an opening.

(5) The signals for the remote operation center or on-site bridge tender to respond to a sound signal for a bridge opening include:

(i) When the draw can be opened immediately—a sound signal of one prolonged blast followed by one short blast and illumination of a fixed white light not more than 30 seconds after the requesting signal; or

(ii) When the draw cannot be opened immediately—five short blasts sounded in rapid succession and illumination of a fixed red light not more 30 seconds after the vessel's opening signal.

(6) The signals for the remote operation center or on-site bridge tender to respond to a visual signal for a bridge opening include:

(i) When the draw can be opened immediately—illumination of a fixed white light not more than 30 seconds after the requesting signal; or

(ii) When the draw cannot be opened immediately—illumination of a fixed red light not more 30 seconds after the vessel's opening signal.

(7) The fixed white light will remain illuminated until the bridge reaches the fully open position. The fixed white and red lights will be positioned on the east (New Jersey) bridge abutment adjacent to the navigation span.

Dated: November 14, 2018.

G.G. Stump,

Captain, U.S. Coast Guard, Acting Commander, Fifth Coast Guard District.

[FR Doc. 2018–25544 Filed 11–21–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–1010]

Drawbridge Operation Regulation; Three Mile Slough, Rio Vista, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the California Route 160 Drawbridge across Three Mile Slough, mile 0.1, near Rio Vista, CA. The deviation is necessary to conduct preventative maintenance. This deviation allows the bridge to remain in the closed-to-navigation position.

DATES: This deviation is effective from 7 a.m. on November 26, 2018, through 4 p.m. on November 27, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–1010, is available at *http://www.regulations.gov*. Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Carl T. Hausner, Chief, Bridge Section, Eleventh Coast Guard District; telephone 510–437–3516, email *Carl.T.Hausner@uscg.mil*.

SUPPLEMENTARY INFORMATION: The California Department of Transportation has requested a temporary change to the operation of the California Route 160 Drawbridge over Three Mile Slough, mile 0.1, near Rio Vista, CA The drawbridge navigation span provides a vertical clearance of 12 feet above Mean High Water in the closed-to-navigation position. The draw opens on signal as required by 33 CFR 117.5. Navigation on the waterway is commercial and recreational.

The drawspan will be secured in the closed-to-navigation position from 7 a.m. on November 26, 2018, through 4 p.m. on November 27, 2018, to allow the bridge owner to perform necessary preventative maintenance and non-destructive testing on the bridge's lift span gear box. This temporary deviation has been coordinated with the waterway users. No objections to the proposed temporary deviation were raised.

Vessels able to pass through the bridge in the closed position may do so at anytime. The bridge will not be able to open for emergencies. The Sacramento River and San Joaquin River can be used as alternate routes for vessels unable to pass through the bridge in the closed position. The Coast Guard will also inform the users of the waterway through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

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

Dated: November 15, 2018.

Carl T. Hausner,

District Bridge Chief, Eleventh Coast Guard District.

[FR Doc. 2018–25455 Filed 11–21–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–1030]

RIN 1625–AA00

Safety Zones; Pipeline Construction, Tennessee River Miles 465 to 466, Chattanooga, TN

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters of the Tennessee River from mile marker (MM) 465 to MM 466. This safety zone is necessary to protect persons, property, and the marine environment from potential hazards associated with the construction of an underground pipeline. Entry of vessels or persons into this zone is prohibited unless authorized by the Captain of the Port Sector Ohio Valley or a designated representative.

DATES: This rule is effective without actual notice from November 23, 2018 through 7:30 p.m. on January 25, 2019. For the purposes of enforcement, actual notice will be used from November 19, 2018, through November 23, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2018–1030 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Nicholas Jones, Marine Safety Detachment Nashville, U.S. Coast Guard; telephone 615–736–5421, email *MSDNashville@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. We must establish this safety zone by November 19, 2018, and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule. On November 1, 2018, Reynolds Construction, LLC notified Marine Safety Detachment Nashville that their underwater pipeline construction operations at mile marker 465.2 of the Tennessee River would be ready to commence on November 19,

2018. Reynolds Construction estimates that the work will take 10 weeks, excluding November 22–25, December 8–9, December 22–25, and December 29–January 1.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because immediate action is needed to respond to potential safety hazards associated with the underwater pipeline construction.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Sector Ohio Valley (COTP) has determined that potential hazards associated with the underwater blasting and pipeline construction will be a safety concern for anyone on a one-mile stretch of the Tennessee River. This rule is necessary to protect persons, vessels, and the marine environment during the construction operations.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from mile marker (MM) 465 to MM 466 on the Tennessee River in Chattanooga, TN from 6:30 a.m. on November 19, 2018, through 7:30 p.m. on January 25, 2019. The safety zone will be enforced from 6:30 a.m. through 7:30 p.m. each day, excluding November 22–25, December 8–9, December 22–25, and December 29–January 1. A safety vessel will coordinate all vessel traffic during the enforcement periods. The COTP may terminate enforcement of this rule if the work is finished earlier. The duration of the safety zone is intended to protect persons, vessels, and the marine environment during the construction operations.

No vessel or person is permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of Sector Ohio Valley, U.S. Coast Guard. They may be contacted on VHF Channel 13 or 16, or at 1–800–253–7465. All persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all directions issued by the COTP or the designated representative. The COTP or a designated representative will inform the public of the enforcement times and dates for this safety zone through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs), as appropriate.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. This safety zone prohibits transit on a one-mile stretch of the Tennessee River for about 13 hours, on workdays only, during a ten-week period. The rule also allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In

particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule prohibits transit on a one-mile stretch of the Tennessee River for about 13 hours on workdays only during a ten-week period. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.2.

■ 2. Add § 165.35T08–1030 to read as follows:

§ 165.35T08–1030 Safety Zone; Pipeline Construction, Tennessee River, Miles 465 to 466, Chattanooga, TN.

(a) *Location.* The following area is a safety zone: All navigable waters of the Tennessee River from mile marker (MM) 465.0 to MM 466.0, Chattanooga, TN.

(b) *Effective period.* This section is effective without actual notice from November 23, 2018 through 7:30 p.m. on January 25, 2019. For the purposes of enforcement, actual notice will be used from November 19, 2018 through November 23, 2018.

(c) *Enforcement periods.* This section will be enforced each day during the effective period from 6:30 a.m. through 7:30 p.m., excluding November 22–25, December 8–9, December 22–25, and December 29–January 1. The Captain of the Port Sector Ohio Valley (COTP) may terminate enforcement of this section if the work is finished earlier.

(d) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into this area is prohibited unless authorized by the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of Sector Ohio Valley, U.S. Coast Guard.

(2) Persons or vessels requiring entry into or passage through the area must request permission from the COTP or a designated representative. U.S. Coast Guard Sector Ohio Valley may be contacted on VHF Channel 13 or 16, or at 1–800–253–7465.

(3) A designated safety vessel will coordinate all vessel traffic during the enforcement of this safety zone. All persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all directions issued by the COTP or the designated representative.

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

Dated: November 19, 2018.

M.B. Zamperini,

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

[FR Doc. 2018–25536 Filed 11–21–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG- 2018–1022]

Safety Zone; Lower Mississippi River, Mile Markers 94 to 95 Above Head of Passes, New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for a fireworks display located between mile marker (MM) 94 and (MM) 95, above Head of Passes. This action is needed to provide for the safety of life on navigable waterways during this event.

DATES: The regulations in 33 CFR 165.845 will be enforced from 8:15 p.m. through 9:15 p.m. on December 29, 2018.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Lieutenant Commander Benjamin Morgan, Sector New Orleans, U.S. Coast Guard; telephone 504–365–2281, email *Benjamin.P.Morgan@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone located in 33 CFR 165.845 for the fireworks display from 8:15 p.m. through 9:15 p.m. on December 29, 2018. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Eighth Coast Guard District, § 165.845, specifies the location of the regulated area between mile markers 94 and 95 above Head of Passes on the Lower Mississippi River. If you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the local notice to mariners and marine information broadcasts.

Dated: November 16, 2018.

K.M. Luttrell,

Captain, U.S. Coast Guard, Captain of the Port Sector New Orleans.

[FR Doc. 2018–25434 Filed 11–21–18; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2016–0585; FRL–9986–14–Region 8]

Approval and Promulgation of Air Quality Implementation Plans; State of Utah; Logan Nonattainment Area Fine Particulate Matter State Implementation Plan for Attainment of 2006 24-Hour Fine Particulate Matter National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing approval of the emissions inventory, modeled attainment demonstration, determination for Major Stationary Source Reasonably Available Control Technology (RACT), determination for On-Road Mobile Sources Reasonably Available Control Measures (RACM), determination for Cache County Inspection and Maintenance (I/M) Program as additional reasonable measures, determination for Off-Road Mobile Sources RACM, and the 2015 Motor Vehicle Emission Budgets (MVEB) portions of the attainment plan submitted by Utah on December 16, 2014, to address Clean Air Act (CAA or the Act) requirements for the 2006 24-hour fine particulate matter ($PM_{2.5}$) national ambient air quality standards (NAAQS) in the Logan, Utah (UT)—Idaho (ID) Moderate $PM_{2.5}$ nonattainment area. These actions are being taken under section 110 of the CAA.

DATES: This final rule is effective on December 24, 2018.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2016–0585. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Crystal Ostigaard, Air Program, U.S. EPA, Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–6602, *ostigaard.crystal@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' means the EPA.

I. Background

On October 17, 2006 (71 FR 61144), the Environmental Protection Agency (EPA) revised the level of the 24-hour fine particulate matter ($PM_{2.5}$) National Ambient Air Quality Standard (NAAQS), lowering the primary and secondary standards from the 1997 standard of 65 micrograms per cubic meter ($\mu g/m^3$) to 35 $\mu g/m^3$. On November 13, 2009 (74 FR 58688), the EPA designated three nonattainment areas in Utah for the 24-hour $PM_{2.5}$ NAAQS of 35 $\mu g/m^3$. These are the Salt Lake City, Utah (UT); Provo, UT; and Logan, UT-Idaho (ID) nonattainment areas. The State of Utah submitted the Logan, UT-ID Moderate $PM_{2.5}$ state implementation plan (SIP) on December 16, 2014, to address the requirements under part D of title I of the Clean Air Act (CAA) for the Logan UT-ID $PM_{2.5}$ nonattainment area.

On December 4, 2017 (82 FR 57183), the EPA proposed to approve portions of the December 16, 2014 Logan, UT-ID Moderate $PM_{2.5}$ SIP submittal. Specifically, we proposed to approve:

- The 2010 base year and 2015 projection year emissions inventories;
- The modeled attainment demonstration;
- The RACM/RACT and additional reasonable measure determinations for on-road mobile, including the Cache County I/M Program, off-road mobile, and major stationary sources; and
- The direct $PM_{2.5}$, nitrogen oxides (NO_X) and volatile organic compound (VOC) MVEBs for 2015 and the MVEB trading mechanism.

Our proposal provides details on the EPA's evaluation of these portions of the State's submittal.

II. Response to Comments

The EPA received seven public comments on the proposed action. After reviewing the comments received, the EPA has determined that the comments, with the exception of a portion of one comment, fall outside the scope of our proposed action or fail to identify any material issue necessitating a response.

A portion of one comment (EPA–R08–OAR–2016–0585–0017) generally alleges that the EPA lacks actual measurements of what agriculture emits in the form of $PM_{2.5}$, and that agriculture is not a major emitter of $PM_{2.5}$. The comment states that the data used to develop ''the inventory'' was based on erroneous emission factors published by ''CPA'' [1] for cattle feed yards, feed mills, grain elevators, and dust from farmers' field operations; however, according to the comment, there ''has never been any actual PM–2.5 emission data taken on agricultural tillage equipment using EPA approved PM–2.5 samplers.'' The comment also alleges that ''wildfire emissions were not added to the data.''

Assuming that the comment is intended to refer to the emissions inventories that Utah prepared and submitted for the Logan, UT-ID Moderate $PM_{2.5}$ SIP and that the EPA proposed to approve, we respond as follows. The comment alleges the use of ''erroneous'' emission factors without identifying any specific error in the emission factors. Under the SIP Requirements Rule, Utah was not required to run tests on agricultural tillage equipment to develop emissions inventories; instead the requirements for emissions inventories are set forth in 40 CFR 51.1008. *See* Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements, 81 FR 58010, 58027–33 (Aug. 24, 2016). The comment does not indicate any way in which the inventories fail to meet those requirements. Finally, for the purposes of $PM_{2.5}$ nonattainment areas such as the Logan, UT-ID area, wildfire emissions are generally accounted for through the EPA's Exceptional Events Rule,[2] not through emissions inventories.

III. Final Action

For the reasons stated in our proposal, the EPA is finalizing approval of portions of Utah's SIP found at R307–110–10, Section IX Control Measures for Area and Point Sources, Part A, Fine Particulate Matter for the Logan, UT-ID nonattainment area and at SIP Subsection IX.A.23: Control Measures for Area and Point Sources, Fine Particulate Matter for the Logan, UT-ID nonattainment area. Specifically, we are approving the following portions of the Logan, UT-ID Moderate $PM_{2.5}$ SIP submitted by the State on December 16, 2014:

- The 2010 base year and 2015 projection year emissions inventories;
- The modeled attainment demonstration;
- The RACM/RACT and additional reasonable measure demonstrations for on-road mobile, including the Cache

[1] The comment does not define this acronym, but we assume the comment intended to refer to EPA.

[2] 40 CFR 50.14.

County I/M Program, off-road mobile and major stationary sources; and

• The direct $PM_{2.5}$, nitrogen oxides (NO_X) and VOC MVEBs for 2015 and the MVEB trading mechanism.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the approval of portions of the Logan, UT-ID $PM_{2.5}$ Moderate SIP submitted by the State of Utah as discussed in the proposed rule. The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 8 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by the EPA for inclusion in the state implementation plan, have been incorporated by reference by the EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[3]

V. Statutory and Executive Order Reviews

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

• Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);

• is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;

• does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

• is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

• does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

• does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 22, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Ammonia, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide, Volatile organic compounds.

Dated: November 16, 2018.

Douglas Benevento,

Regional Administrator, EPA, Region 8.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart TT—Utah

■ 2. Section 52.2320 is amended by:

■ a. Revising the entry for ''R307–110–10'' in the table in paragraph (c); and

■ b. Adding the entry, in numerical order, ''Section IX.A.23. Fine Particulate Matter, $PM_{2.5}$ SIP for the Logan, UT–ID Nonattainment Area'' in the table in paragraph (e).

The revision and addition reads as follows:

§ 52.2320 Identification of plan.

* * * * *

(c) * * *

[3] 62 FR 27968 (May 22, 1997).

Rule No.	Rule title	State effective date	Final rule citation, date	Comments
*	*	*	*	*
R307–110. General Requirements: State Implementation Plan				
*	*	*	*	*
R307–110–10	Section IX. Control Measures for Area and Point Sources, Part A, Fine Particulate Matter.	12/4/2014	[Insert **Federal Register** citation], 11/23/2018.	
*	*	*	*	*

* * * * * (e) * * *

Rule title	State effective date	Final rule citation, date	Comments
*	*	*	*
IX. Control Measures for Area and Point Sources			
*	*	*	*
Section IX.A.23. Fine Particulate Matter, $PM_{2.5}$ SIP for the Logan, UT–ID Nonattainment Area.	12/4/2014	[Insert **Federal Register** citation], 11/23/2018.	Except for Chapters 1–3, Area Sources found in Chapter 6.6, Chapter 8 and Chapter 9.
*	*	*	*

[FR Doc. 2018–25486 Filed 11–21–18; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 83, No. 226
Friday, November 23, 2018

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

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Rural Housing Service

Rural Utilities Service

Farm Service Agency

7 CFR Part 1970

RIN 0572–AC44

Rural Development Environmental Regulation for Rural Infrastructure Projects

AGENCY: Rural Business-Cooperative Service, Rural Housing Service, Rural Utilities Service, Farm Service Agency, USDA.

ACTION: Proposed rule.

SUMMARY: The United States Department of Agriculture (USDA) Rural Development (RD), comprised of the Rural Business-Cooperative Service (RBS), Rural Housing Service (RHS), and Rural Utilities Service (RUS), hereafter referred to as the Agency, proposes amending the Agency's Environmental Policies and Procedures regulation to allow the Agency Administrators limited flexibility to obligate federal funds for infrastructure projects prior to completion of the environmental review while ensuring full compliance with National Environmental Policy Act (NEPA) procedures prior to project construction and disbursement of funding. The proposed change will allow RD to more fully meet the Administration's goals to speed the initiation of infrastructure projects and encourage planned community economic development without additional cost to taxpayers or change to environmental review requirements.

DATE: Electronic and written comments must be received on or before December 24, 2018.

ADDRESSES: Submit your comments on this rule by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and, in the lower ''Search Regulations and Federal Actions'' box, select ''Rural Utilities Service'' from the agency drop-down menu, then click on ''Submit.'' In the Docket ID column, select RUS–18–AGENCY–0005 to submit or view public comments and to view supporting and related materials available electronically. Information on using *Regulations.gov*, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.
- *Postal Mail/Commercial Delivery:* Please send your comment addressed to Michele Brooks, Rural Development Innovation Center, Regulations Team Lead, U.S. Department of Agriculture, 1400 Independence Ave. SW, Stop 1522, Room 1562, Washington, DC 20250. Please state that your comment refers to Docket No. RUS–18–AGENCY–0005.

Other Information: Additional information about Rural Development and its programs is available on the internet at *https://www.usda.gov/topics/rural*.

FOR FURTHER INFORMATION CONTACT: Kellie McGinness Kubena, Director, Engineering and Environmental Staff, Rural Utilities Service, USDA Rural Development, 1400 Independence Ave. SW, Mail Stop 1571, Room 2242, Washington, DC 20250–1571, Phone: 202–720–1649.

SUPPLEMENTARY INFORMATION: In the rules section of this issue of the **Federal Register**, Rural Development is concurrently publishing this action as a direct final rule without prior proposal because the Agency views this as a non-controversial action and anticipates no adverse comments. The language in the direct final rule will also serve as the language for this proposed rule. See the **SUPPLEMENTARY INFORMATION** provided in the direct final rule for the applicable **SUPPLEMENTARY INFORMATION** on this action. If no adverse comments are received in response to the direct final rule, no further action will be taken on this proposed rule and the action will become effective at the time specified in the direct final rule. If the Agency receives adverse comments, a timely document will be published withdrawing the direct final rule and all public comments received will be addressed in a subsequent final rule based on this action.

Dated: November 9, 2018.

Anne C. Hazlett,

Assistant to the Secretary, Rural Development.

Bill Northey,

Under Secretary, Farm Production and Conservation.

[FR Doc. 2018–25522 Filed 11–21–18; 8:45 am]

BILLING CODE P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Parts 704 and 713

RIN 3133–AE87

Fidelity Bonds

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed rule.

SUMMARY: The NCUA Board (Board) is seeking comment on a proposed rule that would amend its regulations regarding fidelity bonds under Part 704 for corporate credit unions and under Part 713 for natural person credit unions. The proposed rule would accomplish four objectives. First, it would strengthen a board of directors' oversight of a credit union's fidelity bond coverage. Second, it would ensure that there is an adequate period to discover and file fidelity bond claims following a credit union's liquidation. Third, it would codify a 2017 NCUA Office of General Counsel legal opinion that permits a natural person credit union's fidelity bond to include coverage for certain credit union service organizations (CUSOs). Fourth, it would clarify the documents subject to Board approval and require that all bond forms receive Board approval every ten years.

DATES: Comments must be received on or before January 22, 2019.

ADDRESSES: You may submit comments by any of the following methods (Please send comments by one method only):

- *NCUA website: http://www.ncua.gov/news/proposed_regs/proposed_regs.html*. Follow the instructions for submitting comments.

• *Email:* Address to *regcomments@ncua.gov*. Include ''[Your name] Comments on Notice of Proposed Rulemaking (Fidelity Bonds)'' in the email subject line.

• *Fax:* (703) 518–6319. Use the subject line described above for email.

• *Mail:* Address to Gerard Poliquin, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

• *Hand Delivery/Courier:* Same as mail address.

Public inspection: All public comments are available on the agency's website at *http://www.ncua.gov/RegulationsOpinionsLaws/comments* as submitted, except as may not be possible for technical reasons. Public comments will not be edited to remove any identifying or contact information. Paper copies of comments may be inspected in the NCUA's law library, 1775 Duke Street, Alexandria, Virginia 22314, by appointment weekdays between 9:00 a.m. and 3:00 p.m. To make an appointment, call (703) 518–6540 or send an email to *OGCMail@ncua.gov*.

FOR FURTHER INFORMATION CONTACT: Rob Robine, Trial Attorney, or Rachel Ackmann, Staff Attorney, Office of General Counsel, 1775 Duke Street, Alexandria, VA 22314–3428 or telephone (703) 548–2601.

SUPPLEMENTARY INFORMATION:

I. Introduction

a. Background and Legal Authority

The Federal Credit Union Act (FCU Act) requires that certain credit union employees and appointed and elected officials be subject to fidelity bond coverage.[1] The FCU Act directs the Board to promulgate regulations concerning both the amount and character of fidelity bond coverage and to approve bond forms.[2] The pertinent portion of the FCU Act provides:

> The Board is . . . directed to require that every person appointed or elected by any Federal credit union to any position requiring the receipt, payment, or custody of money or other personal property owned by a Federal credit union or in its custody or control as collateral or otherwise, give bond in a corporate surety company holding a certificate of authority from the Secretary of Treasury . . . as an acceptable surety on Federal bonds. Any such bond or bonds shall be in a form approved by the Board with a view to providing surety coverage to the Federal credit union with reference to loss by reason of acts of fraud or dishonesty including forgery, theft, embezzlement, wrongful abstraction, or misapplication on the part of the person, directly or through connivance with others, and such other surety coverages as the Board may determine to be reasonably appropriate. Any such bond or bonds shall be in such an amount in relation to the . . . assets of the Federal credit union as the Board may from time to time prescribe by regulation[.] [3]

Parts 704 and 713 of the NCUA's regulations implement the requirements of the FCU Act regarding fidelity bonds.[4] Parts 704 and 713 reiterate the statutory requirement that certain credit union employees and appointed and elected officials are subject to fidelity bond coverage. The parts also establish the requirements for a fidelity bond, the acceptable bond forms, and the minimum permissible coverage. Both parts require a credit union's board of directors to review annually its fidelity bond coverage to ensure it is adequate in relation to the potential risks facing the credit union and the minimum requirements set by the Board. Part 713 is made applicable to all federally insured, state-chartered credit unions (FISCUs) through § 741.201 of the NCUA's regulations.[5]

Part 704 was recently revised to amend the provision that determines the maximum amount a credit union may pay for a covered loss, or deductible, before the fidelity bond insurer makes a payment. The NCUA restricts the deductible a corporate credit union may pay to limit the potential losses to it if there is a covered claim. The maximum deductible allowed is a percentage of a corporate credit union's capital based on its leverage ratio. For example, if a corporate credit union has a greater than 2.25 leverage ratio then it may have a maximum deductible that is 15 percent of its tier 1 capital. The recent final rule updated this provision to reference tier 1 capital instead of core capital.[6] Part 713, however, has not been substantively revised since 2005 when the NCUA issued a final rule modernizing Part 713.[7]

b. Regulatory Reform Task Force

In August 2017, the Board published and sought comment on the NCUA's regulatory reform agenda (Agenda).[8] The Agenda identifies those regulations the Board intends to amend or repeal because they are outdated, ineffective, or excessively burdensome. This is consistent with the spirit of Executive Order 13777.[9] Although the NCUA, as an independent agency, is not required to comply with Executive Order 13777, the Board has chosen to comply with it in spirit and has reviewed all of the NCUA's regulations to that end. One of the items in the Agenda is related to the NCUA's regulations on fidelity bonds. The Agenda supports exploring ways to implement the requirements of the FCU Act in this context in the least costly way possible. The Agenda further notes that while the FCU Act mandates fidelity bond coverage, the NCUA's objective should be to allow a credit union to make a business decision based on its own circumstances and needs. This would effectively reduce the NCUA's involvement in a credit union's operational decisions while remaining consistent with the FCU Act.

c. The 2017 Legal Opinion

As discussed above, Part 713 establishes the minimum requirements for a fidelity bond for a natural person credit union. One such requirement under Part 713 is that fidelity bonds be purchased in an ''individual policy.'' [10] The ''individual policy'' provision was intended to prevent multiple credit unions from being insured under one fidelity bond policy. The Board prohibited such joint coverage because the loss suffered by one or two of the joint policyholders could reduce the amount of available coverage for the other policyholders to below the required minimum amount.[11] Before 2017, the NCUA's Office of General Counsel (OGC) had issued legal opinions stating that a credit union may not include one or more CUSOs or other parties as additional insureds under its fidelity bond because of the ''individual policy'' limitation.[12] It came to OGC's attention, however, that some bond issuers may have been interpreting their policies to permit the issuance of bonds that covered credit unions and their

[1] 12 U.S.C. 1761a, 1761b, and 1766.

[2] The FCU Act also grants the Board the powers to require such other surety coverage as the Board may determine to be reasonably appropriate; to approve a blanket bond in lieu of individual bonds; and to approve bond coverage in excess of minimum surety coverage.

[3] 12 U.S.C. 1766(h).

[4] 12 CFR pts. 704 and 713.

[5] 12 CFR 741.201.

[6] 80 FR 25932 (May 6, 2015).

[7] 70 FR 61713 (Oct. 26, 2005. In 2012, the NCUA revised Part 713 by removing reference to the agency's former Regulatory Flexibility Program. 77 FR 74112 (Dec. 13, 2012).

[8] 82 FR 39702 (Aug. 22, 2017).

[9] E.O. 13771 (Jan. 30, 2017).

[10] 12 CFR 713.3(a). There is not an analogous provision for corporate credit unions under Part 704, therefore, the legal opinion relates only to fidelity bonds for natural person credit unions under Part 713.

[11] 64 FR 28178 (May 27, 1999).

[12] OGC Legal Op. 14–0311 (Mar. 21, 2014); see also OGC Legal Op. 04–0744 (Sept. 21, 2004).

CUSOs, despite OGC's opinions to the contrary. This prompted OGC to review the regulation and approved bond forms. As a result of that review, OGC issued another legal opinion in September 2017 that rescinded and replaced all previous legal opinions that addressed the ''individual policy'' requirement.[13] The 2017 opinion concluded that the ''individual policy'' requirement of § 713.3(a) of the NCUA's regulations generally prohibits joint coverage under fidelity bonds, but does not prohibit a credit union from purchasing a fidelity bond that covers both the credit union and certain of its CUSOs, as discussed more fully below.

II. Proposed Rule

OGC's review of Part 713 extended beyond the issue of joint coverage and revealed several inconsistencies between the regulation and approved bond forms. The review also revealed several outdated provisions the Board now seeks to update to ensure the safe and sound operation of credit unions and to protect the National Credit Union Share Insurance Fund (NCUSIF). The Board believes that many of the concerns identified by OGC, as discussed more fully below, are also relevant for corporate credit unions. Therefore, where appropriate, the Board is also proposing amendments to the NCUA's corporate credit union regulations under Part 704. The specific details of the proposed amendments are discussed below.

III. Section-by-Section Analysis

Part 704

In general, Part 704 applies to all federally insured corporate credit unions. Section 704.18 provides the fidelity bond requirements for such credit unions. Proposed changes to the specific subparagraphs of § 704.18 are discussed below.

Sec. 704.18 Fidelity Bond Coverage

18(a)

The proposed rule would not make any changes to paragraph (a).

18(b)

The proposed rule would amend current § 704.18(b) by dividing paragraph (b) into two subparts. Current paragraph (b) would remain unchanged and be designated paragraph (b)(1). The proposed rule would add a new paragraph as (b)(2). Proposed paragraph (b)(2) would require that a corporate credit union's board of directors and supervisory committee must review all applications for purchase or renewal of its fidelity bond coverage. After review, the corporate credit union's board must pass a resolution approving the purchase or renewal of fidelity bond coverage and delegate one member of the board, who is not an employee of the corporate credit union, to sign the purchase or renewal agreement and all attachments. No board members may be a signatory on consecutive purchase or renewal agreements for the same fidelity bond coverage policy. This proposed amendment is identical to proposed changes to Part 713 for natural person credit unions. For additional background, see the discussion below for proposed changes to § 713.2(b).

18(c)

The proposed rule would make significant revisions to current § 704.18(c). In the proposed rule, § 704.18(c) is split into five new subparagraphs, each of which is described in more detail below.

18(c)(1)

The proposed rule would state that a corporate credit union's fidelity bond coverage must be purchased from a company holding a certificate of authority from the Secretary of the Treasury. This is not a substantive change from the current requirements and has only been amended to reflect the comparable language in Part 713.

18(c)(2)

Proposed § 704.18(c)(2) would state that fidelity bonds must provide coverage for the fraud and dishonesty of all employees, directors, officers, and supervisory and credit committee members. This is not a substantive change from the current requirements.

18(c)(3)

The proposed rule would substantively amend the requirements for a corporate credit union's approved bond forms. The revised requirements reflect the changes proposed for natural person credit unions in Part 713. The proposed rule would require the Board to approve all bond forms before a corporate credit union may use them. In addition, a credit union may not use any bond form that has been amended since receiving Board approval or any rider, endorsement, renewal, or other document that limits coverage of approved bond forms without first receiving approval from the Board. As would be required under proposed Part 713, approval of all bond forms expires 10 years after the date the Board approved or reapproved use of the bond form. Any currently approved bond forms would expire on January 1, 2029. For additional background, see the discussion below for proposed changes to § 713.4.

18(c)(4)

The proposed rule would add a new § 704.18(c)(4) to ensure there is an adequate discovery period, the period to discover and file a claim, following a corporate credit union's liquidation. The revised requirements reflect the changes proposed for natural person credit unions in Part 713. The proposed rule would require fidelity bonds to include an option for the liquidating agent to purchase coverage in the event of an involuntary liquidation that extends the discovery period for a covered loss for at least two years after liquidation. In the case of a voluntary liquidation, fidelity bonds would be required to remain in effect, or provide that the discovery period is extended, for at least four months after the final distribution of assets. For additional background, see the discussion below for proposed changes to §§ 713.3(a)(3) and (4).

18(c)(5)

The proposed rule would require corporate credit union bonds to include a provision requiring written notification by surety to the NCUA when a credit union's bond is terminated or when the coverage of an employee, director, officer, supervisory or credit committee member has been terminated. The NCUA also must be notified in writing by surety if a deductible is increased above permissible limits. This is not a substantive change from the current requirements.

18(d)–18(f)

The proposed rule would not make any changes to paragraphs (d), (e), and (f).

Part 713

In general, Part 713 applies to all federally insured natural person credit unions and provides the fidelity bond requirements for them. Proposed changes to the specific subsections of Part 713 are discussed below.

Sec. 713.1 What is the scope of this section?

The proposed rule would retain most of the current § 713.1 without change, with the following exceptions. The proposed rule would add the words ''federally insured'' before the words ''credit union'' to more precisely describe which credit unions are subject to the section. The current rule uses the

[13] OGC Legal Op. 17–0959 (Sept. 26, 2017).

term ''credit union'' and ''federal credit union'' interchangeably to mean ''federal credit union.'' As discussed in the background section, the requirements in Part 713 are applicable to both federal credit unions and FISCUs.[14] For clarity, the proposed rule would cross reference the requirement in Part 741 that FISCUs must comply with Part 713 and would refer to federally insured credit unions (FICUs) throughout the rule instead of federal credit unions. The Board does not intend any substantive changes by this amendment and only intends to increase the clarity and internal consistency of Part 713.

The proposed rule would also include a cross reference for corporate credit unions and would state that corporate credit unions must comply with § 704.18 instead of Part 713.

Sec. 713.2 What are the responsibilities of a federally insured credit union's board of directors under this section?

2(a)

The proposed rule would amend current § 713.2 by dividing the section into two subparagraphs. Current § 713.2 would become paragraph (a). The proposed rule would retain most of the current § 713.2 without change, with the following exception. For consistency with the rest of Part 713, the term ''Federal credit union'' would be revised to ''federally insured credit union.''

2(b)

The proposed rule would add a new paragraph (b) to § 713.2. Proposed paragraph (b) increases a board of directors' oversight responsibility of its FICU's fidelity bond coverage. Specifically, the Board is proposing to require a FICU's board, and, if applicable, a FICU's supervisory committee, to review all applications for purchase or renewal of bond coverage and to pass a board resolution approving the purchase or renewal. The proposed rule would also require a FICU's board to delegate one board member, who is not an employee of the FICU, to sign the attestation for bond purchase or renewal. This proposal would prohibit the same board member from signing the attestation for renewal in consecutive years.

The Board notes the current rule already requires a FICU's board to annually review its fidelity bond and other insurance coverage to ensure it is adequate. The proposed rule would take that review a step further and require a FICU's board, and, if applicable, its supervisory committee, to review all applications for purchase or renewal of fidelity bond coverage. The Board believes this change will help ensure the board is addressing the adequacy of the coverage at all stages, rather than at an annual point in time that may be retrospective, and require additional steps by the FICU to remedy a deficiency.

The Board is also proposing to require a FICU's supervisory committee to conduct a review of all applications for purchase or renewal of fidelity coverage, in addition to the board. The Board believes this is a function within the responsibilities of a FICU's supervisory committee and will add an additional layer of review. For FISCUs operating without a supervisory committee, its board should implement controls or establish procedures for conducting their own analysis of the FISCU's fidelity bond coverage, as opposed to relying on recommendations from the FISCU's officers.

As noted, the proposed rule would also require a FICU's board to, after conducting its review, pass a resolution approving the purchase or renewal of fidelity coverage and designating a member of the board, who is not an employee of the FICU, to sign applications for purchase, bond renewals, and any accompanying attestations. Also as mentioned, the Board is proposing to require that the member of the board acting as signatory rotate each time the FICU purchases or renews fidelity coverage. The purpose of these requirements is to address the issue of rescission of fidelity coverage when the signatory to the application to purchase or renew coverage is knowledgeable of fraudulent activity. If the signatory to the application for purchase or renewal is knowledgeable of fraudulent activity, the bond issuer may void the policy and not make a payout when losses are discovered. The NCUA believes that a non-employee board member, who would not be involved in the day-to-day operations of a FICU, is less likely to be responsible for a fraudulent activity than an employee. The NCUA also believes that rotating signatories would reduce the potential for the signatory to be knowledgeable of the fraudulent activity.

In the case where the NCUA is a liquidating agent of a FICU, the NCUSIF would suffer losses due to the fidelity bond being voided. In recent years, the NCUSIF has sustained increased losses due to voided fidelity bond coverage. Before 2010, bond rescission was not a material concern for the NCUA. Since 2010, however, the NCUA has had at least three claims denied due to rescinded fidelity bond coverage and the NCUA is concerned that the frequency of rescinded coverage will continue to increase. As of June 2018, the NCUSIF has already lost in excess of $10 million from fidelity bonds that were voided due to the signatory being aware of the fraudulent activities and litigation related to denied claims is ongoing and may result in additional expenses.

The Board believes the proposed changes are only a minimal increase in regulatory burden as the FICU's board is already required to annually review its fidelity bond coverage, but would meaningfully mitigate the risk to the NCUSIF associated with fidelity bond coverage rescission. The Board notes that this proposed requirement is also advantageous to individual FICUs, as this will help prevent them from losing coverage absent involuntary liquidation.

Sec. 713.3 What bond coverage must a federally insured credit union have?

The proposed rule would amend current § 713.3 by renumbering and revising the section. Current § 713.3 would become paragraph (a), current paragraphs (a) and (b) would be renumbered as paragraphs (a)(1) and (a)(2), and two new subparagraphs would be added as (a)(3) and (a)(4). Finally, a new paragraph (b) would also be added.

3(a)(2)

Current paragraph (b) of § 713.3 states that, at a minimum, a credit union's fidelity bond coverage must include fidelity bonds that cover fraud and dishonesty. The proposed rule would remove the redundant phrase ''[i]nclude fidelity bonds that'' in current paragraph (b). The proposed rule would read ''At a minimum, your bond coverage must: . . . Cover fraud and dishonesty by all employees, directors, officers, supervisory committee members, and credit committee members;''. The change is non-substantive and only intended to remove the unnecessary language and clarify the requirement.

3(a)(3)

The proposed rule would add a new paragraph (a)(3) to § 713.3. Proposed paragraph (a)(3) would require a FICU to have fidelity bond coverage that includes an option for the liquidating agent to purchase coverage that extends

[14] Part 713 is applicable to all FISCUs through § 741.201 of the NCUA's regulations, which states that any credit union which makes application for share insurance must have the minimum fidelity bond coverage stated in Part 713 in order for its application to be approved and for such share insurance coverage to continue.

the discovery period, the period to discover and file a claim, for at least two years after liquidation. Fidelity bonds mitigate the risk presented by fraudulent and other dishonest acts to the NCUSIF and have served as a significant source of recovery in liquidations caused by fraud. However, the NCUA, as liquidating agent, can only file a claim if it discovers the loss during the contractual period permitted for filling a claim. Historically, it had been standard for fidelity bonds to permit a reasonable period for discovery and filing a claim following a FICU's involuntary liquidation. The NCUA has identified approximately $1 million in claims paid to the NCUSIF that were identified during an extended discovery period from 2006 to 2013. Since then, however, insurers have removed standard discovery coverage provisions from fidelity bond contracts. Currently, most fidelity bonds provide that the bond's coverage terminates immediately upon a credit union's liquidation and that the ability to purchase an additional period to discover loss is at the *sole discretion of the insurer*.

Under such contracts, the NCUA, as liquidating agent, would not have authority to extend the discovery period following a FICU's closure. There are some instances when liquidation occurs unexpectedly and there is insufficient time to discover a claim before liquidation, or where there is a covered loss, but it is unknown with the specificity required for filing a claim. In such a case, even if the liquidating agent subsequently discovers a covered loss, the fidelity bond issuer may deny the claim. If this happens when the NCUA is liquidating agent, the NCUA would either be forced into litigation to receive payment for the covered loss or not recover for the loss. In either situation, the NCUSIF bears additional losses than if the fidelity bond permitted a reasonable period of discovery. In addition to reducing losses to the NCUSIF, any funds recovered due to an extended discovery period may also be available to pay the failed FICU's creditors and uninsured depositors.[15]

In an attempt to address this gap in coverage, it has been the NCUA's practice to provide notice that there may be a potential claim before a liquidation. This informal solution, however, lacks legal clarity and results in unnecessary risk that an insurer may deny a claim following an involuntary liquidation. The proposed rule would provide the NCUA with an explicit right to extend the discovery period, which should prevent unnecessary losses to the NCUSIF due to contract technicalities.

The proposed rule would require that fidelity bond coverage provide a discovery period of *two years* because the FCU Act provides members with 18 months after the appointment of a liquidating agent to claim their insured accounts.[16] Therefore, the Board is providing six months to discover and make a claim for fidelity bond coverage following the end of the 18-month statutory period for unclaimed accounts. Further, in the Board's experience, most liquidations are resolved within two years. The Board considers two years a reasonable period to resolve the FICU's affairs, discover any losses from fraudulent or dishonest acts, and file a claim under the fidelity bond. The Board does not expect this proposed requirement to result in any additional cost or burden on FICUs. The liquidating agent would bear the cost of any extension of a discovery period following an involuntary liquidation.

3(a)(4)

The Board is also proposing to add a new paragraph (a)(4) to § 713.3 to include a requirement that, for voluntary liquidations, a FICU's fidelity bond coverage remain in effect, or provide that the discovery period is extended, for at least four months after the final distribution of assets. The Board notes that this is currently required for federal credit unions in Part 710, the NCUA's voluntary liquidation regulations, and that this proposed change only reflects that requirement, and does not impose an additional burden for federal credit unions.[17] This requirement would represent a new burden, however, for FISCUs. The Board believes that this requirement would impose only a minor burden for FISCUs, and would be beneficial to its members, as any recovery following a voluntary termination would flow through to members.

3(b)

The Board is proposing to amend § 713.3 to allow a FICU to have a fidelity bond that covers both it and certain of its CUSOs, as more fully discussed below. Section 713.3 requires that a bond, at a minimum, must be purchased in ''an individual policy.'' [18] The NCUA added this section to Part 713 in a 1999 final rule in response to a commenter who pointed out that there had been instances of FICUs jointly purchasing fidelity bonds with each other.[19] The commenter was concerned that a loss caused by one or two of the joint policyholders could reduce the amount of available coverage for the other policyholders to below the required minimum amount. In addressing this comment, the Board provided in § 713.3 that a FICU must purchase its own individual policy.[20] The regulation did not, however, define ''individual policy.''

Since inclusion of this provision in the NCUA's regulations, OGC has issued two public legal opinions interpreting the meaning of ''individual policy'' and opining on the type of coverage that is prohibited under § 713.3(a).[21] A 2014 OGC legal opinion states that a FICU may not include one or more of its CUSOs or other parties as additional insureds under its fidelity bond.[22] In a 2004 legal opinion, OGC opined that a CUSO that provides management services for multiple credit unions could not purchase a single fidelity bond with each credit union named as an insured.[23] In both letters, OGC explained the purpose of the individual policy requirement is to avoid diluting the individual credit union's coverage.

As noted above, OGC issued a third legal opinion on the ''individual policy'' requirement in 2017 (2017 legal opinion). The 2017 legal opinion rescinded and replaced the previous two opinions and expanded the permissibility for certain joint coverage provisions under the ''individual policy'' requirement. OGC and the NCUA's Office of Examination and Insurance determined this broader interpretation was both within the NCUA's legal authority under the FCU Act and a safe and sound practice for FICUs. For clarity and ease of reference, the Board now seeks to incorporate the 2017 legal opinion into Part 713.

The Board, therefore, is proposing to amend § 713.3 to permit a FICU to have a fidelity bond that also covers its CUSO(s). This is permissible if the FICU owns greater than 50 percent of a CUSO it wishes to cover, or a covered CUSO is organized by the FICU for the purpose of handling certain of its business transactions and composed exclusively of its employees. The 50 percent threshold reflects the standard for accounting consolidation under generally accepted accounting principles, or GAAP. A FICU would

[15] For the priority of payment following a liquidation, see 12 U.S.C. 1787(b)(11).

[16] 12 U.S.C. 1787(o).

[17] 12 CFR 710.2(c).

[18] 12 CFR 713.3.

[19] 64 FR 28718, 28719 (May 27, 1999).

[20] *Id.* at 28719.

[21] OGC Legal Op. 04–0744 (Sep. 21, 2004); and OGC Legal Op. 14–1013 (Mar. 21, 2014).

[22] OGC Legal Op. 14–1013 (Mar. 21, 2014).

[23] OGC Legal Op. 04–0744 (Sep. 21, 2004).

directly benefit from any fidelity bond insurance proceeds collected by a consolidated CUSO.[24] This proposed rule, however, would not eliminate the prohibition against joint coverage of entities not majority owned by the FICU, such as other credit unions or non-majority-owned CUSOs. The Board believes this amendment will provide greater flexibility to FICUs without affecting safety and soundness.[25]

Sec. 713.4 What bond forms may a federally insured credit union use?

The current rule provides that the NCUA will maintain a current list of bond forms approved by the Board for use by FICUs. The rule also states that a FICU must obtain the approval of the Board before it can use any other basic bond form or any rider or endorsement that limits coverage of an approved bond form. The Board is proposing to amend § 713.4 to make several changes to reflect the practices of the NCUA, clarify the list of documents that must have Board approval, and address the expiration and continuing review of approved bond forms. Any questions regarding the NCUA's approval of fidelity bond forms can be directed to the NCUA's OGC, (703) 518–6540, or the Office of Examination and Insurance, (703) 518–6360.

4(a)

Current § 713.4(a) states that a current listing of basic bond forms that may be used without prior Board approval is on the NCUA's website. The Board is proposing to clarify this requirement by dividing paragraph (a) into two paragraphs. Proposed paragraph (a) would explicitly state that ''the NCUA Board must approve all bond forms before federally insured credit unions may use them.''

4(b)

Proposed paragraph (b) would state that approved bond forms are listed on the NCUA's website and may be used by a FICU without further NCUA approval. If a FICU is unable to access the NCUA's website, it can get a current listing of approved bond forms by contacting the NCUA's Office of Public and Congressional Affairs. The proposed rule would rewrite this provision for clarity, but would not make any substantive changes.

4(c)

Current paragraph (b), renumbered as paragraph (c), sets forth which fidelity bonds and fidelity bond documents require Board approval. The proposed rule also would set forth which fidelity bonds and fidelity bond documents require Board approval, but would rewrite this provision for clarity. The proposed rule states in paragraph (c) that ''Credit unions may not use any of the following without first receiving approval from the NCUA Board.'' No substantive changes are intended by this revision, and the revision is only intended to clarify the Board's expectation for FICUs.

4(c)(1)

The Board is clarifying that any bond form that has been amended or changed since the Board approved it requires new approval from the Board. The Board notes that this policy is the current practice whereby bond issuers submit amended bond forms to the Board for approval under current § 713.4(b)(1). This proposed change is only intended to make the regulation clearer with respect to this requirement.

4(c)(2)

Current § 713.4(b)(2) requires any rider or endorsement that limits coverage of approved basic bond forms to be approved by the Board. The proposed rule would clarify the list of documents that must receive Board approval. The Board is proposing to state explicitly that renewal forms (and any other document) that limit the coverage of approved bond forms must also receive Board approval. The Board is clarifying the list of documents subject to approval because the Board is aware of instances where the renewal or continuation of coverage forms included language affecting the bond coverage, including language that limited the bond coverage. As such, it is the Board's belief that the renewal form is an extension of the bond form and thus this is not an additional burden but further clarification of what constitutes the bond form.

4(d)

The Board is proposing to add a new paragraph (d) to sunset its approval on all bond forms ten years after the form is approved. The impetus for this provision is the discovery that Board approved-bond forms were being interpreted in a way that was contrary to the NCUA's understanding of how the bond forms would be used. In addition, a review of previously approved bond forms, as part of issuing the 2017 legal opinion, revealed several instances of outdated provisions, additions that had not been approved by the Board, and some forms that contained provisions that were contrary to the FCU Act and Part 713 of the NCUA's regulations. To avoid instances of this in the future, the Board is proposing to sunset its approval of a bond form after a period of ten years. This ten-year period will begin on the date the Board approves a bond form. The Board notes, however, that the ten-year period will not toll or start over when a bond carrier submits a revision to an approved bond. For example, if the Board approves a bond form on January 1, 2020, and that bond form is subsequently amended and approved by the Board on January 1, 2021, then the bond form will still expire on January 1, 2030, ten years from the date the Board issued its initial approval.

The Board believes this ten-year sunset provision will provide a definitive date at which an approved bond form will be reviewed by the Board to determine if it is still in compliance with the NCUA's regulations. While this provision will require expired bond forms to be resubmitted to the Board, having a clear date upon which the Board's approval will sunset will help all interested parties prepare to resubmit the bond form to ensure continuity in coverage and operations. The Board also notes that should it determine, upon re-review, that a bond form does not comply with the NCUA's regulations, the Board would not require FICUs with coverage under that bond to seek new coverage. In these situations, the Board would require FICUs to seek new coverage under an approved bond form after its current coverage expires per the terms of the contract between the FICU and the bond issuer.

With respect to bond forms that the Board has approved before 2019, the Board is proposing to allow its approval on these forms to continue until January 1, 2029. The Board believes this date for sunset of its approval will provide all currently approved bonds with at least ten years before they must be submitted for review and re-approval. The Board believes this will achieve the goal of ensuring all approved bond forms comply with the NCUA's regulations without imposing unnecessary burden on FICUs or bond issuers.

[24] As discussed in the 2017 legal opinion, the NCUA has previously approved certain nominee provisions that included limited joint coverage. For example, a nominee provision may state that a loss sustained by any ''nominee'' organized by the insured for the purpose of handling certain of its business transactions and composed exclusively of its employees shall be deemed to be loss sustained by the insured.

[25] Note, the proposal is not making a comparable amendment to Part 704. Corporate credit unions are not required to purchase fidelity bonds subject to an individual policy requirement. Therefore, the proposed amendment to clarify the individual policy requirement is only applicable to natural person credit unions.

In addition to including a sunset provision, the Board is also proposing to clarify its right and ability to review a bond form at any time. The Board notes that if it does undertake a review of an approved bond form during the ten-year period, this will not re-start or toll the expiration period and the Board's approval of that form will still sunset ten years from the date the Board issued its original approval.

Sec. 713.5–§ 713.7

As discussed above, the proposed rule would use the term federally insured credit union instead of federal credit union in each of §§ 713.5, 713.6, and 713.7 for consistency and clarity.

IV. Request for Comment

The Board invites comment on all aspects of this proposed rulemaking. In particular, the Board seeks comment on whether FICUs anticipate any increase in compliance burden under the proposed rule.

V. Regulatory Procedures

a. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) applies to rulemakings in which an agency by rule creates a new paperwork burden on regulated entities or modifies an existing burden. For purposes of the PRA, a paperwork burden may take the form of a reporting, disclosure, or recordkeeping requirement, each referred to as an information collection. The NCUA may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

A proposed change to Part 713 would require NCUA approval on all bond forms expired after a period of 10 years from the date of NCUA approval or reapproved of its use. The bond company would be required to seek NCUA approval before a bond form may be used by a FICU. The information collection burden associated with this proposed new requirements is minimal, only affecting an estimated two entities annually; for an increase of two hours to the currently approved OMB control number 3133–0170.

Title of Information Collection: Fidelity Bond and Insurance Coverage for Federal Credit Unions, 12 CFR part 713.

OMB Control Number: 3133–0170.

Estimated Number of Respondents: 10.

Estimated Annual Frequency of Response: 1.

Estimated Total Annual Reponses: 10.

Estimated Hours per Response: 1.

Estimated Total Annual Burden Hours: 10.

Affected Public: Private Sector: Not-for-profit institutions; Businesses and other for-profits.

The NCUA invites comments on: (a) Whether the collections of information are necessary for the proper performance of the agencies' functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collections, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

All comments are a matter of public record. Comments regarding the information collection requirements of this rule should be sent to (1) Dawn Wolfgang, NCUA PRA Clearance Officer, National Credit Union Administration, 1775 Duke Street, Suite 5080, Alexandria, Virginia 22314, or Fax No. 703–519–8572, or Email at *PRAcomments@ncua.gov* and the (2) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for NCUA, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov*.

b. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that, in connection with a notice of proposed rulemaking, an agency prepare and make available for public comment an initial regulatory flexibility analysis that describes the impact of a proposed rule on small entities. A regulatory flexibility analysis is not required, however, if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities (defined for purposes of the RFA to include credit unions with assets less than $100 million) and publishes its certification and a short, explanatory statement in the **Federal Register** together with the rule.

The Board does not believe that the proposed rule would have a significant economic impact on a substantial number of small entities. Any increased costs for the bond insurer to resubmit their forms every ten years would be spread out among all FICUs and the cost to each FICU would be negligible. Additionally, the proposed requirement that boards, and if applicable, supervisory committees, must approve purchases and renewals would impose no direct cost on FICUs. Accordingly, the NCUA certifies that the proposed rule will not have a significant economic impact on a substantial number of small FICUs.

c. Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. The NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order to adhere to fundamental federalism principles. This proposed rule will not have a direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. The NCUA has therefore determined that this proposed rule does not constitute a policy that has federalism implications for purposes of the executive order.

d. Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this proposed rule would not affect family well-being within the meaning of § 654 of the Treasury and General Government Appropriations Act, 1999, Public Law 105–277, 112 Stat. 2681 (1998).

List of Subjects in 12 CFR Parts 704 and 713

Bonds, Credit unions, Insurance.

By the National Credit Union Administration Board on November 15, 2018.

Gerard Poliquin,

Secretary of the Board.

For the reasons discussed above, the NCUA is proposing to amend 12 CFR parts 704 and 713 as follows:

PART 704—CORPORATE CREDIT UNIONS

■ 1. The authority citation for part 704 is revised to read as follows:

Authority: 12 U.S.C. 1762, 1766(a), 1772a, 1781, 1789, and 1795e.

■ 2. Section 704.18 is amended by revising paragraphs (b) and (c) to read as follows:

§ 704.18 Fidelity bond coverage.

* * * * *

(b) *Review of bond coverage.* (1) The board of directors of each corporate credit union shall, at least annually, carefully review the bond coverage in force to determine its adequacy in relation to risk exposure and to the minimum requirements in this section.

(2) The board of directors and the supervisory committee of each corporate credit union must review all applications for purchase or renewal of its fidelity bond coverage. After review, the credit union's board must pass a resolution approving the purchase or renewal of fidelity bond coverage and delegate one member of the board, who is not an employee of the credit union, to sign the purchase or renewal agreement and all attachments. Provided, however, that no board members may be a signatory on consecutive purchase or renewal agreements for the same fidelity bond coverage policy.

(c) *Minimum coverage; approved forms.* (1) The fidelity bond coverage must be purchased from a company holding a certificate of authority from the Secretary of the Treasury.

(2) Fidelity bonds must provide coverage for the fraud and dishonesty of all employees, directors, officers, and supervisory and credit committee members.

(3) The NCUA Board must approve all bond forms before a corporate credit union may use them. Corporate credit unions may not use any bond form that has been amended since the time the NCUA Board approved the form or any rider, endorsement, renewal, or other document that limits coverage of approved bond forms without receiving approval from the NCUA Board. Approval on all bond forms expires 10 years after the date the NCUA Board approved or reapproved use of the bond form; provided, however, that any bond forms approved before 2019 will expire on January 1, 2029 and an NCUA Board-approved amendment to a bond form does not toll or cause the 10-year period to restart. The NCUA reserves the right to review a bond form at any point after its approval.

(4) Fidelity bonds must include an option for the liquidating agent to purchase coverage in the event of an involuntary liquidation that extends the discovery period for a covered loss for at least two years after liquidation. In the case of a voluntary liquidation, fidelity bonds must remain in effect, or provide that the discovery period is extended, for at least four months after the final distribution of assets.

(5) Notwithstanding the foregoing, all bonds must include a provision, in a form approved by the NCUA Board, requiring written notification by surety to NCUA:

(i) When the fidelity bond of a credit union is terminated in its entirety;

(ii) When fidelity bond coverage is terminated, by issuance of a written notice, on an employee, director, officer, supervisory or credit committee member; or

(iii) When a deductible is increased above permissible limits. Said notification shall be sent to NCUA and shall include a brief statement of cause for termination or increase.

* * * * *

PART 713—FIDELITY BOND AND INSURANCE COVERAGE FOR FEDERALLY INSURED CREDIT UNIONS

■ 3. The authority citation for Part 713 continues to read as follows:

Authority: 12 U.S.C. 1761a, 1761b, 1766(a), 1766(h), 1789(a)(11).

■ 4. The heading for part 713 is revised as set forth above.

■ 5. Revise § 713.1 to read as follows:

§ 713.1 What is the scope of this section?

This section provides the requirements for fidelity bonds for federally insured credit union employees and officials and for other insurance coverage for losses such as theft, holdup, vandalism, etc., caused by persons outside the credit union. Federally insured, state-chartered credit unions are required by § 741.201 of this chapter to comply with the fidelity bond coverage requirements of this part. Corporate credit unions must comply with § 704.18 of this chapter in lieu of this part.

■ 6. Revise § 713.2 to read as follows:

§ 713.2 What are the responsibilities of a federally insured credit union's board of directors under this section?

(a) The board of directors of each federally insured credit union must at least annually review its fidelity and other insurance coverage to ensure that it is adequate in relation to the potential risks facing the federally insured credit union and the minimum requirements set by the NCUA Board; and

(b) The board of directors, and, if applicable, the supervisory committee of each federally insured credit union, must review all applications for purchase or renewal of its fidelity bond coverage. After review, the federally insured credit union's board must pass a resolution approving the purchase or renewal of fidelity bond coverage and delegate one member of the board, who is not an employee of the federally insured credit union, to sign the purchase or renewal agreement and all attachments; provided, however, that no board members may be a signatory on consecutive purchase or renewal agreements for the same fidelity bond coverage policy.

■ 7. Revise § 713.3 to read as follows:

§ 713.3 What bond coverage must a federally insured credit union have?

(a) At a minimum, your bond coverage must:

(1) Be purchased in an individual policy from a company holding a certificate of authority from the Secretary of the Treasury;

(2) Cover fraud and dishonesty by all employees, directors, officers, supervisory committee members, and credit committee members;

(3) Include an option for the liquidating agent to purchase coverage in the event of an involuntary liquidation that extends the discovery period for a covered loss for at least two years after liquidation; and

(4) In the case of a voluntary liquidation, remain in effect, or provide that the discovery period is extended, for at least four months after the final distribution of assets, as required in § 710.2(c) of this chapter.

(b) The requirement in paragraph (a) of this section does not prohibit a federally insured credit union from having a fidelity bond that also covers its credit union service organization (CUSO(s)), provided the federally insured credit union owns more than 50 percent of the CUSO(s) or the CUSO(s) is organized by the federally insured credit union for the purpose of handling certain of its business transactions and composed exclusively of the federally insured credit union's employees.

■ 8. Revise § 713.4 to read as follows:

§ 713.4 What bond forms may a federally insured credit union use?

(a) The NCUA Board must approve all bond forms before federally insured credit unions may use them.

(b) Bond forms the NCUA Board has approved for use by federally insured credit union are listed on the NCUA's website, *http://www.ncua.gov,* and may be used by federally insured credit unions without further NCUA approval. If you are unable to access the NCUA's website, you can obtain a current listing of approved bond forms by contacting the NCUA's Office of Public and Congressional Affairs.

(c) Federally insured credit union unions may not use any of the following without first receiving approval from the NCUA Board:

(1) Any bond form that has been amended or changed since the time the NCUA Board approved the form; and

(2) Any rider, endorsement, renewal, or other document that limits coverage of approved bond forms.

(d) Approval on all bond forms expires after a period of 10 years from the date the NCUA Board approved or reapproved use of the bond form. Provided, however, that:

(1) Any bond forms approved before 2019 will expire on January 1, 2029.

(2) An NCUA Board-approved amendment to a bond form does not toll or cause the 10-year period to restart; and

(3) The NCUA reserves the right to review a bond form at any point after its approval.

§ 713.5 [AMENDED]

■ 9. Section 713.5 is amended by:

■ a. In paragraphs (a) and (b) remove the word ''federal'' before the words ''credit union's'' and add in its place the words ''federally insured'' each place they appear.

■ b. In paragraph (c) add the words ''federally insured'' before the words ''credit union,'' ''credit unions,'' or ''credit union's'' each place they appear.

■ c. In paragraph (e) remove the word ''your'' and add in its place the words ''a federally insured credit union's''.

§ 713.6 [AMENDED]

■ 10. In § 713.6 remove the word ''federal'' before the words ''credit union's'' or ''credit unions'' and add the words ''federally insured'' before the words ''credit union's,'' ''credit unions,'' and ''credit union'' each place they appear.

■ 11. Revise § 713.7 to read as follows:

§ 713.7 May the NCUA Board require a federally insured credit union to secure additional insurance coverage?

The NCUA Board may require additional coverage when the NCUA Board determines that a federally insured credit union's current coverage is inadequate. The federally insured credit union must purchase this additional coverage within 30 days.

[FR Doc. 2018–25402 Filed 11–21–18; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0963; Product Identifier 2018–NM–135–AD]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Dassault Aviation Model FAN JET FALCON, and FAN JET FALCON SERIES C, D, E, F, and G airplanes. This proposed AD was prompted by a determination that new or more restrictive airworthiness limitations and maintenance requirements are necessary. This proposed AD would require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations and maintenance requirements. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by January 7, 2019.

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

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

For service information identified in this NPRM, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; internet *http://www.dassaultfalcon.com*. You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0963; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2018–0963; Product Identifier 2018–NM–135–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

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

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0193, dated September 3, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Dassault Aviation Model FAN JET FALCON and FAN JET FALCON SERIES C, D, E, F, and G airplanes. The MCAI states:

> In June 1988, the Federal Aviation Administration sponsored a conference of ageing aircraft, during which the decision was taken to pay particular attention to those. The ATA [Air Transport Association] and the AIA [Aerospace Industries Association] committed themselves to identify and to set up procedures to ensure continued structural integrity on ageing aircraft. Prompted by these actions, Dassault developed the SSIP [Supplemental Structural Inspection Program], aiming to guarantee the

airworthiness of the Fan Jet Falcon aeroplane which reach and exceed half of the Limit of Validity. The airworthiness limitations and certification maintenance instructions for the affected Fan Jet Falcon aeroplanes, which are approved by EASA, are currently defined and published in the ALS [airworthiness limitations section]. These instructions have been identified as mandatory for continued airworthiness.

Failure to accomplish these instructions could result in an unsafe condition.

Previously, EASA issued AD 2008–0221 to require accomplishment of the maintenance tasks, and implementation of the airworthiness limitations, as specified in ALS at Revision 7.

Since that [EASA] AD was issued, Dassault issued ALS Revisions 8 and 9, which introduced new and more restrictive maintenance requirements and/or airworthiness limitations.

For the reason described above, this [EASA] AD takes over the requirements for Fan Jet Falcon aeroplanes from EASA AD 2008–0221 and requires accomplishment of the actions specified in the ALS.

Once new [EASA] ADs have been published for all the types addressed by EASA AD 2008–0221, EASA plans to cancel that AD.

The unsafe condition is fatigue cracking and damage in principal structural elements; such fatigue cracking and damage could result in reduced structural integrity of the airplane. Because we determined that a separate FAA AD should be issued for each airplane model due to different ALS requirements, we did not issue an AD that corresponded to EASA AD 2008–0221. You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0963.

Related Service Information Under 1 CFR Part 51

Dassault has issued Chapter 5–40, Airworthiness Limitations, DMD 44729, Revision 9, dated November 29, 2017, of the Dassault Aviation Falcon 20 Maintenance Manual. This service information includes life limits for certain airframe components, and describes airworthiness limitations for safe life limits and certification maintenance requirements. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed Requirements of This NPRM

This proposed AD would require revising the existing maintenance or inspection program, as applicable, to include new or more restrictive airworthiness limitations and maintenance requirements.

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

Differences Between This Proposed AD and the MCAI or Service Information

The MCAI specifies that if there are findings from the ALS inspection tasks, corrective actions must be accomplished in accordance with Dassault maintenance documentation. However, this proposed AD would not include those requirements. Operators of U.S.-registered airplanes are required by general airworthiness and operational regulations to maintain their airplanes using methods that are acceptable to the FAA. We consider those methods to be adequate to replace parts, perform maintenance tasks, and address any corrective actions necessitated by the findings of the ALS inspections specified in this proposed AD.

Costs of Compliance

We estimate that this proposed AD affects 61 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

We have determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although we recognize that this number may vary from operator to operator. In the past, we have estimated that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleet, we have determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, we estimate the total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

Authority for This Rulemaking

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

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

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

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

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

1. Is not a ''significant regulatory action'' under Executive Order 12866;

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

3. Will not affect intrastate aviation in Alaska; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities

under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Dassault Aviation: Docket No. FAA–2018–0963; Product Identifier 2018–NM–135–AD.

(a) Comments Due Date

We must receive comments by January 7, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Dassault Aviation Model FAN JET FALCON, and FAN JET FALCON SERIES C, D, E, F, and G airplanes, certificated in any category, all serial numbers, on which the Dassault Fan Jet Falcon Supplemental Structural Inspection Program (Dassault Service Bulletin (SB) 730), has been embodied into the airplane's maintenance program.

(d) Subject

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

(e) Reason

This AD was prompted by a determination that new or more restrictive airworthiness limitations and maintenance requirements are necessary. We are issuing this AD to address, among other things, fatigue cracking and damage in principal structural elements; such fatigue cracking and damage could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Maintenance or Inspection Program Revision

Within 90 days after the effective date of this AD, revise the existing maintenance or inspection program, as applicable, to incorporate the airworthiness limitations specified in Chapter 5–40, Airworthiness Limitations, DMD 44729, Revision 9, dated November 29, 2017, of the Dassault Aviation Falcon 20 Maintenance Manual. The initial compliance time for accomplishing the actions is at the applicable time specified in Chapter 5–40, Airworthiness Limitations, DMD 44729, Revision 9, dated November 29, 2017, of the Dassault Aviation Falcon 20 Maintenance Manual; or within 90 days after the effective date of this AD; whichever occurs later. Where the threshold column in the table in paragraph B, Mandatory Maintenance Operations, of Chapter 5–40, Airworthiness Limitations, DMD 44729, Revision 9, dated November 29, 2017, of the Dassault Aviation Falcon 20 Maintenance Manual specifies a compliance time in years, those compliance times start from the date of issuance of the original airworthiness certificate or date of issuance of the original export certificate of airworthiness.

(h) No Alternative Actions or Intervals

After accomplishing the revision required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions and intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (i)(1) of this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to: *9–ANM–116–AMOC–REQUESTS@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or European Aviation Safety Agency (EASA); or Dassault Aviation's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2018–0193, dated September 3, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0963.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226.

(3) For service information identified in this AD, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; internet *http://www.dassaultfalcon.com*. You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on November 8, 2018.

Chris Spangenberg,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–25385 Filed 11–21–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0962; Product Identifier 2018–NM–125–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Airbus SAS Model A350–941 airplanes. This proposed AD was prompted by reports of an overheat failure mode of the hydraulic engine-driven pump (EDP), and a determination that the affected EDP needs to be replaced with an improved EDP. This proposed AD would require replacement of a certain EDP with an improved EDP. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by January 7, 2019.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

• *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Airbus SAS, Airworthiness Office—EAL, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *continued-airworthiness.a350@airbus.com;* internet *http://www.airbus.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0962; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Kathleen Arrigotti, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2018–0962; Product Identifier 2018–NM–125–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

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

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0178, dated August 23, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus SAS Model A350–941 airplanes. The MCAI states:

> In the Airbus A350 design, the hydraulic fluid cooling system is located in the fuel tanks. Recently, an overheat failure mode of the hydraulic EDP was found, which may cause a fast temperature rise of the hydraulic fluid.
>
> This condition, if not detected and corrected, combined with an inoperative fuel tank inerting system, could lead to an uncontrolled overheat of the hydraulic fluid, possibly resulting in ignition of the fuel-air mixture in the affected fuel tank.
>
> To address this potential unsafe condition, Airbus issued a Major Event Revision (MER) of the A350 Master Minimum Equipment List (MMEL) that incorporates restrictions to avoid an uncontrolled overheat of the hydraulic system. Consequently, EASA issued Emergency AD 2017–0154–E to require implementation of these dispatch restrictions.
>
> After EASA AD 2017–0154–E was issued, following further investigation, Airbus issued another MER of the A350 MMEL that expanded the number of restricted MMEL items. At the same time, Airbus revised Flight Operation Transmission (FOT) 999.0068/17, to inform all operators accordingly. Consequently, EASA issued AD 2017–0180, retaining the requirements of EASA Emergency AD 2017–0154–E, which was superseded, and requiring implementation of the new Airbus A350 MMEL MER and, consequently, restrictions for aeroplane dispatch.
>
> After EASA AD 2017–0180 was issued, Airbus developed HMCA [Hydraulic Monitoring and Control Application] SW [software] S4.2, embodied in production through Airbus mod 112090, and introduced in service through Airbus SB [service bulletin] A350–29–P012. Consequently, EASA issued AD 2017–0200 [which corresponds to FAA AD 2018–19–19, Amendment 39–19419 (83 FR 48203, September 24, 2018)], retaining the requirements of EASA AD 2017–0180, which was superseded, and requiring modification of the aeroplane by installing HMCA SW S4.2.
>
> Since EASA AD 2017–0200 was issued, it was determined that the affected part need to be replaced with improved EDP. Consequently, Airbus issued the SB [Service Bulletin A350–29–P013, dated March 12, 2018] to provide instructions to replace the affected parts with improved EDP, having P/N [part number] 53098–06, which are embodied in production through Airbus mod 112192.
>
> For the reasons described above, this [EASA] AD retains the requirement of EASA AD 2017–0200, which is superseded, and requires replacement of each affected parts with improved EDP.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0962.

Related Service Information Under 1 CFR Part 51

Airbus SAS has issued Service Bulletin A350–29–P013, dated March 12, 2018. This service information describes procedures for replacing a certain EDP with an improved EDP. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed Requirements of This NPRM

This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under ''Differences Between this Proposed AD and the MCAI.''

Differences Between This Proposed AD and the MCAI

This NPRM does not propose to supersede AD 2018–19–19. Rather, we have determined that a stand-alone AD would be more appropriate to address the changes in the MCAI. This proposed AD would require replacing the EDP with an improved EDP.

The MCAI specifies a modification to install HMCA SW S4.2 on certain airplanes. This proposed AD would not require this modification, since the modification is required by AD 2018–19–19. Additionally, the MCAI prohibits installing software prior to HMCA SW S4.2. This proposed AD would not include that prohibition since it has already been prohibited by AD 2018–19–19.

The MCAI specifies changes to the Airbus MMEL to incorporate dispatch restrictions. However, the FAA MMEL is already updated to incorporate these, and all current and future U.S. operators are already required to use the FAA MMEL, so this proposed AD would not

require changes to the MMEL as specified in the MCAI.

Further, the MCAI notes that, after completing the modification by installing HMCA SW S4.2 and replacing the EDP with an improved EDP, Airbus A350 MMEL Minor Change V29ME1732522, dated January 3, 2018, and Airbus A350 MMEL Major Change V29ME1734973, dated January 30, 2018, can be implemented for that airplane, and those changes remove certain restrictions for that airplane. For U.S. registered aircraft, no provisions for relief are to be added to the MMEL with incorporation of this proposed AD. The FAA-approved MMEL currently contains more restrictive operational limitations, and we will update it when relief is justified.

Explanation of Compliance Time

In most ADs, we adopt a compliance time allowing a specified amount of time after the AD's effective date. In this case, however, we are using a fixed compliance date in this proposed AD. The MCAI requires operators of all Airbus SAS Model A350–941 airplanes to replace affected EDPs with improved EDPs to address an identified unsafe condition in a specified amount of time (within 17 months after the MCAI's effective date of September 6, 2018, or February 6, 2020). That compliance time is based on risk analysis requirements, including reports of fuel pump overheats and failures. To support this risk analysis, and to provide for coordinated implementation of EASA's regulations and this proposed AD, we are using the same compliance target in this proposed AD.

Costs of Compliance

We estimate that this proposed AD affects 11 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 25 work-hours × $85 per hour = $2,125	Up to $224,400	Up to $226,525	Up to $2,491,775.

According to the manufacturer, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all known costs in our cost estimate.

Authority for This Rulemaking

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

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

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes to the Director of the System Oversight Division.

Regulatory Findings

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

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

1. Is not a ''significant regulatory action'' under Executive Order 12866;

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

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus SAS: Docket No. FAA–2018–0962; Product Identifier 2018–NM–125–AD.

(a) Comments Due Date

We must receive comments by January 7, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus SAS Model A350–941 airplanes, certificated in any category, all serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 29, Hydraulic power.

(e) Reason

This AD was prompted by reports of an overheat failure mode of the hydraulic engine-driven pump (EDP), and a determination that the affected EDP needs to be replaced with an improved EDP. We are issuing this AD to address the overheat failure mode of the hydraulic EDP, which may cause a fast temperature rise of the hydraulic fluid, and, if combined with an inoperative fuel tank inerting system, could lead to an uncontrolled overheat of the hydraulic fluid, possibly resulting in ignition of the fuel-air mixture of the affected tank.

(f) Compliance

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

(g) Required Action

Before February 6, 2020, replace each EDP having part number (P/N) 53098–04 with an improved EDP, having P/N 53098–06, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A350–29–P013, dated March 12, 2018.

(h) Parts Installation Prohibition

At the applicable time specified in paragraph (h)(1) or (h)(2) of this AD: No person may install an EDP having P/N 53098–04 on any airplane.

(1) For airplanes that, as of the effective date of this AD, have any EDP having P/N 53098–04 installed: After modification of the airplane as specified by paragraph (g) of this AD.

(2) For airplanes that, as of the effective date of this AD, are post-Modification 112192 and do not have any EDP having P/N 53098–04 installed: As of the effective date of this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

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

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

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2018–0178, dated August 23, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0962.

(2) For more information about this AD, contact Kathleen Arrigotti, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218.

(3) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *continued-airworthiness.a350@airbus.com;* internet *http://www.airbus.com*. You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on November 8, 2018.

Chris Spangenberg,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–25386 Filed 11–21–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket No. RM19–5–000]

Public Utility Transmission Rate Changes To Address Accumulated Deferred Income Taxes

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is proposing to require all public utility transmission providers with transmission rates under an Open Access Transmission Tariff (OATT), a transmission owner tariff, or a rate schedule to revise those rates to account for changes caused by the Tax Cuts and Jobs Act of 2017 (Tax Cuts and Jobs Act). Specifically, for transmission formula rates, the Commission is proposing to require that public utilities deduct excess accumulated deferred income taxes (ADIT) from or add deficient ADIT to their rate bases and adjust their income tax allowances by amortized excess or deficient ADIT. The Commission is also proposing to require all public utilities with transmission formula rates to incorporate a new permanent worksheet into their transmission formula rates that will annually track ADIT information. Additionally, the Commission is proposing to require all public utilities with transmission stated rates to determine the amount of excess and deferred income tax caused by the Tax Cuts and Jobs Act's reduction to the federal corporate income tax rate and return or recover this amount to or from customers.

DATES: Comments are due December 24, 2018.

ADDRESSES: Comments, identified by docket number, may be filed electronically at *http://www.ferc.gov* in acceptable native applications and print-to-PDF, but not in scanned or picture format. For those unable to file electronically, comments may be filed by mail or hand-delivery to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426. The Comment Procedures Section of this document contains more detailed filing procedures.

FOR FURTHER INFORMATION CONTACT:

Noah Lichtenstein (Technical Information), Office of Energy Market Regulation, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8696, *noah.lichtenstein@ferc.gov*.

Joshua Walters (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–6098, *joshua.walters@ferc.gov*.

SUPPLEMENTARY INFORMATION:

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1. In this Notice of Proposed Rulemaking (Proposed Rule), we are proposing to require all public utility transmission providers with transmission rates under an Open Access Transmission Tariff (OATT), a transmission owner tariff, or a rate schedule to revise those rates to account for changes caused by the Tax Cuts and Jobs Act of 2017 (Tax Cuts and Jobs Act).[1] These proposed reforms are designed to address the effects of the Tax Cuts and Jobs Act on the Accumulated Deferred Income Taxes (ADIT) reflected in all transmission rates under an OATT, a transmission owner tariff, or a rate schedule of public utility transmission providers. The proposed reforms are intended to ensure that ratepayers receive the benefits of the Tax Cuts and Jobs Act, and that the public utility transmission formula and stated rates are just and reasonable and not unduly discriminatory or preferential following the enactment of the Tax Cuts and Jobs Act. The proposed reforms are also intended to ensure that transmission formula and stated rates meet the Commission's tax normalization requirements such that the income tax component of those rates is calculated as though the taxable income were recognized in the same period and amount by the Internal Revenue Service (IRS) and the Commission.[2]

2. The proposed reforms generally fall into three categories and apply to public utilities with transmission formula rates and stated rates in different ways. First, we propose to require all public utilities with transmission formula rates to include a mechanism in their formula rates to deduct any excess ADIT from or add any deficient ADIT to their rate bases. This will ensure that rate base continues to be treated in a manner similar to that prior to the Tax Cuts and Jobs Act (*i.e.,* that rate base neutrality is preserved). As for public utilities with transmission stated rates, we do not propose any new requirements regarding rate base neutrality.

3. Second, we propose to require all public utilities with transmission formula rates to include a mechanism in their formula rates that decreases or increases their income tax allowances by any amortized excess or deficient ADIT, respectively. This reform will help to ensure that public utilities with transmission formula rates return excess ADIT to or recover deficient ADIT from ratepayers. As a result, ratepayers who contributed to excess ADIT balances will receive the benefit of the Tax Cuts and Jobs Act.

4. With regard to public utility transmission providers with stated rates, we are proposing to require these entities to determine the excess and deficient ADIT caused by the Tax Cuts and Jobs Act based on the ADIT amounts approved in their last rate case and then to return this amount to or recover this amount from customers. This reform is intended to increase the likelihood that those customers who contributed to the related ADIT accounts receive the benefits of the Tax Cuts and Jobs Act.

5. Third, we propose to require all public utilities with transmission formula rates to incorporate a new permanent worksheet into their transmission formula rate that will annually track information related to excess or deficient ADIT. We believe that this reform will increase the transparency surrounding the

[1] An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018, Pub. L. 115–97, 131 Stat. 2054 (2017) (Tax Cuts and Jobs Act). In proposing this new requirement, the Commission relies on existing Commission regulations relating to tax normalization for public utilities as those regulations apply to public utilities with transmission formula or stated rates. *See* 18 CFR 35.24. In this Proposed Rule, the Commission does not propose any generic reforms as to non-public utilities or the non-transmission rates of public utilities. While any conclusions that the Commission makes in this proceeding may be relevant to such rates, they will be addressed on a case-by-case basis. Furthermore, to the extent any entity believes that the Tax Cuts and Jobs Act renders any existing Commission-jurisdictional rate unjust and unreasonable, that entity may submit a complaint to the Commission.

[2] In this Proposed Rule, the Commission refers to comments filed in response to the Notice of Inquiry issued March 15, 2018. *Inquiry Regarding the Effect of the Tax Cuts and Jobs Act on Commission-Jurisdictional Rates,* FERC Stats. & Regs. ¶ 35,582 (2018) (NOI). A list of commenters in that proceeding and the abbreviated names used in this Proposed Rule appears in Appendix A. Any comments to this Proposed Rule should be filed in this proceeding, Docket No. RM19–5–000.

adjustment of rate bases and income tax allowances to account for excess or deficient ADIT by public utilities with transmission formula rates. We do not propose any additional worksheets for public utilities with transmission stated rates because we believe that existing regulations require sufficient transparency.

6. We seek comments on these proposed reforms and areas for further comment within 30 days after publication of this Proposed Rule in the **Federal Register**.

I. Background

A. Tax Cuts and Jobs Act

7. On December 22, 2017, the President signed into law the Tax Cuts and Jobs Act. The Tax Cuts and Jobs Act, among other things, reduced the federal corporate income tax rate from 35 percent to 21 percent, effective January 1, 2018. This means that, beginning January 1, 2018, companies subject to the Commission's jurisdiction will compute income taxes owed to the IRS based on a 21 percent tax rate. The tax rate reduction will result in less corporate income tax expense going forward.[3]

8. Importantly, the tax rate reduction will also result in a reduction in ADIT liabilities and ADIT assets on the books of rate-regulated companies. ADIT balances are accumulated on the regulated books and records of public utilities based on the requirements of the Uniform System of Accounts. ADIT arises from timing differences between the method of computing taxable income for reporting to the IRS and the method of computing income for regulatory accounting and ratemaking purposes.[4] As a result of the Tax Cuts and Jobs Act reducing the federal corporate income tax rate from 35 percent to 21 percent, a portion of an ADIT liability that was collected from customers will no longer be due from public utilities to the IRS and is considered excess ADIT, which must be returned to customers in a cost of service ratemaking context. Additionally, for public utilities that have an ADIT asset, the Tax Cuts and Jobs Act will result in a reduction to that ADIT asset, and public utilities may seek to reflect in rates a portion of such reductions. Public utilities are required to adjust their ADIT assets and ADIT liabilities for the effect of the change in tax rates in the period that the change is enacted.[5]

B. Overview of Public Utility Transmission Rates

9. The Commission is responsible for ensuring that the rates, terms and conditions of service for wholesale sales and transmission of electric energy in interstate commerce are just, reasonable, and not unduly discriminatory or preferential. With respect to the transmission of electric energy in interstate commerce, most jurisdictional entities are subject to cost of service regulation. Cost of service regulation seeks to allow public utilities the opportunity to (1) recover operating costs, including income taxes, (2) recover the cost of capital investments, and (3) earn a just and reasonable return on investments.[6] Public utilities have calculated their cost of service-based transmission rates predominately by using formula rates or stated rates. These rates are contained in numerous agreements, including a public utility's OATT, a regional transmission operator's or independent system operator's OATT, coordination agreements, and wholesale distribution agreements. In this Proposed Rule, we focus on all public utilities with transmission formula or stated rates that are contained in an OATT, a transmission owner tariff, or a rate schedule.

10. When a public utility uses stated rates, if the public utility seeks to change its rate, it files a rate case at the Commission to establish the cost of service revenue requirement, allocate costs to various customer groups, and calculate rates. As an alternative, the Commission permits public utilities to establish rates through formulas, in which the Commission accepts the public utility's cost of service calculation methodologies and input sources and allows the public utility to update those inputs every year.

11. Public utilities must seek changes to their transmission stated rates or formula rates through filings with the Commission under section 205 of the Federal Power Act (FPA),[7] while the Commission and third parties can challenge a rate in a proceeding initiated under section 206 of the FPA.[8]

C. Order No. 144 and 18 CFR 35.24

12. The purpose of tax normalization is to match the tax effects of costs and revenues with the recovery in rates of those same costs and revenues.[9] As noted above, timing differences may exist between the method of computing taxable income for reporting to the IRS and the method of computing income for regulatory accounting and ratemaking purposes. The tax effects of these differences are placed in a deferred tax account to be used in later periods when the differences reverse.[10]

13. The Commission established this policy of tax normalization in Order No. 144 where it required use of ''the provision for deferred taxes [(*i.e.,* ADIT)] as a mechanism for setting the tax allowance at the level of current tax cost.'' [11] In keeping with this normalization policy, and as relevant to the Tax Cuts and Jobs Act's reduction of the federal corporate income tax rate, the Commission in Order No. 144 also required adjustments in the ADIT of public utilities' cost of service when excessive or deficient ADIT has been created as a result of changes in tax rates.[12] Furthermore, the Commission required ''a rate applicant to compute the income tax component in its cost of service by making provision for any excess or deficiency in its deferred tax reserves resulting . . . from tax rate changes.''[13] The Commission required that such provision be consistent with a Commission-approved ratemaking method made specifically applicable to the rate applicant.[14] Where no ratemaking method has been made specifically applicable, the Commission required the rate applicant to advance some method in its next rate case.[15] The Commission stated that it would determine the appropriateness of any proposed method on a case-by-case basis, but as the issue is resolved in a number of cases, a method with wide applicability may be adopted.[16] The Commission codified the requirements

[3] *See* Tax Cuts and Jobs Act, Sec. 13001, 131 Stat. at 2096.

[4] *See* 18 CFR 35.24(d)(2).

[5] *See* 18 CFR 35.24 and 18 CFR 154.305; *see also Regulations Implementing Tax Normalization for Certain Items Reflecting Timing Differences in the Recognition of Expenses or Revenues for Ratemaking and Income Tax Purposes,* Order No. 144, FERC Stats. & Regs. ¶ 30,254 (1981), *order on reh'g,* Order No. 144–A, FERC Stats. & Regs. ¶ 30,340 (1982).

[6] *See Pub. Sys.* v. *FERC,* 709 F.2d 73, 75 (D.C. Cir. 1983).

[7] *See* 16 U.S.C. 824d.

[8] *See* 16 U.S.C. 824e(a).

[9] Order No. 144, FERC Stats. & Regs. ¶ 30,254 at 31,522, 31,530.

[10] *Id.* at 31,554.

[11] *Id.* at 31,530.

[12] *Id.* at 31,519.

[13] Order No. 144, FERC Stats. & Regs. ¶ 30,254 at 31,560. *See also* 18 CFR 35.24(c)(1)(ii); 18 CFR 35.24(c)(2).

[14] Order No. 144, FERC Stats. & Regs. ¶ 30,254 at 31,560. *See also* 18 CFR 35.24(c)(3).

[15] Order No. 144, FERC Stats. & Regs. ¶ 30,254 at 31,560.

[16] *Id. See also* 18 CFR 35.24(c)(3).

of Order No. 144 in its regulations in 18 CFR 35.24.[17]

D. Notice of Inquiry

14. Following the enactment of the Tax Cuts and Jobs Act, the Commission issued the NOI seeking comments on, among other things, whether, and if so, how, the Commission should address the effects of the Tax Cuts and Jobs Act on ADIT.[18] The Commission noted that the Tax Cuts and Jobs Act's reduction to the federal corporate income tax rate would potentially create excess or deficient ADIT on the books of public utilities.[19] As relevant to the reforms proposed in this Proposed Rule, the Commission sought comments on the preservation of rate base neutrality and how public utilities should make related adjustments to their rate bases for excess and deficient ADIT.[20] The Commission also sought comment on how public utilities should adjust their income allowances to return or recover excess or deficient ADIT, respectively,[21] as well as the method used to return or recover excess or deficient protected and unprotected ADIT.[22] Finally, the Commission sought comment on whether it should require public utilities to provide to the Commission, on a one-time basis, additional information to show the computation of excess or deficient ADIT and the corresponding return of excess ADIT to customers or recovery of deficient ADIT from customers. If so, the Commission also sought comments on what types of information public utilities should provide.[23]

II. Discussion

15. Since the issuance of Order No. 144, the landscape of public utility transmission rates has changed dramatically; that is, the vast majority of public utilities now use formula rates rather than stated rates. As described above, unlike stated rates, which are updated only through a rate case initiated by a FPA section 205 application by the public utility or an FPA section 206 action by the Commission or a complaining third party, inputs to formula rates are updated annually to derive a charge assessed to customers. Thus, a rate case no longer remains the appropriate vehicle for formula rates to reflect excess or deficient ADIT in a public utility's cost of transmission service, as contemplated by Order No. 144. The public utility's transmission formula rate should include provisions that accurately reflect excess or deficient ADIT in a public utility's cost of transmission service during the annual updates of the rest of the revenue requirement.

16. Following the NOI, we have determined that this near-industry-wide transition from stated to formula rates has caused a gap in the transmission formula rates of public utilities such that many, if not most, of those rates do not contain provisions to fully reflect any excess or deficient ADIT following a change in tax rates, as required by Order No. 144 and the Commission's regulations in 18 CFR 35.24. Two components are necessary to maintain an accurate cost of service following a change in income tax rates, such as that caused by the Tax Cuts and Jobs Act: (1) Preservation of rate base neutrality through the removal of excess ADIT from or addition of deficient ADIT to rate base; and (2) the return of excess ADIT to or recovery of deficient ADIT from ratepayers.[24]

17. A review of public utility transmission formula rates suggests that only some transmission formula rates contain the first component, while even fewer contain the second. Consequently, as discussed in greater detail below, we propose to require public utilities with transmission formula rates to revise those rates to include these two components. Additionally, to provide greater transparency, we propose to require all public utilities with transmission formula rates to incorporate a new permanent worksheet into their transmission formula rates that will annually track ADIT information related to these two components.

18. Regarding public utilities with transmission stated rates, we propose maintaining Order No. 144's requirement that such public utilities reflect any adjustments made to their ADIT balances as a result of the Tax Cuts and Jobs Act (and any future tax changes) in their next rate case. However, to increase the likelihood that those customers who contributed to the related ADIT accounts receive the benefit of the Tax Cuts and Jobs Act, we propose to require public utilities with transmission stated rates to (1) determine any excess or deficient ADIT caused by the Tax Cuts and Jobs Act and (2) return or recover this amount to or from customers. We believe that the Commission's existing regulations already require all of the information necessary to support the changes proposed herein to reflect the effects of the Tax Cuts and Jobs Act on a transmission stated rate. Therefore, we propose not to require any additional worksheets.

19. The Commission generally does not permit single-issue ratemaking. However, similar to the Commission's actions following the Tax Cuts and Jobs Act,[25] given the limited scope of the reforms proposed here, we propose that compliance filings made in response to this Proposed Rule's final requirements may be considered on a single-issue basis.[26]

A. Ensuring Rate Base Neutrality

1. NOI

20. In the NOI, the Commission sought comment on how to ensure that rate base continues to be treated in a manner similar to that prior to the Tax Cuts and Jobs Act (*i.e.,* how to preserve rate base neutrality), until excess and deficient ADIT have been fully returned or recovered in a just and reasonable manner. The Commission also sought comment on whether, and if so how, public utilities should make adjustments to rate base to reflect excess and deficient ADIT. The Commission asked that commenters address both formula rates and stated rates.[27]

[17] Originally promulgated as part of Order 144, the regulatory text was redesignated as 18 CFR 35.25 in Order No. 144–A. *See* Order No. 144–A, FERC Stats. & Regs. ¶ 30,340 at 30,140. In Order No. 545, the Commission again redesignated the regulatory text to its present designation as 18 CFR 35.24. *See Streamlining Electric Power Regulation,* Order No. 545, FERC Stats. & Regs. ¶ 30,955, at 30,713 (1992) (cross-referenced at 61 FERC ¶ 61,207).

[18] NOI, FERC Stats. & Regs. ¶ 35,582.

[19] *Id.* P 13.

[20] *Id.* PP 14–15.

[21] *Id.* P 21.

[22] *Id.* PP 17, 19. In the NOI, the Commission referred to ''plant-based'' and ''non-plant based'' ADIT. We agree with commenters' recommendation to follow the IRS terminology of ''protected'' and ''unprotected'' ADIT instead of ''plant-based'' and ''non-plant based'' presented in the NOI. The IRS terms for ''protected'' and ''unprotected'' are directly associated with the IRS' normalization protections to ensure a tax payer maintains the benefit of accelerated depreciation over the life of the related asset. Accordingly, we have changed the terms used in this Proposed Rule to better mirror IRS terminology.

[23] *Id.* P 23.

[24] *Id.* P 13. While the Tax Cuts and Jobs Act decreased the federal corporate income tax rate, the reforms proposed in this Proposed Rule are also meant to ensure that transmission formula rates reflect the effects of tax increases, as well.

[25] *See AEP Appalachian Transmission Company, Inc.,* 162 FERC ¶ 61,225 (2018); *Alcoa Power Generating Inc.—Long Sault Division,* 162 FERC ¶ 61,224 (2018).

[26] *See generally Indicated RTO Transmission Owners,* 161 FERC ¶ 61,018, at PP 13–14 (2017); s*ee also Rates Changes Relating to the Federal Corporate Income Tax Rate for Public Utilities,* Order No. 475, FERC Stats. & Regs. ¶ 30,752, *order on reh'g,* 41 FERC ¶ 61,029 (1987) (allowing public utilities to use a voluntary, abbreviated rate filing procedure to reduce their rates to reflect a reduction in the federal corporate income tax rate on a single-issue basis).

[27] NOI, FERC Stats. & Regs. ¶ 35,582 at PP 14–15.

2. Comments

21. Numerous public utilities and other commenters assert that, in order to preserve rate base neutrality, unamortized balances of excess ADIT must continue to be treated as an offset to (*i.e.,* a deduction from) rate base until those balances are flowed back in their entirety to customers.[28] These commenters generally note that, following the passage of the Tax Cuts and Jobs Act, public utilities transferred excess ADIT to Account 254 (Other Regulatory Liabilities) or Account 182.3 (Other Regulatory Assets), as appropriate.[29] Accordingly, these commenters state that, just as the ADIT balances were deducted from or added to rate base, as appropriate, the corresponding amounts recorded in Accounts 254 and 182.3 should be deducted from or added to rate base. While generally agreeing that rate base adjustments are necessary, several commenters assert that there is no ''one-size fits all'' solution.[30]

22. Regarding public utilities with formula rates, several commenters support the addition of a line item to formula rates for rate base adjustments reflecting excess or deficient ADIT recorded in Accounts 254 and 182.3.[31] Many of these commenters suggest that the Commission permit public utilities to make single-issue FPA section 205 filings to make the appropriate changes to their formula rates.[32] EEI suggests that the Commission should permit utilities with formula rates requiring adjustments to address these during their next true-up annual informational filing.[33]

23. Alternatively, APPA and AMP, and Indicated Customers suggest that any excess or deficient ADIT resulting from the implementation of the Tax Cuts and Jobs Act be recorded to the same ADIT accounts (*e.g.,* Accounts 190, 281, 282, and 283) where the original entries for the regulatory assets and regulatory liabilities were established.[34] APPA and AMP state that by keeping the excess or deficient ADIT in sub-accounts within the original ADIT accounts, it will be more transparent and easier to track as the balances are flowed back.[35] As another alternative, the Oklahoma Attorney General asserts that the Commission should consider requiring that the line item currently used to offset rate base with ADIT include both ADIT balances in traditional ADIT-related accounts and those excess ADIT balances in other accounts identified by the Commission.[36]

24. Other commenters note that such a line item adjustment may not be necessary in all cases.[37] Specifically, these commenters assert that certain formula rates (*e.g.,* certain MISO Attachment O, AEP, Exelon, and Eversource formula rates) already provide for the inclusion of excess ADIT in rate base and that the balances in Accounts 254 and 182.3 will naturally flow into rate base without any modification.[38]

25. Regarding public utilities with stated rates, commenters generally agree that adjustments are not necessary to preserve rate base neutrality with respect to stated rates.[39] National Grid and Avangrid state that, under cost-of-service, both ADIT balances and regulatory liability balances should be deducted from rate base in calculating the stated rate.[40] Avangrid asserts that rate base neutrality issues are not raised with transmission stated rates because these rates assume the same amount of ADIT deduction to rate base without regard to how the companies adjusted their books and records.[41]

3. Proposed Requirements

a. Formula Rates

26. We propose to require all public utilities with transmission formula rates to include a mechanism in their formula rates which deducts any excess ADIT from or adds any deficient ADIT to their rate bases under 18 CFR 35.24. As described above, the Commission's regulations in 18 CFR 35.24 require public utilities to reflect any excess or deficient ADIT as a result of any changes in tax rates in their next rate case. As a result of the Tax Cuts and Jobs Act's reduction of the federal corporate income tax from 35 percent to 21 percent, public utilities have collected excess funds for their ADIT liabilities and have not collected sufficient funds for any ADIT assets. To preserve rate base neutrality by accurately matching the tax allowance with the current tax cost as required by Commission regulations, public utilities with transmission formula rates must include provisions in their formula rates to adjust their ADIT for excess or deficient ADIT.[42] We believe our proposal will ensure that public utilities with transmission formula rates will adjust their ADIT for any excess or deficient ADIT caused by the Tax Cuts and Jobs Act or any future changes to tax rates which may give rise to excess or deficient ADIT.

27. While we are proposing to require public utilities with transmission formula rates to include a mechanism to adjust rate base for any excess or deficient ADIT, we are not proposing to prescribe a specific adjustment mechanism which applies to all public utilities with transmission formula

[28] APPA and AMP, Comments to NOI, Docket No. RM18–12–000, at 4–7 (filed on May 22, 2018) (APPA and AMP NOI Comments); Avangrid, Comments to NOI, Docket No. RM18–12–000, at 5 (May 22, 2018) (Avangrid NOI Comments); Consumer Advocates, Comments to NOI, Docket No. RM18–12–000, at 4–5 (filed May 21, 2018) (Consumer Advocates NOI Comments); DEMEC, Comments to NOI, Docket No. RM18–12–000, at 8 (filed May 21, 2018) (DEMEC NOI Comments); Indicated Customers, Comments to NOI, Docket No. RM18–12–000, at 3–6 (filed May 21, 2018) (Indicated Customers NOI Comments); National Grid, Comments to NOI, Docket No. RM18–12–000, at 6–7 (filed May 21, 2018) (National Grid NOI Comments); New York Transco, Comments to NOI, Docket No. RM18–12–000, at 5 (filed May 22, 2018) (New York Transco NOI Comments); Oklahoma Attorney General, Comments to NOI, Docket No. RM18–12–000, at 4 (filed May 22, 2018) (Oklahoma Attorney General NOI Comments); PSEG, Comments to NOI, Docket No. RM18–12–000, at 4 (filed May 22, 2018) (PSEG NOI Comments).

[29] Avangrid NOI Comments at 5; EEI, Comments to NOI, Docket No. RM18–12–000, at 10 (filed May 22, 2018) (EEI NOI Comments).

[30] Kentucky Municipals, Comments to NOI, Docket No. RM18–12–000, at 3–5 (filed May 21, 2018) (Kentucky Municipals NOI Comments); Exelon, Comments to NOI, Docket No. RM18–12–000, at 11–12 (filed May 22, 2018) (Exelon NOI Comments); TAPS, Comments to NOI, Docket No. RM18–12–000, at 3 (filed May 21, 2018) (TAPS NOI Comments); Indicated Transmission Owners, Comments to NOI, Docket No. RM18–12–000, at 7 (filed May 21, 2018) (Indicated Transmission Owners NOI Comments) (''[t]here may be no uniform way to achieve the Commission's rate base neutrality objective given differences between companies in accounting methods and rate structures.'') (citation omitted)).

[31] Oklahoma Attorney General NOI Comments at 4–5; PSEG NOI Comments at 4; Avangrid NOI Comments at 5–9; Eversource, Comments to NOI, Docket No. RM18–12–000, at 4 (filed May 22, 2018) (Eversource NOI Comments); National Grid NOI Comments at 7–8; TAPS NOI Comments at 4.

[32] Eversource NOI Comments at 4–5; Indicated Transmission Owners NOI Comments at 6; PSEG NOI Comments at 4–5; National Grid NOI Comments at 7–8.

[33] EEI NOI Comments at 11.

[34] APPA and AMP NOI Comments at 7–8; Indicated Customers NOI Comments at 6–7.

[35] APPA and AMP NOI Comments at 7–8.

[36] Oklahoma Attorney General NOI Comments at 4–5.

[37] Ameren, Comments to NOI, Docket No. RM18–12–000, at 7–8 (filed May 21, 2018) (Ameren NOI Comments); MISO Transmission Owners, Comments to NOI, Docket No. RM18–12–000, at 7 (filed May 21, 2018) (MISO Transmission Owners NOI Comments); EEI NOI Comments at 11; Exelon NOI Comments at 11–12.

[38] AEP, Comments to NOI, Docket No. RM18–12–000, at 3–4 (filed May 22, 2018) (AEP NOI Comments); Ameren NOI Comments at 7–8; MISO Transmission Owners NOI Comments at 7; Eversource NOI Comments at 3–4; Exelon NOI Comments at 11–12.

[39] National Grid NOI Comments at 7–8; Avangrid NOI Comments at 5–6; EEI NOI Comments at 11.

[40] National Grid NOI Comments at 7–8; Avangrid NOI Comments at 5–6.

[41] Avangrid NOI Comments at 5–6.

[42] Order No. 144, FERC Stats. & Regs. ¶ 30,254 at 31,530, 31,519.

rates. We agree with commenters to the NOI that prescribing a one-size-fits-all approach, such as adding a line item, is not appropriate and that the Commission should instead allow public utilities to propose any necessary changes to their formula rates on an individual basis. Recent filings and comments submitted in the NOI suggest that multiple approaches to modify rate base may be just and reasonable. For example, as noted by MISO Transmission Owners,[43] the Commission accepted proposals by ITC Companies and Ameren in which those companies did not revise their formula rates to modify their adjustments to rate base by adding a new line item for rate base.[44] Instead, those companies demonstrated that, while not visible in their formula rates, their adjustments to rate base were modified by any excess or deficient ADIT prior to their input to the formula rates. Accordingly, we also propose that public utilities with transmission formula rates may demonstrate that their formula rates already meet the proposed ADIT adjustment requirements described in this Proposed Rule.

28. We are not persuaded by commenters to the NOI who suggest that excess or deficient ADIT amounts should be recorded to the same ADIT accounts where the original entries for the regulatory assets and regulatory liabilities were established. The Commission previously issued guidance on this topic, finding that public utilities are required to record a regulatory asset (Account 182.3) associated with deficient ADIT or regulatory liability (Account 254) associated with excess ADIT.[45] As a result, we do not propose any changes to that specific accounting guidance.

b. Stated Rates

29. We do not propose any new requirements regarding rate base neutrality for public utilities with transmission stated rates. As noted by commenters to the NOI, stated rates are calculated based in large part on company data submitted, and projections made, at the time of the last rate case. Thus, while ADIT balances may have changed as a result of the Tax Cuts and Jobs Act, so too will many other aspects of the cost of service and calculations that underlie the stated rate, making it difficult to re-evaluate ADIT and its effect on rate base following a change in tax rates without fully evaluating a public utility's entire cost of service and rates.[46] We believe that the revisions we are proposing below, related to the return or recovery of excess or deficient ADIT, will adequately address the effects of the Tax Cuts and Jobs Act on ADIT and will avoid such complications. Therefore, we do not propose to require adjustments to the rate bases of public utilities with transmission stated rates prior to their next rate case on a generic basis.

B. Return or Recovery of Excess or Deficient ADIT

1. NOI

30. In the NOI, the Commission asked commenters to address how public utilities with stated or formula rates should adjust their income tax allowance such that the allowance would be decreased or increased by the amortization of excess or deficient ADIT, respectively.[47] Additionally, the Commission asked commenters how the Average Rate Assumption Method, and alternatively, the Reverse South Georgia Method or South Georgia Method, as appropriate, will be implemented in the amortization of protected excess or deficient ADIT and how quickly to amortize unprotected excess or deficient ADIT.[48]

2. Comments

31. Commenters generally support adjusting public utilities' income tax allowances by the amortization of excess or deficient ADIT. Many commenters suggest adding a line item or several line items to public utility transmission formula rates to make this adjustment,[49] with some transmission owners noting that they have already submitted or now propose to submit such revisions.[50] MISO Transmission Owners note that the Commission accepted such a proposal by ITC Great Plains.[51] National Grid suggests that adjustments to income tax allowances could also be made through the weighted cost of capital.[52]

32. Commenters also support revisions to transmission stated rates to reflect income tax allowance adjustments for the amortization of excess or deficient ADIT.[53] TAPS states that, to address these adjustments, it supports an approach similar to utility-specific investigations the Commission opened with respect to the change in the federal corporate income tax rate.[54] However, TAPS expresses concern that stated rate customers will find it challenging to verify their utilities' calculation and asserts that, thus, the Commission should encourage utilities to work with customers toward a mutually acceptable solution and require those utilities to file the return mechanism, including detailed documentation and worksheets so that the calculation of excess ADIT can be validated.[55]

33. Some commenters caution the Commission against mandating that public utilities adopt a single method to adjust their formula rates' income tax allowances. Instead, these commenters suggest that the Commission recognize public utilities' specific circumstances by evaluating proposed modifications on a case-by-case basis or recognizing that some formula rates already adjust the income tax allowance by the amortization of excess or deficient ADIT and, therefore, would not require revision.[56] Indicated Transmission Owners argue that the Commission should make any evaluations on a single-issue basis.[57] The Oklahoma Attorney General suggests that the Commission could use ongoing proceedings, such as the show cause proceedings initiated against public utilities whose formula rates would not automatically adjust to reflect the lower federal corporate income tax rate of 21

[43] MISO Transmission Owners NOI Comments at 7.

[44] *Midcontinent Indep. Sys. Operator, Inc.,* 153 FERC ¶ 61,374 (2015); *Midcontinent Indep. Sys. Operator, Inc.,* 163 FERC ¶ 61,163 (2018).

[45] *See* Accounting for Income Taxes, Docket No. AI93–5–000, at 8 (1993).

[46] The Commission previously acknowledged this difficulty in Order No. 475. Order No. 475, FERC Stats. & Regs. ¶ 30,752 at 30,736.

[47] NOI, FERC Stats. & Regs. ¶ 35,582 at P 21.

[48] *Id.* PP 17, 19. Under the South Georgia method, a calculation is taken of the difference between the amount actually in the deferred account and the amount that would have been in the account had normalization continuously been followed. Any deficiency is collected from ratepayers (*i.e.,* South Georgia Method), and any excess is returned to ratepayers (*i.e.,* Reverse South Georgia Method), over the remaining depreciable life of the plant that caused the difference. *Memphis Light, Gas and Water Div.* v. *FERC,* 707 F.2d 565, 569 (D.C. Cir. 1983).

[49] Ameren NOI Comments at 15–16; Avangrid NOI Comments at 11–12; MISO Transmission Owners NOI Comments at 14–17; National Grid NOI Comments at 15; New York Transco NOI Comments at 10; Oklahoma Attorney General NOI Comments at 6; PSEG NOI Comments at 10.

[50] Ameren NOI Comments at 15–16; Avangrid NOI Comments at 11–12; MISO Transmission Owners NOI Comments at 16–17; New York Transco NOI Comments at 10.

[51] MISO Transmission Owners NOI Comments at 15 (citing *Midcontinent Indep. Sys. Operator, Inc.,* 153 FERC ¶ 61,374). *See also Midcontinent Indep. Sys. Operator, Inc.,* 163 FERC ¶ 61,163.

[52] National Grid NOI Comments at 15.

[53] Avangrid NOI Comments at 9, National Grid NOI Comments at 15, TAPS NOI Comments at 6.

[54] TAPS NOI Comments at 6 (citing *Alcoa Power Generating Inc.—Long Sault Div.,* 162 FERC ¶ 61,224).

[55] TAPS NOI Comments at 5–7.

[56] Exelon NOI Comments at 14–15; Indicated Customers NOI Comments at 12–13; MISO Transmission Owners NOI Comments at 17.

[57] Indicated Transmission Owners NOI Comments at 11–12.

percent, to revise formula rates such that the income tax allowance is adjusted by the amortization of excess or deficient ADIT.[58]

34. Consumer Advocates are concerned that absent Commission intervention, jurisdictional entities may begin to amortize their excess ADIT, thereby denying customers the full benefit of the Tax Cuts and Jobs Act. Consumer Advocates argue that to the extent any protected ADIT balances have been amortized to date, the Commission should require such excess protected ADIT amortization credits to be reversed and the liability balance restored to that of the implementation date of the Tax Cuts and Jobs Act.[59]

35. Regarding protected excess or deficient ADIT, commenters agree that the Commission has no need to change its existing regulations or precedent or depart from the Tax Cuts and Jobs Act's normalization provisions.[60] Regarding unprotected excess or deficient ADIT, commenters agree that the Commission should adopt a case-by-case approach for determining how quickly excess or deficient unprotected ADIT should be flowed back to or recovered from customers.[61]

3. Proposed Requirements

a. Formula Rates

36. We propose to require all public utilities with transmission formula rates to include a mechanism in their formula rates which decreases or increases their income tax allowances by any amortized excess or deficient ADIT, respectively, under 18 CFR 35.24. Such a mechanism is necessary because, as described above, the Tax Cuts and Jobs Act's reduction of the federal corporate income tax rate from 35 percent to 21 percent means public utilities have collected from customers funds in excess of what is due to the IRS for ADIT liabilities and, conversely for ADIT assets, funds from customers insufficient to satisfy IRS tax obligations. Similar to the proposed rate base adjustment requirements, these proposed income tax allowance adjustment requirements are intended to satisfy Order No. 144's requirement that the income tax allowance match the current tax cost and reflect the effects of any future changes to tax rates that may give rise to excess or deficient ADIT.

37. Similar to comments regarding adjustments to rate base, we agree with commenters to the NOI that prescribing a one-size-fits-all approach is not appropriate and that the public utilities with transmission formula rates should instead be allowed to propose any necessary changes to their rates on an individual basis. Accordingly, we do not propose that all public utilities with transmission formula rates must use a single method to adjust their income tax allowances for any amortized excess or deficient ADIT. Many public utilities with transmission formula rates use different formats of rate templates or formulas, and a single, prescriptive method, such as the requirement of a single line item, may not fully capture or transparently convey the amortization of excess or deficient ADIT. Additionally, recent filings by public utilities that proposed revisions to their formula rate templates to reflect changes in income tax rates by, among other things, incorporating mechanisms to return excess ADIT demonstrate that company-specific variations are necessary.[62]

38. Regarding the period over which the amortization of excess or deficient ADIT must occur, we believe that public utilities should follow the guidance provided in the Tax Cuts and Jobs Act, where available. As noted by commenters to the NOI, the Tax Cuts and Jobs Act provides a method of general applicability and requires public utilities to return excess protected ADIT[63] no more rapidly than over the life of the underlying asset using the Average Rate Assumption Method, or, where a public utility's books and underlying records do not contain the vintage account data necessary, it must use an alternative method.[64] In contrast, the Tax Cuts and Jobs Act does not specify what method public utilities must use for excess or deficient unprotected ADIT. We agree with commenters to the NOI that, because such a determination depends on the specific facts and circumstances for each public utility, a case-by-case approach to amortizing excess or deficient unprotected ADIT remains appropriate.

39. Consumer Advocates are concerned that a portion of the amounts allowable to be returned to customers under the Average Rate Assumption Method schedule would not be refunded due to the fact that any proposed tariff provisions to return excess ADIT as a result of this Proposed Rule will not be effective until after January 1, 2018. We acknowledge that in applying a tax normalization method (*e.g.,* the Average Rate Assumption Method), public utilities are required to develop a schedule removing ADIT from rate base and returning it to customers, effective January 1, 2018, using the fastest allowable method to return the excess ADIT under the IRS' normalization requirements. However, these requirements represent only the fastest allowable return schedule and do not remove a public utility's obligation to return the excess ADIT. Any amounts allowed to be returned under the Average Rate Assumption Method schedule prior to the effective date of proposed tariff provisions made in compliance with the Proposed Rule should still be refunded to customers. In other words, the full regulatory liability for excess ADIT should be captured in rates, beginning on the effective date of any proposed tariff provision. We do not believe that any specific reforms are necessary to accomplish this because public utilities should not amortize an excess ADIT regulatory liability for accounting purposes until it is included in ratemaking.[65]

[58] Oklahoma Attorney General NOI Comments at 6.

[59] Consumer Advocates NOI Comments at 4.

[60] AEP NOI Comments at 4–5; Ameren NOI Comments at 11; APPA and AMP NOI Comments at 5–6, 10; Avangrid NOI Comments at 8–9; Consumer Advocates NOI Comments at 6–7; DEMEC NOI Comments at 9; EEI NOI Comments at 14, 16–17; Eversource NOI Comments at 7; Exelon NOI Comments at 13; Indicated Customers NOI Comments at 8–9; Indicated Transmission Owners NOI Comments at 8–9; Kentucky Municipals NOI Comments at 6; MISO Transmission Owners NOI Comments at 8–11; National Grid NOI Comments at 10–11; New York Transco NOI Comments at 7–8; Oklahoma Attorney General NOI Comments at 6–7; PSEG NOI Comments at 7–8.

[61] AEP NOI Comments at 6–7 (''However, in the event the Commission develops a broadly applicable amortization period, AEP recommends that period be 25 years or longer''); Avangrid NOI Comments at 9–11; Dominion, Comments to NOI, Docket No. RM18–12–000, at 12 (filed on May 21, 2018); EEI NOI Comments at 17–18; Enable Interstate Pipelines, Comments to NOI, Docket No. RM18–12–000, at 36–37 (filed on May 21, 2018); Enbridge and Spectra, Comments to NOI, Docket No. RM18–12–000, at 26 (filed May 21, 2018); EQT Midstream, Comments to NOI, Docket No. RM18–12–000, at 13–14 (filed May 21, 2018); Eversource NOI Comments at 8–9; Exelon NOI Comments at 13–14; Indicated Transmission Owners NOI Comments at 9–10; National Grid NOI Comments at 11–13; New York Transco NOI Comments at 9.

[62] *See, e.g., Midcontinent Indep. Sys. Operator, Inc.,* 153 FERC ¶ 61,374; *Midcontinent Indep. Sys. Operator, Inc.,* 163 FERC ¶ 61,163; *Midcontinent Indep. Sys. Operator, Inc.,* 164 FERC ¶ 61,113 (2018); *Emera Maine,* 165 FERC ¶ 61,086 (2018).

[63] While the Tax Cuts and Jobs Act does not mention deficient protected ADIT specifically, we expect that public utilities will recover such deficient ADIT in the same manner prescribed for excess protected ADIT.

[64] Tax Cuts and Jobs Act, Sec. 13001(b)(6)(A), 131 Stat. at 2099. If a public utility must use an alternative method, Commission precedent provides that the public utility should use the Reverse South Georgia Method for excess ADIT or the South Georgia Method for deficient ADIT. *See Memphis Light, Gas and Water Div.* v. *FERC,* 707 F.2d at 569.

[65] The description of Account 182.3 (Other regulatory assets) states, ''The amounts recorded in this account are generally to be charged,

Continued

b. Stated Rates

40. We propose to require all public utilities with transmission stated rates to (1) determine the excess and deficient income tax caused by the Tax Cuts and Jobs Act's reduction to the federal corporate income tax rate and (2) return this amount to or recover this amount from customers under 18 CFR 35.24. We also propose for public utilities with transmission stated rates to calculate this excess or deficient ADIT using the ADIT approved in their last rate cases. We believe calculating excess or deficient ADIT in this manner will allow public utilities with transmission stated rates to preserve their costs of service as accepted in their last rate case. We are not seeking to propose a specific way for public utilities with transmission stated rates to return or recover the excess or deficient income taxes to ratepayers; rather, we will evaluate each proposal on an individual basis. We believe the proposed reforms will increase the likelihood that those customers who contributed to the related ADIT accounts receive the benefit of the Tax Cuts and Jobs Act.

41. TAPS expresses concern that the customers of public utilities with transmission stated rates will lack sufficient information to evaluate any proposals to return or recover excess or deficient ADIT, respectively. We note that the Commission's regulations require public utilities filing changes to transmission rates to identify the effect of tax changes on those rates.[66] Accordingly, we expect that public utilities with stated rates would include in their compliance filings resulting from this Proposed Rule supporting information necessary to identify, at minimum, the following: (1) How any ADIT accounts were re-measured and the excess or deficient ADIT contained therein; (2) the accounting of any excess or deficient amounts in Accounts 182.3 and 254; (3) whether the excess or deficient ADIT is protected or unprotected; (4) the accounts to which the excess or deficient ADIT will be amortized; and (5) the amortization period of the excess or deficient ADIT to be returned or recovered through the rates.

42. Finally, as noted above, public utilities with transmission stated rates must conform to the Tax Cuts and Jobs Act's requirements regarding the period over which the amortization of protected excess or deficient ADIT must occur. We will continue to analyze the appropriate amortization period for unprotected ADIT on a case-by-case basis.

C. Support for Excess and Deficient ADIT Calculation and Amortization

1. NOI

43. In the NOI, the Commission sought comment on whether it should require public utilities to provide to the Commission, on a one-time basis, additional information, such as supporting worksheets, to show the computation of excess or deficient ADIT and the corresponding flow-back of excess ADIT to customers or recovery of deficient ADIT from customers. The Commission asked commenters to address what types of information public utilities already record for ADIT-related accounting and whether balances and amortization of regulatory liability and asset accounts, computation of excess and deficient ADIT, delineation between protected and non-protected ADIT, and a description of the allocation method used to determine the transmission-related portion of excess or deficient ADIT would be appropriate to include in a supporting worksheet.[67]

2. Comments

44. Commenters were split regarding the requirement to provide additional worksheets. Some commenters assert that the Commission should not require any additional worksheets at this time.[68] These commenters generally assert that the implementation of general worksheet requirements would be burdensome on the industry.[69] They assert that any data should only be required to be submitted on a company by company basis, as necessary, rather than require a one-time proceeding for the purpose of all public utilities providing the data showing whether and how ADIT balances were re-measured.[70] Certain commenters assert that the Commission should not require additional worksheets as transmission formula rates and associated protocols already include mechanisms to provide details to customers.[71] Avangrid similarly states that the formula rate processes should be used to provide the level of transparency to verify the flowback of excess ADIT ultimately prescribed by the Commission. EEI states that if the Commission does require additional supporting information as part of EEI's proposed show cause orders, the Commission should first provide its proposed financial template, in a rulemaking, to allow for review by public utilities and stakeholders. EEI adds that this would reduce the burden on individual public utilities and the Commission and would be similar to the approach leading up to the Gas Tax Final Rule.[72]

45. Other commenters, however, assert that the Commission should require electric public utilities to provide a one-time filing of additional information to provide transparency regarding excess and deficient ADIT, and how rates will be impacted by any changes.[73] APPA and AMP urge the Commission to require that supporting information be filed regarding excess or deficient ADIT, but not be limited to only ADIT-related material. They assert that public utilities should also describe, with supporting schedules, any current or projected effects on their books associated with the Tax Cuts and Jobs Act's changes to bonus depreciation, or any other potential rate-related impacts.[74] APPA and AMP further state that for public utilities with transmission formula rates, the utilities should provide as part of their annual updates, calculations showing excess ADIT amortization amounts that should be flowed back to customers in the applicable rate period. Consumer Advocates state that in addition to requiring a detailed worksheet identifying all book tax timing differences that comprise deferred tax liability balances, the Commission should evaluate the build-up of net operating losses as deferred tax assets. They assert that such balances should not automatically be inserted as an addition to regulated rate base.[75] New York Transco states that each public utility should be permitted to compile and present this additional information in the manner it deems most efficient and useful for stakeholders. New York

concurrently with the recovery of the amounts in rates. . .'' (emphasis added). 18 CFR part 101, Account 182.3 (Other Regulatory Assets).

[66] 18 CFR 35.13; 18 CFR 35.24.

[67] NOI, FERC Stats. & Regs. ¶ 35,582 at P 23.

[68] *See* AEP NOI Comments at 8; Ameren NOI Comments at 16–18; Avangrid NOI Comments at 13–14; EEI NOI Comments at 20–22; Exelon NOI Comments at 15; Indicated Transmission Owners NOI Comments at 12; MISO Transmission Owners NOI Comments at 18–19; and PSEG NOI Comments at 11–12.

[69] *See* EEI NOI Comments at 20–21; Exelon NOI Comments at 15.

[70] EEI NOI Comments at 20.

[71] *See* AEP NOI Comments at 8; Ameren NOI Comments at 16–17; Avangrid NOI Comments at 13–14; Exelon NOI Comments at 15, Indicated Transmission Owners NOI Comments at 12; and MISO Transmission Owners NOI Comments at 18–19.

[72] EEI NOI Comments at 21, n. 36.

[73] *See* APPA and AMP NOI Comments at 17–18; Consumer Advocates NOI Comments at 10–11; DEMEC NOI Comments at 11–12; Eversource NOI Comments at 11; Indicated Customers NOI Comments at 15; National Grid NOI Comments at 15–16; and New York Transco NOI Comments at 11.

[74] APPA and AMP NOI Comments at 17–18.

[75] Consumer Advocates NOI Comments at 10–11.

Transco states that if stakeholders desire additional information, any interested party can seek that information consistent with the formula rate implementation protocols that address information sharing. While not objecting to the provision of additional information, National Grid states that the Commission should not impose this requirement until after December 2018 as the additional information will not be meaningful until after companies have set the final rate change balance after the filing of their fiscal year 2018 federal corporate income tax returns.[76]

3. Proposed Requirements

a. Formula Rates

46. We propose to require all public utilities with transmission formula rates to incorporate a new permanent worksheet into their transmission formula rates that will annually track information related to excess or deficient ADIT under 18 CFR 35.24. We believe that this reform is necessary to provide interested parties adequate transparency regarding how public utilities with transmission formula rates adjust their rate bases and income tax allowances to account for excess or deficient ADIT. We also believe that requiring public utilities with transmission formula rates to provide this information on an annual basis rather than a one-time basis will better allow interested parties to follow excess or deficient ADIT as it is included in an annual revenue requirement and provide transparency as to any future changes in tax rates. We also believe that updating the proposed worksheet annually will better align with the nature of the vast majority of formula rates where calculation methodologies and input sources are accepted prior to those inputs being populated. Consequently, we do not propose that any worksheet be populated when submitted to the Commission for compliance, only that the function of the worksheet be clear.

47. Similar to other reforms proposed in this Proposed Rule, we do not propose a pro forma worksheet that must be adopted by all public utilities with transmission formula rates; rather, we propose requiring general categories of information that each excess or deficient ADIT tracking worksheet must contain. We propose that each excess or deficient ADIT worksheet must, at minimum, include the following: (1) How any ADIT accounts were re-measured and the excess or deficient ADIT contained therein; (2) the accounting of any excess or deficient amounts in Accounts 182.3 and 254; (3) whether the excess or deficient ADIT is protected or unprotected; (4) the accounts to which the excess or deficient ADIT are amortized; and (5) the amortization period of the excess or deficient ADIT being returned or recovered through the rates. Because we do not propose to define the form any worksheet or worksheets must take, only the information it must contain, we propose evaluating such worksheet or worksheets on an individual basis. We also request comments on whether we should consider additional guiding principles to those described above.

48. We disagree with commenters to the NOI that argue that providing such information is overly burdensome for the industry. Public utilities with transmission formula rates will already have gathered the information we propose to require in the worksheets to re-measure their ADIT balances and develop amortization schedules following the Tax Cuts and Jobs Act's reduction of the federal corporate income tax rate. Further, the Commission has already accepted worksheets that convey information similar to the proposed requirements outlined above.[77]

49. We also disagree with commenters to the NOI that public utilities' existing formula rate protocols should preclude the Commission from proposing an excess or deficient ADIT worksheet. While the Commission established that formula rate protocols should allow for the provision of any information necessary to understand the inputs to the rate in order to provide sufficient transparency to interested parties, the Commission has since required public utilities to revise their formula rates to include greater detail where it has deemed that certain inputs to the rate are complex enough to warrant prior understanding of their effect.[78] As related to excess and deficient ADIT, we believe the proposed worksheet will allow interested parties to ensure they are receiving the benefits of the Tax Cuts and Jobs Act, as well as to track over time any changes in the rate effects of the tax change as, for example, assets are sold or retired.

b. Stated Rates

50. As described above in the proposal for return of excess ADIT or recovery of deficient ADIT, we believe that the Commission's existing regulations require public utilities with transmission stated rates to provide sufficient support for any proposed tax-related changes. As a result, we do not propose any additional information requirements for public utilities with transmission stated rates.

III. Proposed Compliance Procedures

51. We propose to require each public utility with transmission stated or formula rates to submit a compliance filing within 90 days of the effective date of any subsequent final rule in this proceeding to revise its transmission formula or stated rates, as necessary, to demonstrate that it meets the requirements set forth in any subsequent final rule.

52. Some public utilities with transmission formula rates may already have mechanisms in place in their rates that address the issues and concerns addressed by any subsequent final rule. Where these provisions would be modified by any subsequent final rule, the public utility must either comply with any subsequent final rule or demonstrate that these previously approved variations continue to be consistent with or superior to the requirements of any subsequent final rule.

53. The Commission will assess whether each compliance filing satisfies the proposed requirements stated above and issue additional orders as necessary to ensure that each public utility with transmission stated or formula rates meets the requirements of the subsequent final rule.

IV. Information Collection Statement

54. The collection of information contained in this Proposed Rule is subject to review by the Office of Management and Budget (OMB) regulations under section 3507(d) of the Paperwork Reduction Act of 1995 (PRA).[79] OMB's regulations require approval of certain informational collection requirements imposed by an agency.[80] Upon approval of a collection(s) of information, OMB will assign an OMB control number and an expiration date. Respondents subject to the filing requirements will not be

[76] National Grid NOI Comments at 16.

[77] *See, e.g., Arizona Public Service Company,* Docket No. ER18–975–001 (May 22, 2018) (delegated order).

[78] *See, e.g., Midcontinent Indep. Sys. Operator, Inc.,* 153 FERC ¶ 61,374 at P 14 (directing certain transmission companies to revise their transmission formula rates to include worksheets to ensure appropriate transparency). The Commission has also regularly required certain revisions to new formula rates to provide greater transparency. *See, e.g., Xcel Energy Sw. Transmission Co., LLC,* 149 FERC ¶ 61,182 (2014); *Xcel Energy Transmission Dev. Co., LLC,* 149 FERC ¶ 61,181 (2014); *Transource Wisconsin, LLC,* 149 FERC ¶ 61,180 (2014); *Transource Kansas, LLC,* 151 FERC ¶ 61,010 (2015).

[79] 44 U.S.C. 3507(d).

[80] 5 CFR 1320.11.

penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number.

55. The reforms proposed in this Proposed Rule address public utilities that have transmission formula rates and transmission stated rates. The reforms related to transmission formula rates represent new requirements for these entities under the Commission's regulations in 18 CFR 35.24, which we believe are necessary because of the dramatic changes in the rate structure of the electric transmission industry since this provision was originally promulgated in 1981.[81] These new requirements would require each public utility with a transmission formula rate to revise its rate so that any excess or deficient ADIT is properly reflected in its revenue requirement following a change in tax rates, such as those established by the Tax Cuts and Jobs Act. Additionally, each public utility with a transmission formula rate would be required to incorporate a new permanent worksheet into its transmission formula rate to increase transparency.

56. The reforms required by this Proposed Rule will require each public utility with stated rates to calculate the excess and deficient ADIT caused by the Tax Cuts and Jobs Act and to return to or recover from customers those amounts. This reform is intended to increase the likelihood that customers who contributed to the excess ADIT balance timely receive the benefits of the Tax Cuts and Jobs Act.

57. The reforms proposed in this Proposed Rule would require compliance filings with the Commission by each public utility with transmission stated or formula rates to allow the Commission the opportunity to determine whether each such public utility met the requirements detailed in this Proposed Rule.

58. We anticipate the reforms proposed in this Proposed Rule, once implemented, would not significantly change currently existing burdens on an ongoing basis. With regard to those public utilities with transmission stated or formula rates that believe that they already comply with the reforms proposed in this Proposed Rule, they could demonstrate their compliance in the filing required 90 days after the effective date of the final revision in this proceeding. We will submit the proposed reporting requirements to OMB for its review and approval under section 3507(d) of the Paperwork Reduction Act.[82]

59. While we expect the adoption of the reforms proposed in this Proposed Rule to provide significant benefits, the Commission understands that implementation can be a complex and costly endeavor. We solicit comments on the accuracy of provided burden and cost estimates and any suggested methods for minimizing the respondents' burdens.

60. *Burden Estimate and Information Collection Costs:* We believe that the burden estimates below are representative of the average burden on respondents. The estimated burden and cost for the requirements contained in this Proposed Rule follow.

RM19–5–000 NOPR

[Public utility transmission rate changes to address accumulated deferred income taxes]

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden and cost per response[83]	Total annual burden hours and total annual cost	Cost per respondent ($)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Revising formula rates so that excess ADIT is deducted and/or deficient ADIT is added to rate base (one-time)[84].	106	1	106	8 hours; $736	848 hours; $78,016	$736
Revising formula rates so that any excess and/or deficient ADIT is amortized (one-time).	106	1	106	8 hours; $736	848 hours; $78,016	736
Revising transmission stated rates to return or recover excess or deficient ADIT (one-time).	31	1	31	15 hours; $1,380 ..	465 hours; $42,780	1,380
Requiring public utilities with transmission formula rates to incorporate a new permanent worksheet that will annually track ADIT information (one-time).	106	1	106	40 hours; $3,680 ..	4,240 hours; $390,080 ...	3,680
Total (Stated Rates)[85]	.....	.....	31	.....	465 hours; $42,780.	
Total (Formula Rates)[86]	.....	.....	318	.....	5,936 hours; $546,112.	
Total	.....	.....	349	.....	6,532 hours; $588,892.	

Cost to Comply: We have projected the total cost of compliance as follows:[87]

- *Year 1:* $546,112 ($5,152/utility) for public utilities with transmission formula rates; $42,780 ($1,380/utility) for public utilities with transmission stated rates.
- *Year 2:* $0.

[81] *See* discussion *infra* Section II.E.

[82] 44 U.S.C. 3507(d).

[83] The loaded hourly wage figure (includes benefits) is based on the average of the occupational categories for 2017 found on the Bureau of Labor Statistics website (*http://www.bls.gov/oes/current/naics2_22.htm*):

Accountant (Occupation Code: 13–2011): $56.59.

Management (Occupation Code: 11–0000): $94.28.

Legal (Occupation Code: 23–0000): $143.68.

Office and Administrative Support (Occupation Code: 43–0000): $41.34.

These various occupational categories' wage figures are averaged and weighted equally as follows: ($94.28/hour + $61.55/hour + $66.90/hour + $143.68/hour) ÷ 4 = $91.60/hour. The resulting wage figure is rounded to $92.00/hour for use in calculating wage figures in the NOPR in Docket No. RM19–5–000.

[84] One-time burdens apply in Year One only. There will be no subsequent burden in Years 2 and beyond.

[85] Total for Public Utilities with Transmission Stated Rates.

[86] Total for Public Utilities with Transmission Formula Rates.

[87] For a public utility transmission provider with transmission formula rates, the costs for Year 1 would consist of filing proposed changes to its transmission formula rates, including the addition of a new permanent worksheet, with the Commission within 90 days of the effective date of the final revision plus initial implementation. The Commission does not expect any ongoing costs beyond the initial compliance in Year 1. For a public utility transmission provider with transmission stated rates, the costs for Year 1 would consist of filing proposed changes to its transmission stated rates that allow it to return to or recover from customers any excess or deficient ADIT caused by the Tax Cuts and Jobs Act with the Commission within 90 days of the effective date of the final revision plus initial implementation.

After Year 1, the reforms proposed in this Proposed Rule, once implemented, would not significantly change existing burdens on an ongoing basis.

Title: FERC–516, Electric Rate Schedules and Tariff Filings.

Action: Proposed revisions to an information collection.

OMB Control No.: 1902–0096.

Respondents for this Proposal: Businesses or other for profit and/or not-for-profit institutions.

Frequency of Information: One-time during year one.

Necessity of Information: The Federal Energy Regulatory Commission makes this Proposed Rule to ensure that (1) rate base neutrality is preserved following enactment of the Tax Cuts and Jobs Act; (2) the reduction in ADIT on the books of rate-regulated companies that was collected from customers but is no longer payable to the IRS due to the Tax Cuts and Jobs Act is returned to or recovered from ratepayers consistent with general ratemaking principles; and (3) there is increased transparency for the process of excess and deficient ADIT calculation and amortization.

Internal Review: We have reviewed the proposed changes and have determined that such changes are necessary. These requirements conform to the Commission's need for efficient information collection, communication, and management within the energy industry. We have specific, objective support for the burden estimates associated with the information collection requirements.

61. Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426 [Attention: Ellen Brown, Office of the Executive Director], email: *DataClearance@ferc.gov,* phone: (202) 502–8663, fax: (202) 273–0873. Comments concerning the collection of information and the associated burden estimate(s), may also be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission, phone: (202) 395–0710, fax: (202) 395–7285]. Due to security concerns, comments should be sent electronically to the following email address: *oira_submission@omb.eop.gov*. Comments submitted to OMB should include FERC–516 and OMB Control No. 1902–0096.

V. Environmental Analysis

62. We are required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[88] The actions proposed to be taken in this Proposed Rule fall within the categorical exclusion under section 380.4(a)(15) of the Commission's regulations. This section provides a categorical exemption for approval of actions under sections 205 and 206 of the FPA relating to the filing of schedules containing all rates and charges for the transmission or sale of electric energy subject to the Commission's jurisdiction, plus the classification, practices, contracts and regulations that affect rates, charges, classification, and services.[89] The revisions proposed in this Proposed Rule fall within the categorical exemptions provided in the Commission's regulations, and as a result neither an Environmental Impact Statement nor an Environmental Assessment is required.

VI. Regulatory Flexibility Act Certification

63. The Regulatory Flexibility Act of 1980 (RFA)[90] generally requires a description and analysis of proposed rules that will have significant economic impact on a substantial number of small entities. The RFA does not mandate any particular outcome in a rulemaking. It only requires consideration of alternatives that are less burdensome to small entities and an agency explanation of why alternatives were rejected.

64. The Small Business Administration (SBA) revised its size standards (effective January 22, 2014) for electric utilities from a standard based on megawatt hours to a standard based on the number of employees, including affiliates. Under SBA's standards, some transmission owners will fall under the following category and associated size threshold: Electric bulk power transmission and control, at 500 employees.[91]

65. We estimate that the total number of public utility transmission providers with formula rates that would have to develop revisions to their formula rates, including the addition of a new permanent worksheet, and make compliance filings in response to this Proposed Rule is 106. Of these, we estimate that approximately 43 percent are small entities (approximately 46 entities). We estimate the average total cost to each of these entities will be $5,152 in Year 1 and $0 in subsequent years. In addition, we estimate that the total number of public utility transmission providers with stated rates that will have to calculate the excess and deficient income tax to return to or recover from customers is 31. Of these, we estimate that approximately 43 percent are small entities (approximately 13 entities). We estimate the average total cost to each of these entities will be between $1,380 in Year One and $0 in subsequent years. According to SBA guidance, the determination of significance of impact ''should be seen as relative to the size of the business, the size of the competitor's business, and the impact the regulation has on larger competitors.'' [92] We do not consider the estimated burden to be a significant economic impact. As a result, we certify that the revisions proposed in this Proposed Rule will not have a significant economic impact on a substantial number of small entities.

VII. Comment Procedures

66. We invite interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due December 24, 2018. Comments must refer to Docket No. RM19–5–000, and must include the commenter's name, the organization they represent, if applicable, and their address in their comments.

67. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's website at *http://www.ferc.gov*. The Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

68. Commenters that are not able to file comments electronically must send an original of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC, 20426.

69. All comments will be placed in the Commission's public files and may

[88] *Regulations Implementing the National Environmental Policy Act of 1969,* Order No. 486, FERC Stats. & Regs. ¶ 30,783 (1987) (cross-referenced at 41 FERC ¶ 61,284).

[89] 18 CFR 380.4(a)(15).

[90] 5 U.S.C. 601–612.

[91] 13 CFR 121.201, Sector 22 (Utilities), NAICS code 221121 (Electric Bulk Power Transmission and Control).

[92] U.S. Small Business Administration, *A Guide for Government Agencies How to Comply with the Regulatory Flexibility Act,* at 18 (May 2012), *https://www.sba.gov/sites/default/files/advocacy/rfaguide_0512_0.pdf.*

be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

VIII. Document Availability

70. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE, Room 2A, Washington, DC 20426.

71. From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

72. User assistance is available for eLibrary and the Commission's website during normal business hours from the Commission's Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov*.

By direction of the Commission. Commissioner McIntyre is not voting on this order.

Issued: November 15, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

Note: Appendix A will not be published in the **Federal Register**.

Appendix A—List of Commenters to NOI

Short name	Commenter
AEP	American Electric Power Service Corporation.
Ameren	Ameren Services Company on behalf of Union Electric Company d/b/a Ameren Missouri, Ameren Illinois Company d/b/a Ameren Illinois, and Ameren Transmission Company of Illinois.
AOPL	Association of Oil Pipe Lines.
APGA	American Public Gas Association.
APPA and AMP	American Public Power Association and American Municipal Power, Inc.
Avangrid	Avangrid Networks, Inc.
Berkshire	Berkshire Hathaway Energy Pipeline Group.
Boardwalk	Boardwalk Pipeline Partners LP.
CAPP	Canadian Association of Petroleum Producers.
Consumer Advocates	Office of the Attorney General of the Commonwealth of Massachusetts; the Ohio Consumers' Counsel; the Maryland Office of People's Counsel; the Nevada Bureau of Consumer Protection; the Delaware Division of the Public Advocate; the Pennsylvania Office of Consumer Advocate; the Citizens Utility Board of Wisconsin; and the Indiana Office of Utility Consumer Counselor.
DEMEC	Delaware Municipal Electric Corporation, Inc.
Dominion Energy Gas Pipelines	Dominion Energy Transmission, Inc.; Dominion Energy Carolina Gas Transmission, LLC; Dominion Energy Quester Pipeline, LLC; Dominion Energy Overthrust Pipeline, LLC; and Questar Southern Trails Pipeline Company.
EEI	Edison Electric Institute.
Enable Interstate Pipelines	Enable Mississippi River Transmission, LLC and Enable Gas Transmission, LLC.
Enbridge and Spectra	Enbridge Energy Partners, L.P. and Spectra Energy Partners, LP.
EQT Midstream	EQT Midstream Partners, LP.
Eversource	Eversource Energy Service Company.
Exelon	Exelon Corporation.
Indicated Customers	Central Electric Power Cooperative, Inc., North Carolina Electric Membership Corporation, Southern Maryland Electric Cooperative, Inc., and the New Jersey Division of Rate Counsel.
Indicated Local Distribution Companies.	Atmos Energy Corporation; the City of Charlottesville, Virginia; the City of Richmond, Virginia; the Easton Utilities Commission; Exelon Corporation; and Washington Gas Light Company.
Indicated Transmission Owners	American Electric Power Service Corporation; Dominion Energy Services, Inc., on behalf of Virginia Electric and Power Company d/b/a Dominion Energy Virginia; Duquesne Light Company; Exelon Corporation; FirstEnergy Service Company, on behalf of American Transmission Systems, Incorporated; Jersey Central Power & Light Company; Mid-Atlantic Interstate Transmission, LLC; West Penn Power Company; The Potomac Edison Company; Monongahela Power Company; and PPL Electric Utilities Corp.
INGAA	Interstate Natural Gas Association of America.
ITC Great Plains	ITC Great Plains, LLC.
Kentucky Municipals	Frankfort Plant Board of Frankfort, Kentucky; Barbourville Utility Commission of the City of Barbourville, City; Utilities Commission of the City of Corbin; and the Cities of Bardwell, Berea, Falmouth, Madisonville, and Providence, Kentucky.
Kinder Morgan Entities	Natural Gas Pipeline Company of America LLC; Tennessee Gas Pipeline Company, L.L.C.; Southern Natural Gas Company, L.L.C.; Colorado Interstate Gas Company, L.L.C.; Wyoming Interstate Company, L.L.C.; El Paso Natural Gas Company, L.L.C.; Mojave Pipeline Company, L.L.C.; Bear Creek Storage Company, L.L.C.; Cheyenne Plains Gas Pipeline Company, L.L.C.; Elba Express Company, L.L.C.; Kinder Morgan Louisiana Pipeline LLC; Southern LNG Company, L.L.C.; and TransColorado Gas Transmission Company LLC.
Kinder Morgan Subsidiaries	SFPP, L.P.; Calnev Pipe Line, LLC; and Kinder Morgan Cochin, LLC.

Short name	Commenter
MISO Transmission Owners	Ameren Services Company, as agent for Union Electric Company d/b/a Ameren Missouri, Ameren Illinois Company d/b/a Ameren Illinois and Ameren Transmission Company of Illinois; American Transmission Company LLC; Central Minnesota Municipal Power Agency; City Water, Light & Power (Springfield, IL); Cleco Power LLC; Cooperative Energy; Dairyland Power Cooperative; Duke Energy Business Services, LLC for Duke Energy Indiana, LLC; East Texas Electric Cooperative; Entergy Arkansas, Inc.; Entergy Louisiana, LLC; Entergy Mississippi, Inc.; Entergy New Orleans, LLC; Entergy Texas, Inc.; Great River Energy; Indiana Municipal Power Agency; Indianapolis Power & Light Company; International Transmission Company d/b/a ITC*Transmission;* ITC Midwest LLC; Lafayette Utilities System; Michigan Electric Transmission Company, LLC; MidAmerican Energy Company; Minnesota Power (and its subsidiary Superior Water, L&P); Missouri River Energy Services; Montana-Dakota Utilities Co.; Northern Indiana Public Service Company LLC; Northern States Power Company, a Minnesota corporation, and Northern States Power Company, a Wisconsin corporation, subsidiaries of Xcel Energy Inc.; Northwestern Wisconsin Electric Company; Otter Tail Power Company; Prairie Power Inc.; Southern Indiana Gas & Electric Company (d/b/a Vectren Energy Delivery of Indiana); Southern Minnesota Municipal Power Agency; Wabash Valley Power Association, Inc.; and Wolverine Power Supply Cooperative, Inc.
National Grid	National Grid USA.
Natural Gas Indicated Shippers	Aera Energy, LLC; Anadarko Energy Services Company; Apache Corporation; BP Energy Company; ConocoPhillips Company; Hess Corporation; Occidental Energy Marketing, Inc.; Petrohawk Energy Corporation; and XTO Energy, Inc.
New York Transco	New York Transco LLC.
Oklahoma Attorney General	Mike Hunter, Oklahoma Attorney General.
PJM	PJM Interconnection, L.L.C.
Plains	Plains Pipeline, L.P.
Process Gas and American Forest and Paper.	Process Gas Consumers Group and American Forest and Paper Association.
PSEG	Public Service Electric and Gas Company.
Tallgrass Pipelines	Trailblazer Pipeline Company LLC; Tallgrass Interstate Gas Transmission, LLC; and Rockies Express Pipeline LLC.
TAPS	Transmission Access Policy Study Group.
TransCanada	TransCanada Corporation.
United Airlines Petitioners	United Airlines, Inc.; American Airlines, Inc.; Delta Air Lines, Inc.; Southwest Airlines, Co.; BP West Coast Products LLC; ExxonMobil Oil Corporation; Chevron Products Company; HollyFrontier Refining & Marketing LLC; Valero Marketing and Supply Company; Airlines for America; and the National Propane Gas Association.
Williams	Williams Companies, Inc.

[FR Doc. 2018–25370 Filed 11–21–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 20

[REG–106706–18]

RIN 1545–B072

Estate and Gift Taxes; Difference in the Basic Exclusion Amount

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notification of public hearing.

SUMMARY: This document contains proposed regulations addressing the effect of recent legislative changes to the basic exclusion amount used in computing Federal gift and estate taxes. The proposed regulations will affect donors of gifts made after 2017 and the estates of decedents dying after 2017.

DATES: Written and electronic comments must be received by February 21, 2019. Outlines of topics to be discussed at the public hearing scheduled for March 13, 2019, must be received by February 21, 2019. If no outlines of topics are received by February 21, 2019, the hearing will be cancelled.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–106706–18), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions also may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:PA:LPD:PR (REG–106706–18), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224, or sent electronically via the Federal eRulemaking portal at *http://www.regulations.gov* (IRS REG–106706–18). The public hearing will be held in the Auditorium, Internal Revenue Service Building, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Deborah S. Ryan, (202) 317–6859; concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing, Regina L. Johnson at (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

I. Overview

In computing the amount of Federal gift tax to be paid on a gift or the amount of Federal estate tax to be paid at death, the gift and estate tax provisions of the Internal Revenue Code (Code) apply a unified rate schedule to the taxpayer's cumulative taxable gifts and taxable estate on death to arrive at a net tentative tax. The net tentative tax then is reduced by a credit based on the applicable exclusion amount (AEA), which is the sum of the basic exclusion amount (BEA) within the meaning of section 2010(c)(3) of the Code and, if applicable, the deceased spousal unused exclusion (DSUE) amount within the meaning of section 2010(c)(4). In certain cases, the AEA also includes a restored exclusion amount pursuant to Notice 2017–15, 2017–6 I.R.B. 783. Prior to January 1, 2018, for estates of decedents dying and gifts made beginning in 2011, section 2010(c)(3) provided a BEA of $5 million, indexed for inflation after 2011. The credit is applied first against the gift tax, on a cumulative basis, as taxable gifts are made. To the extent that any credit remains at death, it is applied against the estate tax.

This document contains proposed regulations to amend the Estate Tax Regulations (26 CFR part 20) under section 2010(c)(3) of the Code. The proposed regulations would update § 20.2010–1 to conform to statutory changes to the determination of the BEA enacted on December 22, 2017, by sections 11002 and 11061 of the Tax Cuts and Jobs Act, Public Law 115–97, 131 Stat. 2504 (2017) (TCJA).

II. Federal Gift Tax Computation Generally

The Federal gift tax is imposed by section 2501 of the Code on an individual's transfers by gift during each calendar year. The gift tax is determined under a seven-step computation required under sections 2502 and 2505 using the rate schedule set forth in section 2001(c) as in effect for the calendar year in which the gifts are made.

First, section 2502(a)(1) requires the determination of a tentative tax (that is, a tax unreduced by a credit amount) on the sum of all taxable gifts, whether made in the current year or in one or more prior periods (Step 1).

Second, section 2502(a)(2) requires the determination of a tentative tax on the sum of the taxable gifts made in all prior periods (Step 2).

Third, section 2502(a) requires the tentative tax determined in Step 2 to be subtracted from the tentative tax determined in Step 1 to arrive at the net tentative gift tax on the gifts made in the current year (Step 3).

Fourth, section 2505(a)(1) requires the determination of a credit equal to the applicable credit amount within the meaning of section 2010(c). The applicable credit amount is the tentative tax on the AEA determined as if the donor had died on the last day of the current calendar year. The AEA is the sum of the BEA as in effect for the year in which the gift was made, any DSUE amount as of the date of the gift as computed pursuant to § 25.2505–2, and any restored exclusion amount as of the date of the gift as computed pursuant to Notice 2017–15 (Step 4).

Fifth, section 2505(a)(2) and the flush language at the end of section 2505(a) require the determination of the sum of the amounts allowable as a credit to offset the gift tax on gifts made by the donor in all preceding calendar periods. For purposes of this determination, the allowable credit for each preceding calendar period is the tentative tax, computed at the tax rates in effect for the current period, on the AEA for such prior period, but not exceeding the tentative tax on the gifts actually made during such prior period. Section 2505(c). (Step 5).

Sixth, section 2505(a) requires that the total credit allowable for prior periods determined in Step 5 be subtracted from the credit for the current period determined in Step 4. (Step 6).

Finally, section 2505(a) requires that the credit amount determined in Step 6 be subtracted from the net tentative gift tax determined in Step 3 (Step 7).

III. Federal Estate Tax Computation Generally

The Federal estate tax is imposed by section 2001(a) on the transfer of a decedent's taxable estate at death. The estate tax is determined under a five-step computation required under sections 2001 and 2010 using the same rate schedule used for gift tax purposes (thus referred to as the unified rate schedule) as in effect at the decedent's death.

First, section 2001(b)(1) requires the determination of a tentative tax (again, a tax unreduced by a credit amount) on the sum of the taxable estate and the adjusted taxable gifts, defined as all taxable gifts made after 1976 other than those included in the gross estate (Step 1).

Second, section 2001(b)(2) and (g) require the determination of a hypothetical gift tax (a gift tax reduced, but not to below zero, by the credit amounts allowable in the years of the gifts) on all post-1976 taxable gifts, whether or not included in the gross estate. The credit amount allowable for each year during which a gift was made is the tentative tax, computed using the tax rates in effect at the decedent's death, on the AEA for that year, but not exceeding the tentative tax on the gifts made during that year. Section 2505(c). The AEA is the sum of the BEA as in effect for the year in which the gift was made, any DSUE amount as of the date of the gift as computed pursuant to § 25.2505–2, and any restored exclusion amount as of the date of the gift as computed pursuant to Notice 2017–15. This hypothetical gift tax is referred to as the gift tax payable (Step 2).

Third, section 2001(b) requires the gift tax payable determined in Step 2 to be subtracted from the tentative tax determined in Step 1 to arrive at the net tentative estate tax (Step 3).

Fourth, section 2010(a) and (c) require the determination of a credit equal to the tentative tax on the AEA as in effect on the date of the decedent's death. This credit may not exceed the net tentative estate tax. Section 2010(d). (Step 4).

Finally, section 2010(a) requires that the credit amount determined in Step 4 be subtracted from the net tentative estate tax determined in Step 3. (Step 5).

IV. TCJA Amendments

Section 11061 of the TCJA amended section 2010(c)(3) to provide that, for decedents dying and gifts made after December 31, 2017, and before January 1, 2026, the BEA is increased by $5 million to $10 million as adjusted for inflation (increased BEA). On January 1, 2026, the BEA will revert to $5 million. Thus, an individual or the individual's estate may utilize the increased BEA to shelter from gift and estate taxes an additional $5 million of transfers made during the eight-year period beginning on January 1, 2018, and ending on December 31, 2025 (increased BEA period).

In addition, section 11002 of the TCJA amended section 1(f)(3) of the Code to base the determination of annual cost-of-living adjustments, including those for gift and estate tax purposes, on the Chained Consumer Price Index for All Urban Consumers for all taxable years beginning after December 31, 2017. Section 11002 of the TCJA also made conforming changes in sections 2010(c)(3)(B)(ii), 2032A(a)(3)(B), and 2503(b)(2)(B).

Section 11061 of the TCJA also added section 2001(g)(2) to the Code, which, in addition to the necessary or appropriate regulatory authority granted in section 2010(c)(6) for purposes of section 2010(c), directs the Secretary to prescribe such regulations as may be necessary or appropriate to carry out section 2001 with respect to any difference between the BEA applicable at the time of the decedent's death and the BEA applicable with respect to any gifts made by the decedent.

V. Summary of Concerns Raised by Changes in BEA

1. In General

Given the cumulative nature of the gift and estate tax computations and the differing manner in which the credit is applied against these two taxes, commenters have raised two questions regarding a potential for inconsistent tax treatment or double taxation of transfers resulting from the temporary nature of the increased BEA. First, in cases in which a taxpayer exhausted his or her BEA and paid gift tax on a pre-2018 gift, and then either makes an additional gift or dies during the increased BEA period, will the increased BEA be absorbed by the pre-2018 gift on which gift tax was paid so as to deny the taxpayer the full benefit of the increased BEA during the increased BEA period? Second, in cases in which a taxpayer

made a gift during the increased BEA period that was fully sheltered from gift tax by the increased BEA but makes a gift or dies after the increased BEA period has ended, will the gift that was exempt from gift tax when made during the increased BEA period have the effect of increasing the gift or estate tax on the later transfer (in effect, subjecting the earlier gift to tax even though it was exempt from gift tax when made)?

As discussed in the remainder of this Background section, the Treasury Department and the IRS have analyzed the statutorily required steps for determining Federal gift and estate taxes in the context of several different situations that could occur either during the increased BEA period as a result of an increase in the BEA, or thereafter as a result of a decrease in the BEA. Only in the last situation discussed below was a potential problem identified, and a change intended to correct that problem is proposed in this notice of proposed rulemaking. This preamble, however, also includes a brief explanation of the reason why no potential problem is believed to exist in any of the first three situations discussed below. For the sake of simplicity, the following discussion assumes that, as may be the more usual case, the AEA includes no DSUE or restored exclusion amount and thus, refers only to the BEA.

2. Effect of Increase in BEA on Gift Tax

The first situation considered is whether, for gift tax purposes, the increased BEA available during the increased BEA period is reduced by pre-2018 gifts on which gift tax actually was paid. This issue arises for donors, who made both pre-2018 gifts exceeding the then-applicable BEA, thus making gifts that incurred a gift tax liability, and additional gifts during the increased BEA period. The concern raised is whether the gift tax computation will apply the increased BEA to the pre-2018 gifts, thus reducing the BEA otherwise available to shelter gifts made during the increased BEA period and, in effect, allocating credit to a gift on which gift tax in fact was paid.

Step 3 of the gift tax determination requires the tentative tax on all gifts from prior periods to be subtracted from the tentative tax on the donor's cumulative gifts (including the current gift). The gifts from prior periods include the pre-2018 gifts on which gift tax was paid. In this way, the full amount of the gift tax liability on the pre-2018 gifts is removed from the current year gift tax computation, regardless of whether that liability was sheltered from gift tax by the BEA and/or was satisfied by a gift tax payment. Steps 4 through 6 of the gift tax determination then require, in effect, that the BEA for the current year be reduced by the BEA allowable in prior periods against the gifts that were made by the donor in those prior periods. The increased BEA was not available in the years when the pre-2018 gifts were made and thus, was not allowable against those gifts. Accordingly, the gift tax determination appropriately reduces the increased BEA only by the amount of BEA allowable against prior period gifts, thereby ensuring that the increased BEA is not reduced by a prior gift on which gift tax in fact was paid.

3. Effect of Increase in BEA on Estate Tax

The second situation considered is whether, for estate tax purposes, the increased BEA available during the increased BEA period is reduced by pre-2018 gifts on which gift tax actually was paid. This issue arises in the context of estates of decedents who both made pre-2018 gifts exceeding the then allowable BEA, thus making gifts that incurred a gift tax liability, and die during the increased BEA period. The concern raised is whether the estate tax computation will apply the increased BEA to the pre-2018 gifts, thus reducing the BEA otherwise available against the estate tax during the increased BEA period and, in effect, allocating credit to a gift on which gift tax in fact was paid.

Step 3 of the estate tax determination requires that the hypothetical gift tax on the decedent's post-1976 taxable gifts be subtracted from the tentative tax on the sum of the taxable estate and adjusted taxable gifts. The post-1976 taxable gifts include the pre-2018 gifts on which gift tax was paid. In this way, the full amount of the gift tax liability on the pre-2018 gifts is removed from the estate tax computation, regardless of whether that liability was sheltered from gift tax by the BEA and/or was satisfied by a gift tax payment. Step 4 of the estate tax determination then requires that a credit on the amount of the BEA for the year of the decedent's death be subtracted from the net tentative estate tax. As a result, the only time that the increased BEA enters into the computation of the estate tax is when the credit on the amount of BEA allowable in the year of the decedent's death is netted against the tentative estate tax, which in turn already has been reduced by the hypothetical gift tax on the full amount of all post-1976 taxable gifts (whether or not gift tax was paid). Thus, the increased BEA is not reduced by the portion of any prior gift on which gift tax was paid, and the full amount of the increased BEA is available to compute the credit against the estate tax.

4. Effect of Decrease in BEA on Gift Tax

The third situation considered is whether the gift tax on a gift made after the increased BEA period is inflated by a theoretical gift tax on a gift made during the increased BEA period that was sheltered from gift tax when made. If so, this would effectively reverse the benefit of the increased BEA available for gifts made during the increased BEA period. This issue arises in the case of donors who both made one or more gifts during the increased BEA period that were sheltered from gift tax by the increased BEA in effect during those years, and made a post-2025 gift. The concern raised is whether the gift tax determination on the post-2025 gift will treat the gifts made during the increased BEA period as gifts not sheltered from gift tax by the credit on the BEA, given that the post-2025 gift tax determination is based on the BEA then in effect, rather than on the increased BEA.

Just as in the first situation considered in part V(2) of this Background section, Step 3 of the gift tax determination directs that the tentative tax on gifts from prior periods be subtracted from the tentative tax on the donor's cumulative gifts (including the current gift). The gift tax from prior periods includes the gift tax attributable to the gifts made during the increased BEA period. In this way, the full amount of the gift tax liability on the increased BEA period gifts is removed from the computation, regardless of whether that liability was sheltered from gift tax by the BEA or was satisfied by a gift tax payment. All that remains is the tentative gift tax on the donor's current gift. Steps 4 through 6 of the gift tax determination then require that the credit based on the BEA for the current year be reduced by such credits allowable in prior periods. Even if the sum of the credits allowable for prior periods exceeds the credit based on the BEA in the current (post-2025) year, the tax on the current gift cannot exceed the tentative tax on that gift and thus will not be improperly inflated. The gift tax determination anticipates and avoids this situation, but no credit will be available against the tentative tax on the post-2025 gift.

5. Effect of Decrease in BEA on Estate Tax

The fourth situation considered is whether, for estate tax purposes, a gift made during the increased BEA period that was sheltered from gift tax by the increased BEA inflates a post-2025 estate tax liability. This will be the case

if the estate tax computation fails to treat such gifts as sheltered from gift tax, in effect reversing the benefit of the increased BEA available for those gifts. This issue arises in the case of estates of decedents who both made gifts during the increased BEA period that were sheltered from gift tax by the increased BEA in effect during those years, and die after 2025. The concern raised is whether the estate tax computation treats the gifts made during the increased BEA period as post-1976 taxable gifts not sheltered from gift tax by the credit on the BEA, given that the post-2025 estate tax computation is based on the BEA in effect at the decedent's death rather than the BEA in effect on the date of the gifts.

In this case, the statutory requirements for the computation of the estate tax, in effect, retroactively eliminate the benefit of the increased BEA that was available for gifts made during the increased BEA period. This can be illustrated by the following examples.

Example 1. Individual A made a gift of $11 million in 2018, when the BEA was $10 million. A dies in 2026, when the BEA is $5 million, with a taxable estate of $4 million. Based on a literal application of section 2001(b), the estate tax would be approximately $3,600,000, which is equal to a 40 percent estate tax on $9 million (specifically, the $9 million being the sum of the $4 million taxable estate and $5 million of the 2018 gift sheltered from gift tax by the increased BEA). This in effect would impose estate tax on the portion of the 2018 gift that was sheltered from gift tax by the increased BEA allowable at that time.

Example 2. The facts are the same as in *Example 1,* but A dies in 2026 with no taxable estate. Based on a literal application of section 2001(b), A's estate tax is approximately $2 million, which is equal to a 40 percent tax on $5 million. Five million dollars is the amount by which, after taking into account the $1 million portion of the 2018 gift on which gift tax was paid, the 2018 gift exceeded the BEA at death. This, in effect, would impose estate tax on the portion of the 2018 gift that was sheltered from the gift tax by the excess of the 2018 BEA over the 2026 BEA.

This problem occurs as a result of the interplay between Steps 2 and 4 of the estate tax determination, and the differing amounts of BEA taken into account in those steps. Step 2 determines the credit against gift taxes payable on all post-1976 taxable gifts, whether or not included in the gross estate, using the BEA amounts allowable on the dates of the gifts but determined using date of death tax rates. Step 3 subtracts gift tax payable from the tentative tax on the sum of the taxable estate and the adjusted taxable gifts. The result is the net tentative estate tax. Step 4 determines a credit based on the BEA as in effect on the date of the decedent's death. Step 5 then reduces the net tentative estate tax by the credit determined in Step 4. If the credit amount applied at Step 5 is less than that allowable for the decedent's post-1976 taxable gifts at Step 2, the effect is to increase the estate tax by the difference between those two credit amounts. In this circumstance, the statutory requirements have the effect of imposing an estate tax on gifts made during the increased BEA period that were sheltered from gift tax by the increased BEA in effect when the gifts were made.

Explanation of Provisions

To implement the TCJA changes to the BEA under section 2010(c)(3), the proposed regulations would amend § 20.2010–1 to provide that, in the case of decedents dying or gifts made after December 31, 2017, and before January 1, 2026, the increased BEA is $10 million. The proposed regulations also would conform the rules of § 20.2010–1 to the changes made by the TCJA regarding the cost of living adjustment.

Pursuant to section 2001(g)(2), the proposed regulations also would amend § 20.2010–1 to provide a special rule in cases where the portion of the credit as of the decedent's date of death that is based on the BEA is less than the sum of the credit amounts attributable to the BEA allowable in computing gift tax payable within the meaning of section 2001(b)(2). In that case, the portion of the credit against the net tentative estate tax that is attributable to the BEA would be based upon the greater of those two credit amounts. In the view of the Treasury Department and the IRS, the most administrable solution would be to adjust the amount of the credit in Step 4 of the estate tax determination required to be applied against the net tentative estate tax. Specifically, if the total amount allowable as a credit, to the extent based solely on the BEA, in computing the gift tax payable on the decedent's post-1976 taxable gifts, whether or not included in the gross estate, exceeds the credit amount, again to the extent based solely on the BEA in effect at the date of death, the Step 4 credit would be based on the larger amount of BEA. As modified, Step 4 of the estate tax determination therefore would require the determination of a credit equal to the tentative tax on the AEA as in effect on the date of the decedent's death, where the BEA included in that AEA is the larger of (i) the BEA as in effect on the date of the decedent's death under section 2010(c)(3), or (ii) the total amount of the BEA allowable in determining Step 2 of the estate tax computation (that is, the gift tax payable).

For example, if a decedent had made cumulative post-1976 taxable gifts of $9 million, all of which were sheltered from gift tax by a BEA of $10 million applicable on the dates of the gifts, and if the decedent died after 2025 when the BEA was $5 million, the credit to be applied in computing the estate tax is that based upon the $9 million of BEA that was used to compute gift tax payable.

The proposed regulations ensure that a decedent's estate is not inappropriately taxed with respect to gifts made during the increased BEA period. Congress' grant of regulatory authority in section 2001(g)(2) to address situations in which differences exist between the BEA applicable to a decedent's gifts and the BEA applicable to the decedent's estate clearly permits the Secretary to address the situation in which a gift is made during the increased BEA period and the decedent dies after the increased BEA period ends.

Commenters have noted that this problem is similar to that involving the application of the AEA addressed in the DSUE regulations. Section 20.2010–3(b). The DSUE amount generally is what remains of a decedent's BEA that can be used to offset the gift and/or estate tax liability of the decedent's surviving spouse. At any given time, however, a surviving spouse may use only the DSUE amount from his or her last deceased spouse—thus, only until the death of any subsequent spouse. Without those regulations, if a DSUE amount was used to shelter a surviving spouse's gifts from gift tax before the death of a subsequent spouse, and if the surviving spouse also survived the subsequent spouse, those gifts would have had the effect of absorbing the DSUE amount available to the surviving spouse at death, effectively resulting in a taking back of the DSUE amount that had been allocated to the earlier gifts. The DSUE regulations resolve this problem by providing that the DSUE amount available at the surviving spouse's death is the sum of the DSUE amount from that spouse's last deceased spouse, and any DSUE amounts from other deceased spouses that were ''applied to one or more taxable gifts'' of the surviving spouse.

Proposed Effective Date

The amendment to § 20.2010–1 is proposed to be effective on and after the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**.

Special Analyses

These proposed regulations are not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Treasury Department and the Office of Management and Budget regarding review of tax regulations.

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that these proposed regulations will not have a significant economic impact on a substantial number of small entities. These proposed regulations apply to donors of gifts made after 2017 and to the estates of decedents dying after 2017, and implement an increase in the amount that is excluded from gift and estate tax. Neither an individual nor the estate of a deceased individual is a small entity within the meaning of 5 U.S.C. 601(6). Accordingly, a regulatory flexibility analysis is not required.

Pursuant to section 7805(f) of the Internal Revenue Code, this regulation has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written or electronic comments that are submitted timely (in the manner described under the **ADDRESSES** heading) to the IRS. The Treasury Department and the IRS request comments on all aspects of the proposed regulations. All comments will be available at *http://www.regulations.gov,* or upon request. A public hearing on these proposed regulations has been scheduled for March 13, 2019, beginning at 10 a.m. in the Auditorium, Internal Revenue Building, 1111 Constitution Avenue NW, Washington, DC 20224. Due to building security procedures, visitors must enter the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit comments by February 21, 2019, and submit an outline of the topics to be discussed and the time devoted to each topic by February 21, 2019.

A period of 10 minutes will be allotted to each person for making comments. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these proposed regulations is Deborah S. Ryan, Office of the Associate Chief Counsel (Passthroughs and Special Industries). Other personnel from the Treasury Department and the IRS participated in their development.

Statement of Availability of IRS Documents

Notice 2017–15 is published in the Internal Revenue Bulletin (or Cumulative Bulletin) and is available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *http://www.irs.gov*.

List of Subjects in 26 CFR Part 20

Estate taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 20 is proposed to be amended as follows:

PART 20—ESTATE TAX; ESTATES OF DECEDENTS DYING AFTER AUGUST 16, 1954

■ **Par. 1.** The authority citation for part 20 is amended by revising the entry for § 20.2010–1 to read in part as follows:

Authority: 26 U.S.C. 7805.

* * * * *

Section 20.2010–1 also issued under 26 U.S.C. 2001(g)(2) and 26 U.S.C. 2010(c)(6).

* * * * *

■ **Par. 2.** Section 20.2010–1 is amended by:

■ 1. Redesignating paragraphs (c) through (e) as paragraphs (d) through (f) respectively;

■ 2. Adding a new paragraph (c); and

■ 3. Revising newly redesignated paragraphs (e)(3) and (f).

The addition and revisions read as follows:

§ 20.2010–1 Unified credit against estate tax; in general.

* * * * *

(c) *Special rule in the case of a difference between the basic exclusion amount applicable to gifts and that applicable at the donor's date of death*—(1) *Rule.* Changes in the basic exclusion amount that occur between the date of a donor's gift and the date of the donor's death may cause the basic exclusion amount allowable on the date of a gift to exceed that allowable on the date of death. If the total of the amounts allowable as a credit in computing the gift tax payable on the decedent's post-1976 gifts, within the meaning of section 2001(b)(2), to the extent such credits are based solely on the basic exclusion amount as defined and adjusted in section 2010(c)(3), exceeds the credit allowable within the meaning of section 2010(a) in computing the estate tax, again only to the extent such credit is based solely on such basic exclusion amount, in each case by applying the tax rates in effect at the decedent's death, then the portion of the credit allowable in computing the estate tax on the decedent's taxable estate that is attributable to the basic exclusion amount is the sum of the amounts attributable to the basic exclusion amount allowable as a credit in computing the gift tax payable on the decedent's post-1976 gifts. The amount allowable as a credit in computing gift tax payable for any year may not exceed the tentative tax on the gifts made during that year, and the amount allowable as a credit in computing the estate tax may not exceed the net tentative tax on the taxable estate. Sections 2505(c) and 2010(d).

(2) *Example.* Individual A (never married) made cumulative post-1976 taxable gifts of $9 million, all of which were sheltered from gift tax by the cumulative total of $10 million in basic exclusion amount allowable on the dates of the gifts. A dies after 2025 and the basic exclusion amount on A's date of death is $5 million. A was not eligible for any restored exclusion amount pursuant to Notice 2017–15. Because the total of the amounts allowable as a credit in computing the gift tax payable on A's post-1976 gifts (based on the $9 million basic exclusion amount used to determine those credits) exceeds the credit based on the $5 million basic exclusion amount applicable on the decedent's date of death, under paragraph (c)(1) of this section, the credit to be applied for purposes of computing the estate tax is based on a basic exclusion amount of $9 million, the amount used to determine the credits allowable in computing the gift tax payable on the post-1976 gifts made by A.

* * * * *

(e) * * *

(3) *Basic exclusion amount.* Except to the extent provided in paragraph (e)(3)(iii) of this section, the basic exclusion amount is the sum of the

amounts described in paragraphs (e)(3)(i) and (ii) of this section.

(i) For any decedent dying in calendar year 2011 or thereafter, $5,000,000; and

(ii) For any decedent dying after calendar year 2011, $5,000,000 multiplied by the cost-of-living adjustment determined under section 1(f)(3) for the calendar year of decedent's death by substituting ''calendar year 2010'' for ''calendar year 2016'' in section 1(f)(3)(A)(ii) and rounded to the nearest multiple of $10,000.

(iii) In the case of the estates of decedents dying after December 31, 2017, and before January 1, 2026, paragraphs (e)(3)(i) and (ii) of this section will be applied by substituting ''$10,000,000'' for ''$5,000,000.''

(f) *Applicability dates*—(1) *In general.* Except as provided in paragraph (f)(2) of this section, this section applies to the estates of decedents dying after June 11, 2015. For the rules applicable to estates of decedents dying after December 31, 2010, and before June 12, 2015, see § 20.2010–1T, as contained in 26 CFR part 20, revised as of April 1, 2015.

(2) *Exceptions.* Paragraph (c) of this section applies to estates of decedents dying on and after the date of publication of a Treasury decision adopting these rules as final regulations. Paragraph (e)(3) of this section applies to the estates of decedents dying after December 31, 2017.

§ 20.2010–3 [Amended]

■ **Par. 3.** Section 20.2010–3 is amended by removing ''§ 20.2010–1(d)(5)'' wherever it appears and adding in its place ''§ 20.2010–1(e)(5)''.

Kirsten Wielobob,

Deputy Commissioner for Service and Enforcement.

[FR Doc. 2018–25538 Filed 11–20–18; 4:15 pm]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2018–0700; FRL–9986–80–Region 7]

Air Plan Approval; Missouri; Emissions Inventory for the Missouri Jackson County and Jefferson County 2010 Sulfur Dioxide National Ambient Air Quality Standard Nonattainment Areas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve two submissions from the Missouri Department of Natural Resources (MoDNR) revising the State Implementation Plan (SIP) for the State of Missouri. The SIP revision submissions address the Clean Air Act (CAA) section 172 requirement to submit a base year emissions inventory for Missouri's partial Jackson County and partial Jefferson County nonattainment areas of the 2010 1-hour Sulfur Dioxide (SO_2) National Ambient Air Quality Standard (NAAQS).

DATES: Comments must be received on or before December 24, 2018.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–R07–OAR–2018–0700 to *https://www.regulations.gov*. Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received will be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Written Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Tracey Casburn, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219, by telephone at (913) 551–7016, or by email at *casburn.tracey@epa.gov*.

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

Table of Contents

I. Written Comments

Submit your comments, identified by Docket ID No. EPA–R07–OAR–2018–0700, at *https://www.regulations.gov*. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets*.

II. Background Information

On June 22, 2010, the EPA promulgated a new 1-hour primary SO_2 NAAQS of 75 parts per billion (ppb). *See* 75 FR 35520, codified at 40 CFR 50.17(a)–(b). On August 5, 2013, the EPA finalized designations for the 2010 SO_2 NAAQS, including the partial Jackson County and partial Jefferson County nonattainment areas in the State of Missouri. *See* 78 FR 47191, codified at 40 CFR part 81, subpart C. These area designations were effective October 4, 2013. Section 191 of the CAA directs states to submit SIP revisions for areas designated as nonattainment for the SO_2 NAAQS to the EPA within 18 months of the effective date of the designation (*i.e.,* no later than April 4, 2015). Submittal of the state's nonattainment plan SIP revision submissions is discussed in more detail in the ''Have the requirements for approval of a SIP revision been met?'' section of this document.

CAA section 172(c)(3) requires states to develop and submit a comprehensive, accurate, current emissions inventory for all areas designated as nonattainment. An emissions inventory is an estimation of actual emissions of air pollutants in an area that provides data for a variety of air quality planning tasks including establishing baseline emission levels, calculating Federally required emission reduction targets, emission inputs into air quality simulation models, and for tracking emissions over time. The EPA's April 2014 guidance document ''Guidance for 1-Hour SO_2 Nonattainment Area SIP Submissions'' (April 2014 guidance) recommends that the state develop an accurate emissions inventory of current emissions for all sources of SO_2 (*i.e.,* point, area and mobile sources) within the nonattainment area as well as any sources located outside the nonattainment area which may affect attainment in the area.[1]

[1] See page 8 of the April 2014 guidance.

The EPA has reviewed the state's emission inventory SIP revision submissions and is proposing to approve the SIP revision submissions pursuant to sections 110, 191(a), and 172(c)(3) of the CAA.

III. Have the requirements for approval of a SIP revision been met?

The baseline emissions inventory for the Jackson County SO_2 nonattainment area was included in MoDNR's October 2015 SIP revision submission ''Nonattainment Area Plan for the 2010 1-Hour Sulfur Dioxide National Ambient Air Quality Standard—Jackson County Sulfur Dioxide Nonattainment Area'' which met the public notice requirements for a SIP revision submission in accordance with 40 CFR 51.102.[2] The MoDNR provided public notice of the SIP revision submission from March 22, 2015 to July 2, 2015, and held a public hearing on June 25, 2015. The MoDNR received oral comments from three sources during the hearing and written comments from three sources prior to the close of the public comment period.[3]

The baseline emissions inventory for the Jefferson County SO_2 nonattainment area was included in MoDNR's June 2015 SIP revision submission ''Nonattainment Area Plan for the 2010 1-Hour Sulfur Dioxide National Ambient Air Quality Standard—Jefferson County Sulfur Dioxide Nonattainment Area'' which met the public notice requirements for a SIP revision submission in accordance with 40 CFR 51.102.[4] The MoDNR provided public notice of the SIP revision submission from March 26, 2015 to May 7, 2015, and held a public hearing on April 30, 2015. The MoDNR received oral comments from seven sources during the hearing and written comments from three sources prior to the close of the public comment period.[5]

None of the comments the state received were directly related to the baseline year emissions inventories, therefore no changes were made to the baseline emmisions inventories prior to submitting the SIP revision submissions to the EPA. The emissions inventory SIP revision submissions meet the procedural requirements for SIP submittals in the CAA, including section 110 and implementing regulations.

IV. What is the EPA's analysis of the SIP revision submissions?

The baseline emissions inventory in both SIP revision submissions was taken from the 2011 National Emissions Inventory (NEI) database. The MoDNR developed a comprehensive statewide emissions inventory for 2011 as required by the EPA's Air Emissions Reporting Requirements (AERR) rule. See 73 FR 76539 codified at 40 CFR 51.1–51.50. The inventory was submitted to the NEI through the EPA's Emission Inventory System (EIS). The 2011 baseline emissions inventory in both SIP revision submissions included point, area (or nonpoint), and mobile emissions sources of SO_2 in accordance with the EPA's April 2014 Guidance. Both 2011 baseline emissions SIP revision submissions were county wide (*i.e.,* not limited to the partial county nonattainment boundary) and SO_2 emissions data was reported in tons per year (tpy).[6]

TABLE 1—COUNTY WIDE 2011 BASELINE SO_2 EMISSIONS

[Tpy]

Emission category	Jackson County	Jefferson County
Point Source	27,513	43,713
Area (Nonpoint) Source	92	51
Mobile Source	92	27

V. What action is the EPA taking?

The EPA is proposing to approve the two SIP revision submissions from the MoDNR addressing the CAA section 172(c)(3) requirement to submit a base year emissions inventory for Missouri's partial Jackson County and partial Jefferson County nonattainment areas of the 2010 1-hour SO_2 NAAQS. The EPA proposes that these emission inventory SIP revision submissions were submitted in accordance with sections 110, 191(a), and 172(c)(3) of the CAA. Final rulemaking will occur after consideration of any comments.

VI. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866.
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of the National Technology Transfer and Advancement Act (NTTA) because this rulemaking does not involve technical standards; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian

[2] The MoDNR withdrew the ''Nonattainment Area Plan for the 2010 1-Hour Sulfur Dioxide National Ambient Air Quality Standard—Jackson County Sulfur Dioxide Nonattainment Area'' SIP submission, except the EI, from the EPA's consideration on June 11, 2018.

[3] The Sierra Club submitted letters from 78 citizens.

[4] The MoDNR withdrew the National Ambient Air Quality Standard—Jefferson County Sulfur Dioxide Nonattainment Area'' SIP submission, except the EI, from the EPA's consideration on March 30, 2018.

[5] The Sierra Club submitted postcards and signatures from 240 citizens.

[6] The MoDNR developed separate model input inventories based on 2012 emissions that included sources inside of and outside of the nonattainment areas. Nonpoint and mobile sources emissions were considered part of the background in the modeling scenarios.

country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Emissions Inventory, Incorporation by reference, Sulfur oxides.

Dated: November 16, 2018.

James B. Gulliford,

Regional Administrator, Region 7.

For the reasons stated in the preamble, the EPA proposes to amend part 52 as set forth below:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart—AA Missouri

■ 2. Amend the table in § 52.1320, paragraph (e) by adding new entries ''(76)'' and ''(77)'' in numerical order to read as follows:

§ 52.1320 Identification of Plan.

* * * * *

(e) * * *

EPA-APPROVED MISSOURI NONREGULATORY SIP PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanation
*	*	*	*	*
(76) Jackson County 1-Hour SO_2 NAA Baseline Emissions Inventory.	Jackson County	10/15/2015	[Date of publication of the final rule in the **Federal Register**], [**Federal Register** citation of the final rule].	[EPA–R07–OAR–2018–0700; FRL–9986–80–Region 7].
(77) Jefferson County 1-Hour SO_2 NAA Baseline Emissions Inventory.	Jefferson County	6/1/2015	[Date of publication of the final rule in the **Federal Register**], [**Federal Register** citation of the final rule].	[EPA–R07–OAR–2018–0700; FRL–9986–80–Region 7].

[FR Doc. 2018–25553 Filed 11–21–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[EPA–R06–OAR–2018–0624; FRL–9986–54–Region 6]

Air Quality Designation for the 2010 Sulfur Dioxide (SO_2) Primary National Ambient Air Quality Standard; Arkansas; Redesignation of the Independence County Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On April 20, 2018, the State of Arkansas (AR), through the Arkansas Department of Environmental Quality (ADEQ) submitted a request for the Environmental Protection Agency (EPA) to assess new available information and redesignate the Independence County, AR unclassifiable area (hereinafter referred to as the ''County'' or ''Area'') for the 2010 sulfur dioxide (SO_2) primary national ambient air quality standard (NAAQS) to attainment/unclassifiable. The EPA is proposing that it now has sufficient information to determine that the Area is attaining the 2010 SO_2 primary NAAQS, and, therefore, is proposing to approve the State's request and redesignate the Area to attainment/unclassifiable for the 2010 primary SO_2 NAAQS.

DATES: Comments must be received on or before December 24, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R06–OAR–2018–0624 at *https://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets*.

FOR FURTHER INFORMATION CONTACT: Mr. Ruben Casso, (214) 665–6763, *casso.ruben@epa.gov*. To inspect the hard copy materials, please schedule an appointment with Mr. Casso.

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' or ''our'' means the EPA.

I. Background

The Clean Air Act (CAA or Act) establishes a process for air quality management through the establishment and implementation of the NAAQS. After the promulgation of a new or revised NAAQS, EPA is required to designate all areas of the country, pursuant to section 107(d)(1) of the CAA. For the 2010 SO_2 primary NAAQS, designations were based on the EPA's application of the nationwide analytical approach to, and technical assessment of, the weight of evidence for each area, including but not limited to available air quality monitoring data and air quality modeling results. The EPA issued updated designations guidance through a March 20, 2015, memorandum from Stephen D. Page, Director, U.S. EPA, Office of Air Quality Planning and Standards, to Air Division Directors, U.S. EPA Regions 1–10 titled, ''Updated Guidance for Area Designations for the 2010 Primary Sulfur Dioxide National Ambient Air Quality Standard,'' which contains the factors the EPA intends to evaluate in determining the appropriate designations and associated boundaries, including: (1) Air quality

characterization via ambient monitoring or dispersion modeling results; (2) emissions-related data; (3) meteorology; (4) geography and topography; and (5) jurisdictional boundaries. The guidance also references the EPA's non-binding Monitoring Technical Assistance Document (Monitoring TAD) and Modeling Technical Assistance Document (Modeling TAD),[1] which contain scientifically sound recommendations on how air agencies should conduct such monitoring or modeling.

Entergy Corporation Independence Steam Electric Station (Independence Station). Independence Station is located in northeastern Arkansas in the eastern portion of Independence County, approximately 5 kilometers (km) southeast of Newark, Arkansas. Independence Station is a large Electrical Generating Unit that was included in the list of facilities to be designated pursuant to a March 2, 2015 Consent Decree.[2] There is one other major emitter of SO_2 in Independence County.[3] The Future Fuel Corporation facility (Future Fuel) located approximately 12 km to the west-northwest of Independence Station.

Independence County was designated unclassifiable on July 12, 2016.[4] The unclassifiable designation was based on the information the state of Arkansas and the Sierra Club provided to the EPA. Specifically, the designation and associated boundaries were based on the EPA's evaluation of the State's air dispersion modeling analysis, as well as the additional modeling analysis submitted by Sierra Club for the area surrounding Independence Station. In summary, the EPA's evaluation of the state's modeling supported the need for refined emission estimates for the Future Fuel facility to accurately assess potential maximum impacts in Independence County. Both ADEQ's and Sierra Club's previous modeling provided to the EPA in 2015 and 2016 were premised on several factors that were not consistent with recommendations in the Modeling TAD and were unreliable for determining whether the area was or was not meeting the 2010 SO_2 NAAQS. After careful evaluation of the State's recommendation, all timely comments and information received, the EPA concluded that it could not determine whether the area around the Independence Station was meeting or not meeting the 2010 SO_2 primary NAAQS and designated that area unclassifiable in July 2016. The boundaries for this designation were the jurisdictional boundaries of Independence County, based upon the State's recommendation, its submitted analysis and our concurrence on the State's reasoning.

Detailed rationale, analyses, and other information supporting our original designation for this area can be found in the final action's technical support document for Arkansas.[5] This document, along with all other supporting materials for the original 2010 SO_2 primary NAAQS designation for Independence County, can be found at *www.regulations.gov* in Docket ID EPA–HQ–OAR–2014–0464. The technical support document for this proposed action is included in the docket for this action (Docket EPA–R06–OAR–2018–0624).[6]

II. What are the criteria for redesignating an area from unclassifiable to attainment/unclassifiable?

Section 107(d)(3)(A) provides that the Administrator may notify the Governor of any state that the designation of an area should be revised ''on the basis of air quality data, planning and control considerations, or any other air quality-related considerations the Administrator deems appropriate.'' The Act further provides in section 107(d)(3)(D) that even if the Administrator has not notified a state Governor that a designation should be revised, the Governor of any state may, on the Governor's own motion, submit a request to revise the designation of any area, and the Administrator must approve or deny the request.

When approving or denying a request to redesignate an area, the EPA bases its decision on the air quality data for the area as well as the considerations provided under section 107(d)(3)(A).[7] The EPA defines an attainment/unclassifiable area[8] as: An area for which available information does not indicate that the area violates the NAAQS or contributes to ambient air quality in a nearby area that does not meet the NAAQS or an area for which the EPA has determined the available information indicates the area meets the NAAQS and does not indicate the area contributes to ambient air quality in a nearby area that does not meet the NAAQS. We are proposing to find that Independence County would fall under the second definition.

III. What is EPA's rationale for proposing to redesignate the area?

Independence County was designated unclassifiable by the EPA on July 12, 2016. As discussed previously, modeling results provided by Arkansas and Sierra Club in 2015 and 2016 were not refined enough to make a clear determination of the area's attainment status. Since that designation, the EPA has worked with ADEQ and the two facilities in refining the modeling approaches and inputs resulting in modeling that is acceptable for assessing whether the area is attaining or not attaining the 1-hour SO_2 NAAQS. Specifically, ADEQ and the facilities have made refinements in the modeling including: Revising Future Fuel's emissions estimates to vary emissions based on coal usage, using more accurate stack parameters and utilizing a meteorological approach which employs the EPA-generated Weather Research and Forecasting (WRF) meteorological modeling and the Mesoscale Model InterFace (MMIF) program to generate representative meteorological data for the Independence County area. The original modeling used 2012–2014 meteorological data from the Little Rock area which is over 70 miles from Future Fuel and Independence Station, so ADEQ wished to use the new 2013–2015 WRF based data to better represent the local meteorology in Independence County. EPA worked with ADEQ to review the meteorological modeling results within the region and at

[1] ''Sulfur Dioxide ($S0_2$) National Ambient Air Quality Standards Designations Modeling Technical Assistance Document''. August 2016 draft *https://www.epa.gov/sites/production/files/2016-0706/documents/areadesignso2modelingtad.pdf*. Note. the EPA released earlier drafts of this document in May and 2013 and February 2016.

[2] See Sierra Club et al. v. McCarthy, Civil Action No. 3:13–cv–3953–SI (N.D. Cal.), and 79 FR 31325 (June 2, 2014).

[3] Sources over 100 tons per year emissions of SO_2 using EPA's 2014 National Emission Inventory.

[4] 2010 SO_2 primary NAAQS Round 2 Designations for Arkansas were signed on June 30, 2016, and can be found at 81 FR 45039, July 12, 2016.

[5] Final AR SO_2 designation TSD can be found at *www.regulations.gov;* Docket EPA–HQ–OAR–2014–0464–0410).

[6] See ''Independence Redesignation TSD.pdf''.

[7] While CAA section 107(d)(3)(E) also lists specific requirements for redesignations, those requirements only apply to redesignations of nonattainment areas to attainment and, therefore, are not applicable in the context of a redesignation of an area from unclassifiable to attainment/unclassifiable.

[8] Historically, the EPA has designated most areas that do not meet the definition of nonattainment as ''unclassifiable/attainment.'' EPA has reversed the order of the label to be ''attainment/unclassifiable'' to better convey the definition of the designation category and so that the category is more easily distinguished from the separate unclassifiable category. *See, e.g.,* 83 FR 1098, 1099 (January 9, 2018) and 83 FRN 25776, 25778 (June 4, 2018). EPA reserves the ''attainment'' category for when EPA redesignates a nonattainment area that has attained the relevant NAAQS and has an approved maintenance plan.

surrounding meteorological stations to assess whether the meteorological model was performing adequately. EPA also assessed whether the use of the WRF data with 12 km grid resolution was acceptable for simulating the meteorological data for Independence County. EPA determined model was acceptable to simulate the meteorological parameters in Independence County and EPA approved the use of the WRF/MMIF meteorological data for use in AERMOD [9] modeling of Independence County.[10] This approval is included in the docket for this action (Docket EPA–R06–OAR–2018–0624). ADEQ submitted an updated analysis and letter signed by Governor Asa Hutchinson on April 20, 2018 requesting that the EPA redesignate Independence County, Arkansas as attainment/unclassifiable for the 1-hour SO_2 primary NAAQS.

According to the EPA's guidance on redesignations, SO_2 nonattainment areas using modeling to demonstrate attainment for a redesignation request would be expected to use maximum allowable emissions.[11] However, these statements derive from the requirements of CAA section 107(d)(3)(E), which do not pertain to the redesignation of unclassifiable areas. For redesignations of unclassifiable areas, the necessary analysis is equivalent to what would be required in a designation in the first instance since we have not found the area to be attainment or nonattainment. In this first instance, the goal is to establish existing ambient air quality. As such, it is appropriate to use actual emissions for estimating existing air quality. The EPA's acceptance of modeling using actual emissions [12] in this instance should not be construed to define what would be needed for a demonstration of attainment and maintenance for purposes of a redesignation of a nonattainment area to attainment.

The EPA has reviewed the modeling provided by the state with their redesignation request and finds that it comports with the EPA's, current Modeling TAD [13] and the EPA's Guideline on Air Quality Models (40 CFR part 51 Appendix W) and is acceptable for assessing the attainment status of Independence County, Arkansas. The state's modeling indicates that the predicted maximum Design Value at any receptor in the modeling domain is 159.6 μg/m^3, or 60.92 parts per billion (ppb).[14] The EPA's review confirms the modeling results appropriately characterize the air quality in Independence County, Arkansas and that predicted ambient SO_2 concentrations are below the 2010 SO_2 primary NAAQS of 196.4 μg/m^3, or 75 ppb.

IV. Proposed Action

The EPA is proposing to approve Arkansas' April 20, 2018, request to change the EPA's previous designation and redesignate Independence County from unclassifiable to attainment/unclassifiable for the 2010 SO_2 primary NAAQS. The EPA has reviewed the modeling provided by the state with its redesignation request and finds that it comports with the EPA's, current Modeling TAD and the EPA's Guideline on Air Quality Models (40 CFR part 51 Appendix W) and is acceptable for assessing the attainment status of Independence County, Arkansas. If finalized, approval of the redesignation request would change the legal designation for the Area, found at 40 CFR part 81, from unclassifiable to attainment/unclassifiable for the 2010 SO_2 primary NAAQS.

V. Statutory and Executive Order Reviews

Under the CAA, redesignation of an area to attainment/unclassifiable is an action that affects the status of a geographical area and does not impose any additional regulatory requirements on sources beyond those imposed by state law. A redesignation to attainment/unclassifiable does not in and of itself create any new requirements. Accordingly, this proposed action merely proposes to redesignate an area to attainment/unclassifiable and does not impose additional requirements. For that reason, this proposed action:

- Is exempt from review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because it is exempt under Executive Order 12866;
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is not subject to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4);
- is not subject because it does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it does not establish an environmental standard intended to mitigate health or safety risks;
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because this action does not involve technical standards;
- will not have disproportionate human health or environmental effects under Executive Order 12898 (59 FR 7629, February 16, 1994); and
- does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000) because no tribal lands are located within the Area and the redesignation does not create new requirements. The EPA notes this proposed action will not impose substantial direct costs on Tribal governments or preempt Tribal law.

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

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

Dated: November 16, 2018.

Anne Idsal,

Regional Administrator, Region 6.

[FR Doc. 2018–25477 Filed 11–21–18; 8:45 am]

BILLING CODE 6560–50–P

[9] American Meteorological Society (AMS) and U.S. Environmental Protection Agency (EPA) Regulatory Model (AERMOD). AERMOD is the preferred regulatory model listed in 40 CFR part 51 App. W for atmospheric dispersion of primary pollutants within 50 km in this terrain situation.

[10] Email from Mr. Erik Snyder of EPA Region 6 to Mr. David Clark of ADEQ on January 23, 2018 approving the use of surface and upper air data from WRF/MMIF for a representative location in Independence County, Arkansas.

[11] Guidance for 1-Hour SO_2 Nonattainment Area SIP Submissions, April 2014, at 67; Kent Berry Memorandum ''Use of Actual Emissions in Maintenance Demonstrations for ozone and Carbon Monoxide (CO) Nonattainment Areas,'' Nov. 30, 1993, at 3.

[12] Actual emissions were used for most sources with the exception of using allowables for a few minor sources at the Future Fuel facility.

[13] ''Sulfur Dioxide ($S0_2$) National Ambient Air Quality Standards Designations Modeling Technical Assistance Document''. August 2016 draft *https://www.epa.gov/sites/production/files/2016-0706/documents/areadesignso2modelingtad.pdf*. Note. the EPA released earlier drafts of this document in May and 2013 and February 2016.

[14] The SO_2 NAAQS and the Design Value compared to the NAAQS is the 3-year average of the annual 99th percentile of 1-hour daily maximum concentrations.

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Parts 555, 571, and 591

[Docket No. NHTSA–2018–0092]

RIN 2127–AL99

Pilot Program for Collaborative Research on Motor Vehicles With High or Full Driving Automation; Extension of Comment Period

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Advance notice of proposed rulemaking (ANPRM); extension of comment period.

SUMMARY: In response to a request from the public, NHTSA is announcing a two-week extension of the comment period on the ANPRM on a Pilot Program for Collaborative Research on Motor Vehicles with High or Full Driving Automation. The comment period for the ANPRM was originally scheduled to end on November 26, 2018. It will now end on December 10, 2018.

DATES: The comment period for the ANPRM published on October 10, 2018 at 83 FR 50872 is extended. Written comments on the ANPRM must be received on or before December 10, 2018 in order to be considered timely.

ADDRESSES: Comments must be submitted by one of the following methods:

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

Regardless of how you submit your comments, they must include the docket number identified in the heading of this notice.

Note that all comments received, including any personal information provided, will be posted without change to *http://www.regulations.gov*. Please see the ''Privacy Act'' heading below.

You may call the Docket Management Facility at 202–366–9324.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or the street address listed above. We will continue to file relevant information in the docket as it becomes available.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its decision-making process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy*. Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.).

FOR FURTHER INFORMATION CONTACT: For research and pilot program issues: Dee Williams, Office of Vehicle Safety Research, 202–366–8537, *Dee.Williams@dot.gov,* National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

For legal issues: Stephen Wood, Assistant Chief Counsel, Vehicle Rulemaking and Harmonization, Office of Chief Counsel, 202–366–2992, *Steve.Wood@dot.gov,* at the same address.

SUPPLEMENTARY INFORMATION: On October 10, 2018, NHTSA published an ANPRM to obtain public comments on the factors and structure that are appropriate for the Agency to consider in designing a national pilot program that will enable the Agency to facilitate, monitor and learn from the testing and development of the emerging advanced vehicle safety technologies and to assure the safety of those activities. The ANPRM stated that the closing date for comments is November 26, 2018.

On November 16, 2018, NHTSA received a request from the Uber Technologies, Inc. for a two-week extension of the comment period. The request can be found in the docket for the ANPRM listed above under **ADDRESSES**. NHTSA has considered this request and believes that a 14-day extension beyond the original due date is desirable to provide additional time for the public to comment on the complex and novel questions in the ANPRM. This is to notify the public that NHTSA is extending the comment period on the ANPRM, and allowing it to remain open until December 10, 2018.

Issued in Washington, DC, pursuant to authority delegated in 49 CFR 1.81 and 1.95.

Heidi Renate King,

Deputy Administrator.

[FR Doc. 2018–25532 Filed 11–19–18; 4:15 pm]

BILLING CODE 4910–59–P

Notices

Federal Register
Vol. 83, No. 226
Friday, November 23, 2018

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agency Information Collection Activities: Extension of Approved Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

November 19, 2018.

AGENCY: Animal and Plant Health Inspection Service, Department of Agriculture.

ACTION: 30-Day notice of submission of information collection approval from the Office of Management and Budget and request for comments.

SUMMARY: As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, the Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) has submitted a Generic Information Collection Request (Generic ICR): ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery'' to OMB for approval under the Paperwork Reduction Act (PRA).

DATES: Comments must be submitted December 24, 2018.

ADDRESSES: Written comments may be submitted to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602.

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Ruth Brown (202) 720–8958.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Abstract: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

The Agency received one comment in response to the 60-day notice published in the **Federal Register** of August 22, 2018 (83 FR 42459).

Animal and Plant Health Inspection Service—0579–0377

Current Actions: Extension of Currently Approved Information Collection.

Type of Review: Extension.

Affected Public: Individuals and Households; Businesses and Organizations; State, Local or Tribal governments; and foreign federal governments.

Average Expected Annual Number of Activities: 29.

Respondents: 70,000.

Annual Responses: 70,000.

Frequency of Response: Once per request.

Average Minutes per Response: 0.25.

Burden Hours: 17,500.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget control number.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2018–25493 Filed 11–21–18; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

November 19, 2018.

The Department of Agriculture has submitted the following information collection requirement(s) to Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological

collection techniques or other forms of information technology.

Comments regarding this information collection received by December 24, 2018 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725—17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Utilities Service

Title: Advance of Loan Funds and Budgetary Control and Related Burdens.

OMB Control Number: 0572–0015.

Summary of Collection: The Rural Utilities Service (RUS) is authorized by the Rural Electrification Act (RE Act) of 1936, as amended, ''to make loans in several States and territories of the United States for rural electrification and for the purpose of furnishing and improving electric and telephone service in rural areas and to assist electric borrowers to implement demand side management, energy conservation programs, and on-grid and off-grid renewable energy systems.'' Borrowers will provide the agency with information that supports the use of the funds as well as identify the type of projects for which they will use the funds.

Need and use of the Information: RUS electric borrowers will submit RUS form 595 and 219. Form 595, Financial Requirement & Expenditure Statement, to request an advance of loan funds remaining for an existing approved loan and to report on the expenditure of previously advanced loan funds. Form 219, Inventory of Work Orders, serves as a connecting line and provides an audit trail that verifies the evidence supporting the propriety of expenditures for construction of retirement projects that supports the advance of funds. The information collected will ensure that loan funds are expended and advanced for RUS approved budget process and amounts. Failure to collect proper information could result in improper determinations of eligibility or improper use of funds.

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

Number of Respondents: 574.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 13,959.

Rural Utility Service

Title: 7 CFR 1773, Policy on Audits of RUS Borrowers.

OMB Control Number: 0572–0095.

Summary of Collection: Under the authority of the Rural Electrification Act of 1936 (ACT), as amended 7 U.S.C. 901 *et seq.,* the Administrator is authorized and empowered to make loans under certain specified circumstances for rural electrification and the furnishing of electric energy to persons in rural areas and for the purpose of furnishing and improving telephone service in rural areas. RUS, in representing the Federal Government as Mortgagee, relies on the information provided by the borrowers in their financial statements to make lending decisions as to borrowers' credit worthiness and to assure that loan funds are approved, advanced and disbursed for proper Act purposes. Borrowers are required to furnish a full and complete report of their financial condition, operations and cash flows, in form and substance satisfactory to RUS.

Need and Use of the Information: RUS will collect information to evaluate borrowers' financial performance, determine whether current loans are at financial risk, and determine the credit worthiness of future losses. If information is not collected, it would delay RUS' analysis of the borrowers' financial strength, thereby adversely impacting current lending decisions.

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

Number of Respondents: 1,300.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 14,439.

Rural Utility Service.

Title: Substantially Underserved Trust Areas (SUTA), 7 CFR 1700, Subpart D.

OMB Control Number: 0572–0147.

Summary of Collection: The 2008 Farm Bill (P.L. 110–246) authorized the Substantially Underserved Trust Area (SUTA) initiative. The SUTA initiative identifies the need and improves the availability of Rural Utility Service (RUS) programs to reach trust areas. The initiative gives the Secretary of Agriculture certain discretionary authorities relating to financial assistance terms and conditions that can enhance the financing possibilities in areas that are underserved by certain RUS electric, water and waste, and telecom and broadband programs.

Need and use of the Information: RUS provides loan, loan guarantee and grant programs for rural electric, water and waste, and telecommunications and broadband infrastructure. Eligible applicants notify RUS in writing, at the time of application, that it seeks consideration under the requirements of 7 CFR 1700, subpart D. The data covered by this collection are those materials necessary to allow the agency to determine applicant and community eligibility, and an explanation and documentation of the high need for the benefits of the SUTA provisions. Without this information RUS would not be able to make a prudent loan decision.

Description of Respondents: State, Local or Tribal Government.

Number of Respondents: 1.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 30.

Rural Utility Service.

Title: The Rural Alaska Village Grant (RAVG) Program; 7 CFR part 1784.

OMB Control Number: 0572–0150.

Summary of Collection: The Rural Alaska Village Grant (RAVG) Program is authorized under (Section 3061 of the Consolidated Farm and Rural Development Act (CONACT), (7 U.S.C. 1926(d)), as amended. Governing regulations are codified in 7 CFR part 1784. Under the RAVG program, the Secretary may make grants to the State of Alaska for the benefit of rural or Native Villages in Alaska to provide for the development and construction of water and wastewater systems to improve the health and sanitation conditions in those villages. To be eligible to receive a grant under the RAVG program, the project must provide 25 percent in matching funds from the State of Alaska. The matching funds must come from non-Federal sources.

Need and use of the Information: The Rural Utilities Service (RUS) will collect information using several forms. RUS state and field offices collect the information from applicants, grantees, and consultants. The collected information is used to determine applicant eligibility and project feasibility. RUS also uses the information to ensure that grantees

operate on a sound basis and use the grants funds for authorized purposes.

Description of Respondents: Not-for-profit institutions; State, Local or Tribal Government.

Number of Respondents: 25.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 469.

Kimble Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2018–25499 Filed 11–21–18; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

November 19, 2018.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by December 24, 2018 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal and Plant Health Inspection Service

Title: Contract Pilot and Aircraft Acceptance.

OMB Control Number: 0579–0298.

Summary of Collection: The Plant Protection Act (7 U.S.C. 7701 *et seq.*) authorizes the Secretary of Agriculture, either independently or in cooperation with States, to carry out operations or measures to detect, eradicate, suppress, control, prevent, or retard the spread of plant pests and noxious weeds that are new to or not widely distributed within the United States. This authority has been delegated to the Administrator, Animal and Plant Health Inspection Service (APHIS). APHIS carries out this program primarily by treating infested lands by aerial spraying of pesticides from aircraft.

Need and Use of the Information: Contract Pilot and Aircraft Acceptance Form (PPQ–816) and SIT Pilot and Aircraft Cheek-In Sheet (PPQ Form 818) are used by the Plant Protection and Quarantine personnel who are involved with contracts for aerial application services for emergency pest outbreaks. The forms are used to document that the pilot and aircraft meet contract specifications. If APHIS did not collect this information or collected it less frequently, APHIS would not be able to verify if APHIS contracts for aerial application services met specifications.

Description of Respondents: Businesses.

Number of Respondents: 15.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 8.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2018–25476 Filed 11–21–18; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2018–0072]

Notice of Request for an Extension of Approval of an Information Collection; Nomination Request Form; Animal Disease Training

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with training related to animal diseases.

DATES: We will consider all comments that we receive on or before January 22, 2019.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0072*.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2018–0072, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0072* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on training related to animal diseases, contact Ms. Alicia D. Love, Program Specialist, Professional Development Services Branch, VS, APHIS, 4700 River Road, Unit 27, Riverdale, MD 20737; (301) 851–3425. For more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: Nomination Request Form; Animal Disease Training.

OMB Control Number: 0579–0353.

Type of Request: Extension of approval of an information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture is authorized, among other things, to protect the health of U.S. livestock and poultry populations by preventing the introduction and interstate spread of serious diseases and pests of livestock and by eradicating such diseases from the United States

when feasible. In connection with this mission, APHIS' Veterinary Services (VS) program provides vital animal disease training to State, Tribal, international, university, and industry personnel.

Individuals who wish to attend animal disease-related training must submit a Nomination Request Form (VS Form 1–5) to VS to help the program coordinate courses and select participants. VS develops rosters with course participants' names and contact information to notify them of future training courses and to encourage contact among participants throughout their careers.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of Burden: The public burden for this collection of information is estimated to average 0.33 hours per response.

Respondents: State, Tribal, international, university, and industry personnel.

Estimated Annual Number of Respondents: 350.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Annual Number of Responses: 350.

Estimated Total Annual Burden on Respondents: 116 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 15th day of November 2018.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2018–25462 Filed 11–21–18; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request To Conduct a New Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 this notice announces the intention of the National Agricultural Statistics Service (NASS) to seek approval to conduct a new information collection to gather economic data from a sample of homeowners, golf courses, sod producers, turfgrass service providers, and commercial businesses with turfgrass in New Jersey.

DATES: Comments on this notice must be received by January 22, 2019 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535–NEW, by any of the following methods:

- *Email: omboffi cer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *E-fax:* (855) 838–6382.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.
- *Hand Delivery/Courier:* Hand deliver to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT: Kevin L. Barnes, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–4333. Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS—OMB Clearance Officer, at (202) 690–2388 or at *omboffi cer@nass.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Turfgrass Economic Survey.

OMB Control Number: 0535–NEW.

Type of Request: Intent to seek approval to conduct a new information collection for a period of three years.

Abstract: The primary objective of the National Agricultural Statistics Service (NASS) is to collect, prepare and issue State and national estimates of crop and livestock production, prices, and disposition; as well as economic statistics, environmental statistics related to agriculture and also to conduct the Census of Agriculture.

The Turfgrass Economic Survey program will collect economic information from a sample of homeowners, golf courses, sod producers, turfgrass service providers, and commercial businesses with turfgrass in New Jersey. The results of the data collection will track the turfgrass industry's contribution to the New Jersey economy. All questionnaires included in this information collection will be voluntary. This project is conducted as a cooperative effort with Rutgers University. Funding for this survey is being provided by Rutgers University.

Authority: These data will be collected under authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985 as amended, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents. This Notice is submitted in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–113, 44 U.S.C. 3501, *et seq.*) and Office of Management and Budget regulations at 5 CFR part 1320.

NASS also complies with OMB Implementation Guidance, ''Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA),'' **Federal Register**, Vol. 72, No. 115, June 15, 2007, p. 33362.

Estimate of Burden: Public reporting burden for this information collection is based on similar surveys with expected response time of 45 minutes. The estimated sample size will be approximately 1,400. The frequency of data collection for the different surveys is annual. Estimated number of responses per respondent is 1. Publicity materials and instruction sheets will account for approximately 5 minutes of additional burden per respondent. Respondents who refuse to complete a survey will be allotted 2 minutes of burden per attempt to collect the data.

Respondents: Homeowners, golf courses, sod producers, turfgrass service

providers, and commercial businesses with turfgrass in New Jersey.

Estimated Number of Respondents: 1,400.

Estimated Total Annual Burden on Respondents: 1,200 hours.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, through the use of appropriate automated, electronic, mechanical, technological, or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, November 08, 2018

Kevin L. Barnes,

Associate Administrator.

[FR Doc. 2018–25496 Filed 11–21–18; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–75–2018]

Foreign-Trade Zone (FTZ) 87—Lake Charles, Louisiana, Notification of Proposed Production Activity, Driftwood LNG, LLC (Liquified Natural Gas Processing), Sulphur, Louisiana

The Lake Charles Harbor and Terminal District, grantee of FTZ 87, submitted a notification of proposed production activity to the FTZ Board on behalf of Driftwood LNG, LLC (Driftwood LNG), located in Sulphur, Louisiana. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on November 16, 2018.

The Driftwood LNG facility is located within Subzone 87G. The facility (currently proposed for construction) will be used for liquified natural gas processing. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status material and specific finished products described in the submitted notification and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Driftwood LNG from customs duty payments on the foreign-status gaseous natural gas (duty-free) used in export production. On its domestic sales, for the foreign-status gaseous natural gas, Driftwood LNG would be able to choose the duty rates during customs entry procedures that apply to: Liquified natural gas and stabilized condensate by-product (duty rates are duty-free and 10 cents/barrel, respectively). Driftwood LNG would be able to avoid duty on the foreign-status material which becomes scrap/waste. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The request indicates that gaseous natural gas is subject to special duties under Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is January 2, 2019.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Diane Finver at *Diane.Finver@trade.gov* or (202) 482–1367.

Dated: November 16, 2018.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2018–25518 Filed 11–21–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–74–2018]

Foreign-Trade Zone (FTZ) 18—San Jose, California; Notification of Proposed Production Activity; Bloom Energy Corporation (Commercial Fuel Cells and Related Subassemblies), Sunnyvale and Mountain View, California

The City of San Jose, California, grantee of FTZ 18, submitted a notification of proposed production activity to the FTZ Board on behalf of Bloom Energy Corporation (Bloom), located at sites in Sunnyvale and Mountain View, California. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on November 15, 2018.

The Bloom facility is located within Subzone 18I. The facility is used for the production of commercial fuel cells and related subassemblies. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Bloom from customs duty payments on the foreign-status components used in export production. On its domestic sales, for the foreign-status materials/components noted below, Bloom would be able to choose the duty rates during customs entry procedures that apply to: Piping manifolds; water distribution modules; fuel processing units; fuel cell power modules (DC generators); nickel iron alloy fuel cell power module enclosures (housings); power inverters; and, energy storage and distribution modules (duty rates range from duty-free to 3.8%). Bloom would be able to avoid duty on foreign-status components which become scrap/waste. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The components and materials sourced from abroad include: Glass powder; ceramic substrates; plastic labels; plastic containers with sleeves; plastic enclosure bags; plastic cable ties; rubber grommets; adhesives; cardboard boxes; textile paper filters; zirconia alumina shaping stones; ceramic heat plating; glass fiber insulation jackets; nickel alloy wire probes; alloy steel adapters; stainless steel tubing; stainless steel coated tubing; stainless steel

spacers; stainless steel pipes; stainless steel flanges; stainless steel pipe fixtures; stainless steel clamps; stainless steel screws; stainless steel washers; stainless steel cable; stainless steel spacers; nickel plates; nickel mesh; chromium alloy powder; iron and steel flexible tubing with fittings; cooling fans; prototype compressors; axial fan motors; fan cable connectors; fan mount rubber gaskets; aluminum plate-fin heat exchangers; heat exchange units; water filtering machinery; stainless steel weldments; filtering equipment; gas filtering canisters; gas filtering canister brackets; hoists; aluminum screens with frames; stainless steel valves; solenoid valves; inlet/outlet manifolds; housing units for fuel cells; iron/nickel alloy and ceramic fuel cell dielectrics; dielectric transformers for inverters; transformers 1kVA power handling capacity; power inverters; fuel cell control units; rectifier and static converter power cards; rectifier and static converter circuit boards; rectifier and static converter mounting brackets; mixed alloy rectifier and static converter casings; static converters; holding magnets; electric capacitors; electric capacitor caps; programmable controllers; printed circuit boards; electrical contactors; electrical terminators; electrical fuses; printed circuit boards; contactors; electrical controller backplanes and handles; multimodal switchboard antennas; multimodal switchboard mounting switches; internal frames for multimodal switchboards; electrical controllers; diodes; cables for telemetry equipment; electrical conductors fitted with connectors; electrical conductors for telecommunication; copper electrical conductors; cables with fitted connectors; plastic insulating fittings; thermocouples; probe wires; electrical thermocouple assemblies; thermocouple assembly terminals; gas flow meters; transducers; electricity meters; programmable load boxes; fuel cell output (harmonics, temperature and luminosity) measuring devices; mass flow controllers; power conditioning systems regulating power control in fuel cell; mixed alloy interconnecting plates; and, chromium iron interconnect plates (duty rates range from duty-free to 8.5%). The request indicates that textile paper filters will be admitted to the zone in privileged foreign status (19 CFR 146.41), thereby precluding inverted tariff benefits on such items. The request also indicates that certain materials/components are subject to special duties under Section 232 of the Trade Expansion Act of 1962 (Section 232) and Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 232 and Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is January 2, 2019.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Diane Finver at *Diane.Finver@trade.gov* or (202) 482–1367.

Dated: November 16, 2018.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2018–25517 Filed 11–21–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–870]

Notice of Commencement of a Compliance Proceeding Pursuant to Section 129 of the Uruguay Round Agreements Act

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable November 23, 2018.

SUMMARY: The Department of Commerce (Commerce) is commencing a proceeding to gather information, analyze record evidence, and consider the determinations which would be necessary to bring its measures into conformity with the recommendations and rulings of the Dispute Settlement Body (DSB) of the World Trade Organization (WTO) in *United States—Antidumping Measures on Certain Oil Country Tubular Goods from Korea* (*WTO/DS488*). This dispute concerns the final determination issued in the antidumping duty (AD) investigation of certain oil country tubular goods (OCTG) from the Republic of Korea (Korea).

FOR FURTHER INFORMATION CONTACT: Erin Kearney, AD/CVD Operations Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0167.

SUPPLEMENTARY INFORMATION:

Background

On February 9, 2018, the United States informed the DSB that the United States intends to implement the DSB's recommendations and rulings in *WTO/DS488,* pursuant to section 129 of the Uruguay Round Agreements Act (URAA), 19 U.S.C. 3538. The AD investigation at issue is:

Case No.	Full title	FR cite/publication date
A–580–870	Certain Oil Country Tubular Goods from the Republic of Korea: Final Determination of Sales at Less Than Fair Value and Negative Final Determination of Critical Circumstances.	79 FR 41983 (July 18, 2014).

Commencement of Section 129 Proceeding

In accordance with section 129(b)(1) of the URAA, Commerce consulted with the Office of the United States Trade Representative, and on November 7, 2018, pursuant to those consultations, opened a segment in the AD investigation at issue to commence administrative action to comply with the DSB's recommendations and rulings. The segment will consist of a separate administrative record with its own administrative protective order. In accordance with 19 CFR 351.305(b), interested parties may request access to business proprietary information in this segment of the proceeding in which they are participating. For this Section 129 segment, we may request additional information and we may conduct verification of such information. Consistent with section 129(d) of the URAA, Commerce intends to make a preliminary determination in this Section 129 segment, intends to provide interested parties with an opportunity to provide written comments on the preliminary determination, and may hold a hearing.

Filing Requirements & Letter of Appearance

In accordance with Commerce's regulations, all submissions to Commerce must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). An electronically filed document must be received successfully in its entirety by the time and date it is due. Documents exempted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.[1]

Pursuant to 19 CFR 351.103(d)(l), to be included on the public service list for the Section 129 determination for the aforementioned proceeding, all interested parties, including parties that were part of the public service list in the underlying investigation and any parties otherwise notified of Commerce's commencement of this Section 129 proceeding, must file a letter of appearance. The letter of appearance must be filed separately from any other document (with the exception of an application for administrative protective order (APO) access; parties applying for and granted APO access would automatically be on the public service list). Parties wishing to enter an appearance or submit information with regard to this proceeding must upload their filing(s) to each relevant case number. Additionally, for each submission made in ACCESS, parties must select ''S 129–SEC 129'' as the segment and enter ''DS488'' in the segment specific information field.

Submission of Factual Information

Unless notified otherwise, the administrative record is closed for submitting new factual information. At this time, Commerce does not intend to seek new factual information in addition to information already on the record of the investigation. If Commerce determines that additional factual information is necessary, it will notify the parties.

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). The regulation requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Parties should review the regulations prior to submitting factual information in this segment.

Extension of Time Limits Regulation

Parties may request an extension of time limits before the expiration of a time limit established under Part 351, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under Part 351 expires. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. Eastern Time on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under limited circumstances we will grant untimely-filed requests for the extension of time limits. *Review Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm* prior to submitting factual information in this segment.

Certification Requirements

Any party submitting factual information in an AD or countervailing duty (CVD) proceeding must certify to the accuracy and completeness of that information.[2] Parties are hereby reminded that revised certification requirements are in effect for company/government officials, as well as their representatives. Investigations initiated on the basis of petitions filed on or after August 16, 2013, and other segments of any AD or CVD proceedings initiated on or after August 16, 2013, should use the formats for the revised certifications provided at the end of the *Final Rule*.[3] Commerce intends to reject factual submissions if the submitting party does not comply with the applicable revised certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. On January 22, 2008, Commerce published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Parties wishing to participate in this proceeding should ensure that they meet the requirements of these procedures (*e.g.,* the filing of letters of appearance as discussed at 19 CFR 351.103(d)).

This notice is published in accordance with section 129(b)(1) of the URAA.

Dated: November 15, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2018–25384 Filed 11–21–18; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See, generally,* 19 CFR 351.303 (for general filing requirements).

[2] *See* section 782(b) of the Act.

[3] *See Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (Final Rule); *see also* frequently asked questions regarding the Final Rule, available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–857]

Certain Oil Country Tubular Goods From India: Notice of Correction to the Amended Final Determination and Amendment of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is correcting the amended final antidumping duty determination and order for certain oil country tubular

goods (OCTG) from India with respect to the ''all-others'' companies.

DATES: March 26, 2017.

FOR FURTHER INFORMATION CONTACT: Andrew Huston, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4261.

SUPPLEMENTARY INFORMATION: On July 18, 2014, Commerce published its final determination of sales at LTFV and final negative determination of critical circumstances in this proceeding.[1] As part of the *Final Determination,* Commerce calculated an all-others rate of 5.79 percent.[2] A summary of that determination and resulting litigation can be found in the *Amended Final Determination,* which was published in the **Federal Register** on April 12, 2017.[3] Subsequently, Commerce issued an *Amended Order,* which was published in the **Federal Register** on June 20, 2017.[4] Commerce then published a correction to the *Amended Final Determination* and to the *Amended Order* on July 28, 2017.[5] Commerce is now issuing a second correction to the *Amended Final Determination* and to the *Amended Order* as they concern the rate for all other producers and exporters. The rates for the two mandatory respondents remain unchanged.

In June 2018, U.S. Steel sought to enforce the final judgment of the United States Court of International Trade (CIT) that is referenced in the *Amended Final Determination.*[6] Specifically, U.S. Steel requested that the Court require Commerce to recalculate the all-others rate consistent with the revised weighted-average dumping margins reflected in the *Amended Final Determination* and *Amended Order.*[7] On October 17, 2018, the CIT granted, in part, U.S. Steel's motion for enforcement of judgment in *U.S. Steel II,* and ordered Commerce to issue a revised notice, recalculating the all-others rate.[8]

On October 17, 2018, the CIT granted, in part, plaintiff U.S. Steel's motion to enforce the Court's March 16, 2017, order sustaining the remand redetermination by Commerce pertaining to the less-than-fair-value (LTFV) investigation of OCTG from India. Accordingly, Commerce is issuing this notice to correct its earlier amended final determination and amended antidumping duty order with respect to the all-others rate.

Correction to the Amended Final Determination

We are correcting the *Amended Final Determination* to reflect the recalculated all-others rate. The relevant text of the *Amended Final Determination* should have appeared as follows:

Amended Final Determination

Because there is now a final court decision, Commerce is amending the *Final Determination* with respect to GVN single entity (comprised of GVN Fuels Limited, Maharashtra Seamless Limited and Jindal Pipes Limited),[9] Jindal SAW, Limited, and the ''all-others'' companies. The revised weighted-average dumping margins for the period July 1, 2012, through June 30, 2013, are as follows:

Exporter or producer	Estimated weighted-average dumping margins (percent)	Cash deposit rate (percent) [10]
GVN Fuels Limited, Maharashtra Seamless Limited and Jindal Pipes Limited (collectively, GVN or GVN single entity)	1.07 (*de minimis*)	0.00
Jindal SAW, Limited	11.24	0.00
All-Others	11.24 [11]	0.60 [12]

Amended Cash Deposit Rates

Neither the GVN single entity nor Jindal SAW, Limited have a superseding cash deposit rate (*e.g.,* from a subsequent administrative review) and, therefore, Commerce will issue revised cash deposit instructions to U.S. Customs and Border Protection. The revised cash deposit rates are indicated above, and effective March 26, 2017.

The all-others cash deposit rate, effective March 26, 2017, will be 0.60 percent, the weighted average all-others dumping margin adjusted by the rate of export subsidies determined for all-other producers and exporters in the companion CVD investigation.

Correction to the Amended Order

We are correcting the *Amended Order* to reflect the recalculated all-others rate. The relevant text of the *Amended Order* should have appeared as follows:

Estimated Weighted-Average Dumping Margins

The estimated weighted-average dumping margins are as follows:

Exporter or producer	Estimated weighted-average dumping margins (percent)	Cash deposit rate (percent) [13]
Jindal SAW, Limited	11.24	0.00
All-Others	11.24	0.60

[1] *See Final Determination of Sales at Less Than Fair Value and Final Negative Determination of Critical Circumstances: Certain Oil Country Tubular Good from India,* 79 FR 41981 (July 18, 2014) (*Final Determination*), and accompanying issues and decision memorandum (IDM).

[2] *Id.,* 79 FR at 41982.

[3] *See Certain Oil Country Tubular Goods from India: Notice of Court Decision Not in Harmony with Final Determination of Sales at Less Than Fair Value and Final Negative Determination of Critical Circumstances and Notice of Amended Final Determination,* 82 FR 17631 (April 12, 2017) (*Amended Final Determination*).

[4] *See Certain Oil Country Tubular Goods from India: Amendment of Antidumping Duty Order,* 82 FR 28045 (June 20, 2017) (*Amended Order*).

[5] *See Certain Oil Country Tubular Goods from India: Notice of Correction to Amended Final Determination and Amendment of Antidumping Duty Order,* 82 FR 35182 (July 28, 2017) (*Correction to Amended Final Determination* and *Amendment of the Order*).

[6] *See Amended Final Determination,* 82 FR at 17631 (citing *United States Steel Corp.* v. *United States,* 219 F. Supp. 3d 1300 (CIT 2017) (*U.S. Steel II*)).

[7] *See Amended Order; see also Correction to Amended Final Determination* and *Amendment of the Order.*

[8] *See United States Steel Corp.* v. *United States,* Consol. Ct. No. 14–00263, Slip Op. 18–139 (CIT October 17, 2018) (*U.S. Steel Enforcement Order*).

[9] *See Final Determination,* 79 FR at 41982, and accompanying IDM at Comment 9.

[10] Cash deposit rates are lower than estimated weighted-average dumping margins due to offsets for export subsidies.

[11] The all-others weighted-average dumping margin is based on the rate calculated for Jindal SAW, the only above *de minimis* rate calculated in this proceeding.

[12] *See* Memorandum, ''Calculation of Export Subsidy Rate for All Others,'' dated concurrently with this notice.

[13] Cash deposit rates are lower than estimated weighted-average dumping margins due to offsets for export subsidies.

This correction to the *Amended Final Determination* and to the *Amended Order* is issued and published in accordance with sections 735(d), 736(a), and 777(i) of the Tariff Act of 1930, as amended.

Dated: November 19, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2018–25516 Filed 11–21–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG533

Determination of Overfishing or an Overfished Condition

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

ACTION: Notice.

SUMMARY: This action serves as a notice that NMFS, on behalf of the Secretary of Commerce (Secretary), has found that the following stocks are subject to overfishing or overfished. Gulf of Mexico gray snapper is now subject to overfishing. Thorny skate is still overfished. NMFS, on behalf of the Secretary, notifies the appropriate regional fishery management council (Council) whenever it determines that overfishing is occurring, a stock is in an overfished condition or a stock is approaching an overfished condition.

FOR FURTHER INFORMATION CONTACT: Regina Spallone, (301) 427–8568.

SUPPLEMENTARY INFORMATION: Pursuant to section 304(e)(2) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1854(e)(2), NMFS, on behalf of the Secretary, must notify Councils, and publish in the **Federal Register**, whenever it determines that a stock or stock complex is subject to overfishing, overfished, or approaching an overfished condition.

NMFS has determined that the Gulf of Mexico stock of gray snapper is now subject to overfishing. The most recent benchmark assessment for this stock was finalized in 2018, using data through 2015. The assessment supports a determination that the stock is subject to overfishing because the current estimate of fishing mortality ($F_{2013–2015}$), 0.138, is greater than the maximum fishing mortality threshold (MFMT), 0.115. NMFS has informed the Gulf of Mexico Fishery Management Council (Gulf Council) that it must prepare and implement a plan amendment or proposed regulations to end overfishing immediately and prevent overfishing from occurring in the fishery. The Gulf Council has already started working on a fishery management plan amendment to address the results of this stock assessment.

NMFS has determined that thorny skate is still overfished. A stock status update was completed for this stock in 2018, using data through 2017. The update supports a determination that the stock remains overfished because the three-year average biomass index ($B_{2015–2017}$), 0.285kg/tow, is below the biomass threshold, 2.06 kg/tow. Thorny skate is currently in year 15 of a 25-year rebuilding plan that was implemented in 2003. NMFS continues to work with the New England Fishery Management Council to rebuild this stock.

Dated: November 19, 2018.

Karen H. Abrams,

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

[FR Doc. 2018–25558 Filed 11–21–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Coastal and Estuarine Land Conservation, Planning, Protection, or Restoration.

OMB Control Number: 0648–0459.

Form Number(s): None.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 51.

Average Hours per Response:: CELCP Plans, 120 hours to develop, 35 hours to revise or update; project application and checklist, 20 hours; semi-annual and annual reporting, 5 hours each.

Burden Hours: 1,410.

Needs and Uses: This request is for extension of a currently approved information collection.

NOAA has, or is given, authority under the Coastal Zone Management Act (CZMA), annual appropriations or other authorities, to issue funds to coastal states, localities or other recipients for planning, conservation, acquisition, protection, restoration, or construction projects. The required information enables NOAA to implement the CELCP, under its current or future authorization, and facilitate the review of similar projects under different, but related, authorities.

This includes projects funded through:

- The Coastal and Estuarine Land Conservation Program (CZMA Section 307A) to protect important coastal and estuarine areas that have significant conservation, recreation, ecological, historical, or aesthetic values, or that are threatened by conversion, and procedures for eligible applicants who choose to participate in the program to use when developing state conservation plans, proposing or soliciting projects under this program, applying for funds, and carrying out projects under this program in a manner that is consistent with the purposes of the program pursuant to program guidelines which can be found on NOAA's website at: *www.coast.noaa.gov/czm/landconservation/* or may be obtained upon request via the contact information listed above;
- the National Estuarine Research Reserve System (CZMA Section 315) Land Acquisition and Construction program;
- the Coastal Zone Management Program's low-cost acquisition and construction program (CZMA Section 306A); or the
- Fish and Wildlife Coordination Act.

Affected Public: State, local or tribal government; not-for-profit institutions.

Frequency: One time and semi-annually.

Respondent's Obligation: Required to obtain or retain benefits.

This information collection request may be viewed at *reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: November 19, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–25488 Filed 11–21–18; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG600

Fisheries of the Northeastern United States; Atlantic Surfclam and Ocean Quahog Fisheries; Notice That Vendor Will Provide 2019 Cage Tags

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

ACTION: Notice of vendor to provide fishing year 2019 cage tags.

SUMMARY: NMFS informs surfclam and ocean quahog individual transferable quota (ITQ) allocation holders that they will be required to purchase their fishing year 2019 (January 1, 2019—December 31, 2019) cage tags from the National Band and Tag Company. The intent of this notice is to comply with regulations for the Atlantic surfclam and ocean quahog fisheries and to promote efficient distribution of cage tags.

FOR FURTHER INFORMATION CONTACT: Aimee Ahles, Fishery Management Specialist, (978) 281–9373; fax (978) 281–9161.

SUPPLEMENTARY INFORMATION: The Federal Atlantic surfclam and ocean quahog fishery regulations at 50 CFR 648.77(b) authorize the Regional Administrator of the Greater Atlantic Region, NMFS, to specify in the **Federal Register** a vendor from whom cage tags, required under the Atlantic Surfclam and Ocean Quahog Fishery Management Plan (FMP), shall be purchased. Notice is hereby given that National Band and Tag Company of Newport, Kentucky, is the authorized vendor of cage tags required for the fishing year 2019 Federal surfclam and ocean quahog fisheries. Detailed instructions for purchasing these cage tags will be provided in a letter to ITQ allocation holders in these fisheries from NMFS within the next several weeks.

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

Dated: November 19, 2018.

Karen H. Abrams,

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

[FR Doc. 2018–25504 Filed 11–21–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG602

Nominations to the Marine Fisheries Advisory Committee

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

ACTION: Notice; request for nominations.

SUMMARY: Nominations are being sought for appointment by the Secretary of Commerce to fill vacancies on the Marine Fisheries Advisory Committee (MAFAC or Committee). MAFAC is the only Federal advisory committee with the responsibility to advise the Secretary of Commerce (Secretary) on all matters concerning living marine resources that are the responsibility of the Department of Commerce. The Committee makes recommendations to the Secretary to assist in the development and implementation of Departmental regulations, policies, and programs critical to the mission and goals of NMFS. Nominations are encouraged from all interested parties involved with or representing interests affected by NMFS actions in managing living marine resources. Nominees should possess demonstrable expertise in a field related to the management of living marine resources and be able to fulfill the time commitments required for two annual meetings and year round subcommittee work. Individuals serve for a term of three years for no more than two consecutive terms if re-appointed. NMFS is seeking qualified nominees to fill current vacancies.

DATES: Nominations must be postmarked or have an email date stamp on or before December 24, 2018.

ADDRESSES: Nominations should be sent to Heidi Lovett, MAFAC Assistant Director, NMFS Office of Policy, 14th Floor, 1315 East-West Highway, Silver Spring, MD 20910 or email: *heidi.lovett@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Heidi Lovett, MAFAC Assistant Director; (301) 427–8034; email: *heidi.lovett@noaa.gov.*

SUPPLEMENTARY INFORMATION: The MAFAC was approved by the Secretary on December 28, 1970, and subsequently chartered under the Federal Advisory Committee Act, 5 U.S.C. App. 2, on February 17, 1971. The Committee meets twice a year with supplementary subcommittee meetings as determined necessary by the Committee Chair and Subcommittee Chairs. No less than 15 and no more than 21 individuals may serve on the Committee. Membership is comprised of highly qualified, diverse individuals representing commercial, recreational, subsistence, and aquaculture fisheries interests; seafood industry; environmental organizations; academic institutions; tribal and consumer groups; and other living marine resource interest groups from a balance of U.S. geographical regions, including the Western Pacific and Caribbean.

A MAFAC member cannot be a Federal employee, member of a Regional Fishery Management Council, registered Federal lobbyist, state employee, or agent of a foreign principal. Selected candidates must pass a security check and submit a financial disclosure form. Membership is voluntary, and except for reimbursable travel and related expenses, service is without pay.

Each nomination submission should include the nominee's name, a cover letter describing the nominee's qualifications and interest in serving on the Committee, curriculum vitae or resume of the nominee, and no more than three supporting letters describing the nominee's qualifications and interest in serving on the Committee. Self-nominations are acceptable. The following contact information should accompany each nominee's submission: Name, address, telephone number, fax number, and email address (if available).

Nominations should be sent to Heidi Lovett (see **ADDRESSES**) and must be received by December 24, 2018. The full text of the Committee Charter and its current membership can be viewed at the NMFS' web page at *www.fisheries.noaa.gov/topic/partners#marine-fisheries-advisory-committee.*

Dated: November 19, 2018.

Jennifer Lukens,

Director for the Office of Policy, National Marine Fisheries Service.

[FR Doc. 2018–25521 Filed 11–21–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No.: PTO–P–2018–0065]

Grant of Interim Extension of the Term of U.S. Patent No. 8,311,629; OPTIMIZER® Smart Implantable Pulse Generator

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of interim patent term extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting interim extension for a one-year interim extension of the term of U.S. Patent No. 8,311,629.

FOR FURTHER INFORMATION CONTACT: Mary C. Till by telephone at (571) 272–7755; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313–1450; by fax marked to her attention at (571) 273–7755; or by email to *Mary.Till@uspto.gov.*

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to one year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On October 26, 2018, Impulse Dynamic N.V., the patent owner of record, timely filed an application under 35 U.S.C. 156(d)(5) for an interim extension of the term of U.S. Patent No. 8,311,629. The patent claims the medical device, the OPTIMIZER Smart Implantable Pulse Generator. The application for patent term extension indicates that a Premarket Approval Application (PMA) P180036 was submitted to the Food and Drug Administration (FDA) on September 5, 2018.

Review of the patent term extension application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for one year as required by 35 U.S.C. 156(d)(5)(B). Because the regulatory review period will continue beyond the original expiration date of the patent, November 16, 2018, interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 8,311,629 is granted for a period of one year from the original expiration date of the patent.

Dated: November 15, 2018.

Robert Bahr,

Deputy Commissioner for Patent Examination Policy, United States Patent and Trademark Office.

[FR Doc. 2018–25539 Filed 11–21–18; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO–P–2018–0064]

Grant of Interim Extension of the Term of U.S. Patent No. 8,260,416; OPTIMIZER® Smart Implantable Pulse Generator

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of interim patent term extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting interim extension for a one-year interim extension of the term of U.S. Patent No. 8,260,416.

FOR FURTHER INFORMATION CONTACT: Mary C. Till by telephone at (571) 272–7755; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313–1450; by fax marked to her attention at (571) 273–7755; or by email to *Mary.Till@uspto.gov.*

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to one year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On October 26, 2018, Impulse Dynamic N.V., the patent owner of record, timely filed an application under 35 U.S.C. 156(d)(5) for an interim extension of the term of U.S. Patent No. 8,260,416. The patent claims methods of using the medical device, the OPTIMIZER Smart Implantable Pulse Generator. The application for patent term extension indicates that a Premarket Approval Application (PMA) P180036 was submitted to the Food and Drug Administration (FDA) on September 5, 2018.

Review of the patent term extension application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for one year as required by 35 U.S.C. 156(d)(5)(B). Because the regulatory review period will continue beyond the original expiration date of the patent, November 19, 2018, interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 8,260,416 is granted for a period of one year from the original expiration date of the patent.

Dated: November 15, 2018.

Robert Bahr,

Deputy Commissioner for Patent Examination Policy, United States Patent and Trademark Office.

[FR Doc. 2018–25537 Filed 11–21–18; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF DEFENSE

Department of the Army

Army Education Advisory Subcommittee Meeting Notice

AGENCY: Department of the Army, DoD.

ACTION: Notice of open subcommittee meeting.

SUMMARY: The Department of the Army is publishing this notice to announce the following Federal advisory committee meeting of the Defense Language Institute Foreign Language Center Board of Visitors, a subcommittee of the Army Education Advisory Committee. This meeting is open to the public.

DATES: The Defense Language Institute Foreign Language Center (DLIFLC) Board of Visitors Subcommittee will meet from 8:00 a.m. to 5:00 p.m. on December 12 and 13, 2018.

ADDRESSES: Defense Language Institute Foreign Language Center, Building 326, Weckerling Center, Presidio of Monterey, CA 93944.

FOR FURTHER INFORMATION CONTACT: Mr. Detlev Kesten, the Alternate Designated Federal Officer for the subcommittee, in writing at Defense Language Institute Foreign Language Center, ATFL–APAS–AA, Bldg. 614, Presidio of Monterey, CA 93944, by email at *Detlev.kesten@dliflc.edu,* or by telephone at (831) 242–6670.

SUPPLEMENTARY INFORMATION: The subcommittee meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of

1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the Meeting: The purpose of the meeting is to provide the subcommittee with briefings and information focusing on the Institute's plan for its students to achieve higher proficiency scores on the Defense Language Proficiency Test (DLPT), to include updates on curriculum and faculty development efforts.

Proposed Agenda: December 12—The subcommittee will receive briefings associated with DLIFLC's higher proficiency goals and the Institute's actions in supporting said goal. The subcommittee will complete administrative procedures and appointment requirements. December 13—The subcommittee will have time to discuss and compile observations pertaining to agenda items. General deliberations leading to provisional findings will be referred to the Army Education Advisory Committee for deliberation by the Committee under the open-meeting rules.

Public Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b, as amended, and 41 CFR 102–3.140 through 102–3.165, and subject to the availability of space, this meeting is open to the public. Seating is on a first to arrive basis. Attendees are requested to submit their name, affiliation, and daytime phone number seven business days prior to the meeting to Mr. Kesten, via electronic mail, the preferred mode of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. Because the meeting of the subcommittee will be held in a Federal Government facility on a military base, security screening is required. A photo ID is required to enter base. Please note that security and gate guards have the right to inspect vehicles and persons seeking to enter and exit the installation. Weckerling Center is fully handicap accessible. Wheelchair access is available on the right side of the main entrance of the building. For additional information about public access procedures, contact Mr. Kesten, the subcommittee's Alternate Designated Federal Officer, at the email address or telephone number listed in the **FOR FURTHER INFORMATION CONTACT** section.

Written Comments or Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the Federal Advisory Committee Act, the public or interested organizations may submit written comments or statements to the subcommittee, in response to the stated agenda of the open meeting or in regard to the subcommittee's mission in general. Written comments or statements should be submitted to Mr. Kesten, the subcommittee Alternate Designated Federal Officer, via electronic mail, the preferred mode of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. Each page of the comment or statement must include the author's name, title or affiliation, address, and daytime phone number. The Alternate Designated Federal Official will review all submitted written comments or statements and provide them to members of the subcommittee for their consideration. Written comments or statements being submitted in response to the agenda set forth in this notice must be received by the Alternate Designated Federal Official at least seven business days prior to the meeting to be considered by the subcommittee. Written comments or statements received after this date may not be provided to the subcommittee until its next meeting.

Pursuant to 41 CFR 102–3.140d, the Committee is not obligated to allow a member of the public to speak or otherwise address the Committee during the meeting. Members of the public will be permitted to make verbal comments during the Committee meeting only at the time and in the manner described below. If a member of the public is interested in making a verbal comment at the open meeting, that individual must submit a request, with a brief statement of the subject matter to be addressed by the comment, at least seven business days in advance to the subcommittee's Alternate Designated Federal Official, via electronic mail, the preferred mode of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. The Alternate Designated Federal Official will log each request, in the order received, and in consultation with the Subcommittee Chair, determine whether the subject matter of each comment is relevant to the Subcommittee's mission and/or the topics to be addressed in this public meeting. A 15-minute period near the end of the meeting will be available for verbal public comments. Members of the public who have requested to make a verbal comment and whose comments have been deemed relevant under the process described above, will be allotted no more than three minutes during the period, and will be invited to speak in the order in which their requests were received by the Alternate Designated Federal Official.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2018–25503 Filed 11–21–18; 8:45 am]

BILLING CODE 5001–03–P

DEPARTMENT OF DEFENSE

Department of the Army

Expeditionary Technology Search (xTechSearch) II Prize Competition Announcement

AGENCY: Department of the Army, DoD.

ACTION: Announcement of competition.

SUMMARY: Under the provisions of applicable laws and regulations, the Assistant Secretary of the Army for Acquisition, Logistics and Technology (ASA(ALT)) is announcing the second cohort of the Army Expeditionary Technology Search—xTechSearch II Prize Competition—for the Army to enhance engagements with the entrepreneurial funded community, small businesses, and other non-traditional defense partners. The xTechSearch program will provide an opportunity for businesses to pitch novel technology solutions, either a new application for an existing technology or an entirely new technology concept, to the Army.

DATES:

1. December 31, 2018 at 12:59PM PST. Deadline for submission of White Papers to the xTechSearch competition. Submissions received after the deadline will not be considered.

2. February 25–March 8, 2019. Semifinalists—Up to 60 participants conduct technology pitches to xTechSearch panels.

3. March 26–28, 2019. Up to 25 finalists featured at the Association of the United States Army Global Force Symposium and Exposition in Huntsville, AL.

4. October 2019. Capstone Demonstration with Army subject matter experts and Leadership.

ADDRESSES: Proposals must be submitted at Challenge.gov: *https://challenge.gov/a/buzz/challenge/88/ideas/top.*

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer Smith, Deputy Director for Laboratory Management (ASA(ALT)) Office of the Deputy Assistant Secretary of the Army, Research and Technology, (703) 697–0685 or via Email at: *usarmy.pentagon.hqda-asa-alt.mbx.xtechsearch@mail.mil.*

SUPPLEMENTARY INFORMATION:

Eligibility: The entities allowed to participate in this competition are small businesses as defined in 13 CFR part 121. To qualify, the participating entity must fall within the size standard by North American Industry Classification System code 541713, 541714, and 541715.

There may be only one submission per business. In addition, each entity:

- Shall be incorporated in and maintain a primary place of business in the United States;
- May not be a Federal entity or Federal employee acting within the scope of their employment.
- Sole proprietors may participate in xTechSearch if the individual is a citizen or permanent resident of the United States and the business is registered in the United States.
- Foreign companies may participate in xTechSearch by establishing a US domestic business relationship (*e.g.,* wholly owned US subsidiary) or partner with a US based company.
- Companies that have previously participated in the xTechSearch competition are eligible to participate for new technology concepts or improvements to prior submitted proposals.

Registered participants shall be required to agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from their participation in a prize competition, whether the injury, death, damage, or loss arises through negligence or otherwise.

Participants shall be required to obtain liability insurance or demonstrate financial responsibility, in amounts determined by the Army, for claims by—

- Third parties for death, bodily injury, or property damage, or loss resulting from an activity carried out in connection with participation in a prize competition, with the Federal Government named as an additional insured under the registered participant's insurance policy and registered participants agreeing to indemnify the Federal Government against third party claims for damages arising from or related to prize competition activities; and

The Federal Government for damage or loss to Government property resulting from such an activity.

Prizes will be offered under 15 U.S.C. Section 3719 (Prize competitions).

- The total prize pool is $2.18M.

Evaluation Criteria and Process

Phase I: Concept White Paper Contest

The Phase I proposal must be a white paper describing the novel technology concept, innovative application concept and integration with one or more of the Army's technology focus areas. The proposal must be submitted via the Challenge.gov portal as a single searchable PDF file containing:

- Title.
- Author(s).
- *Army Technology Focus Area:* Choose from the eight (8) Technology Focus Area(s):
  - Long Range Precision Fires.
  - Next Generation Combat Vehicle.
  - Future Vertical Lift.
  - Network with hardware, software, and infrastructure.
  - Air and Missile Defense.
  - Soldier Lethality.
  - Medical Technologies.
  - Military Engineering Technologies.
- *Keyword(s):* Provide up to ten (10) keywords that describe the technology.
- *Abstract:* Provide an abstract (up to 250 words).
- *White Paper:* Technology proposal concept, no greater than 1000 words (not including title, author(s), keywords, abstract, company bio, graphs, figures or images). The word limit on the White Paper submission will be strictly enforced.
- *List of prior SBIR awards in the past 5 years:* Include Date award received, Funding organization, Phase of awards, and Topic Title awarded.
- *Company Biography (Optional):* Company background information, up to 1 page.

Contestants' concept papers will be reviewed by a panel of subject matter experts who will select the contestants to be invited to the xTechSearch Technology Pitch Forums. Companies selected by the panel will receive a prize of $4,000 and an invitation to Phase II: xTechSearch Technology Pitches.

Concept White Papers will be ranked using the following Scoring Criteria:

- Potential for Impact/ Revolutionizing the Army—50%.
- Scientific and Engineering Viability—50%.

Phase II: xTechSearch Technology Pitches

- Up to sixty (60) selected contestant semi-finalists will be invited to complete an in-person venture style pitch to a panel of Army subject matter experts and judges at locations across the United States.
- Companies will pitch their technology and a proposed live proof-of-concept demonstration for Phase III (15 minute pitch followed by 10 minutes for questions and answers).
- Up to twenty five (25) semifinalists selected by the judge panel will receive a prize of $10,000 and be invited to display an exhibit and make a formal public oral presentation of their proposal at the 2019 AUSA Global Force Symposium and Exposition Innovators' Corner in Huntsville, AL.
- Scoring Criteria:
  - Potential for Impact/ Revolutionizing the Army—40%.
  - Scientific and Engineering Viability—40%.
  - Proof-of-Concept Demonstration Plan—10%.
  - Team Ability—10%.

Phase III: AUSA Innovators' Corner

- The AUSA Innovators' Corner phase provides up to twenty five (25) xTechSearch semifinalists to be featured at the AUSA Innovators' Corner at the AUSA Global Force meeting, 26–28 March 2019 in Huntsville, AL. The finalists will leverage Army-sponsored exhibit space to engage with Department of Defense (DoD) customers, Army leadership, industry partners, and academia.
- Up to twelve (12) Phase III prize winner finalists will be announced at AUSA and provided a prize of $120,000 and 6 months to demonstrate proof-of-concept for their xTechSearch technology at the Phase IV: xTechSearch Capstone Demonstration.

Phase IV: xTechSearch Finale Demonstration—October 2019

- Each Phase III finalist will demonstrate proof-of-concept for their technology solution to Army subject matter experts and DoD leadership at the AUSA Annual Meeting and Exposition, October 2019, Washington DC. A single grand-prize winner will be selected for the technology concept with the greatest potential for impact and to revolutionize the Army.
- The winner of the Finale Demonstration will be awarded a prize of $250,000.

Authority: 15 U.S.C. Section 3719; Pub. L. 96–480, Section 24, as added Pub. L. 111–358, title I, Section 105a, Jan. 4, 2011 Stat. 3989.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2018–25502 Filed 11–21–18; 8:45 am]

BILLING CODE 5001–03–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DOD–2018–OS–0048]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by December 24, 2018.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: DoD Enterprise-Wide Contractor Manpower Reporting Application (ECMRA); OMB Control Number 0704–0491.

Type of Request: Revision.

Number of Respondents: 5,582.

Responses per Respondent: 4.

Annual Responses: 22,328.

Average Burden per Response: 5 minutes.

Annual Burden Hours: 1,860.667.

Needs and Uses: The information collection requirement is necessary to achieve the collection of direct labor hours and associated costs in order to meet the requirements set for the DoD by section 2330a of Title 10, United States Code. Furthermore, ECMRA collections enable DoD organizations to understand the extent of contracted support, the associated level of effort in achieving mission, the reliance on contracted services necessary to facilitate their workforce planning process, and to support statutory requirements set forth in sections 115a, 129a, 235, 2461, and 2463 of Title 10, United States Code.

Affected Public: Businesses or other for-profit.

Frequency: Annually.

Respondent's Obligation: Mandatory.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Mr. Frederick Licari.

Requests for copies of the information collection proposal should be sent to Mr. Licari at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: November 16, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–25457 Filed 11–21–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DOD–2018–HA–0067]

Submission for OMB Review; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by December 24, 2018.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Cortney Higgins, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: TRICARE Select Survey of Civilian Providers; OMB Control Number 0720–0031.

Type of Request: Revision.

Number of Respondents: 20,000.

Responses per Respondent: 1.

Annual Responses: 20,000.

Average Burden per Response: 5 minutes.

Annual Burden Hours: 1,667.

Needs and Uses: As mandated by Congress, the information collection requirement is necessary to determine how many providers are aware of the TRICARE health benefits program, and specifically accept new TRICARE Select patients in each market area. The original requirement is outlined in Section 711 Fiscal Year (FY) 2015 National Defense Authorization Act (NDAA) (Pub. L. 110–181) and was reaffirmed in Section 721 FY12 NDAA (Pub. L. 112–81). Section 712 of FY15 NDAA extended the requirement to conduct the survey from 2017 through 2020. Surveys of civilian physician and non-physician behavioral health care providers will be conducted in a number of locations in the United States each year. Respondents include civilian physicians (M.D.s & D.O.s) and non-physician behavioral health providers (clinical psychologists, clinical social workers and other TRICARE authorized behavioral health providers). The locations surveyed will include areas where the TRICARE Prime benefit is offered (known as TRICARE PRIME Service Areas) and geographic areas where TRICARE Prime is not offered. Respondents will be contacted by mail with a telephone follow-up to complete the survey.

Affected Public: Individuals or households.

Frequency: Annually.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Cortney Higgins.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Mr. Frederick Licari.

Requests for copies of the information collection proposal should be sent to Mr. Licari at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: November 16, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–25466 Filed 11–21–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2018–OS–0092]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness (OUSD (P&R)), Federal Voting Assistance Program (FVAP), DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 22, 2019.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Federal Voting Assistance Program, ATTN: Sarah Gooch, 4800 Mark Center Drive, Mailbox 10, Alexandria, Virginia 22350–5000 or call 703–588–1584.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Federal Post Card Application (FPCA), Standard Form 76 (SF–76); OMB Control Number 0704–0503.

Needs and Uses: The Uniformed and Overseas Citizens Absentee Voting Act (UOCAVA), 52 U.S.C. 203, requires the Presidential designee (Secretary of Defense) to prescribe official forms, containing an absentee voter registration application, an absentee ballot request application and a backup ballot for use by the States to permit absent uniformed services voters and overseas voters to participate in general, special, primary and runoff elections for Federal office. The authority for the States to collect personal information comes from UOCAVA. The burden for collecting this information resides in the States. The Federal government neither collects nor retains any personal information associated with these forms.

The collected information will be used by election officials to process uniformed service members, spouses and overseas citizens who submit their information to register to vote, receive an absentee ballot or cast a write-in ballot. The collected information will be retained by election officials to provide election materials, including absentee ballots, to the uniformed services, their eligible family members and overseas voters during the form's eligibility period provided by State law. No information from the Federal Post Card Application (FPCA) is collected or retained by the Federal government.

Affected Public: Individuals or Households.

Annual Burden Hours: 300,000.

Number of Respondents: 1,200,000.

Responses per Respondent: 1.

Annual Responses: 1,200,000.

Average Burden per Response: 15 minutes.

Frequency: On occasion.

The applicant is required to update and resubmit the information annually, whenever they change their mailing address or as otherwise required by State law. If the information is not submitted annually or whenever they change their mailing address, the applicant may not receive ballots for elections for Federal office in that calendar year.

Dated: November 16, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2018–25438 Filed 11–21–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DOD–2018–OS–0064]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by December 24, 2018.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Military One-Source Case Management System (CMS) Intake; OMB Control Number 0704–0528.

Type of Request: Reinstatement with Change.

Number of Respondents: 225,584.

Responses per Respondent: 1.

Annual Responses: 225,584.

Average Burden per Response: 15 minutes.

Annual Burden Hours: 56,396.

Needs and Uses: This information collection is necessary to support the Military One-Source Case Management System, which was established for the purpose of providing comprehensive information to members of the Armed Forces and their families about the benefits and services available to them.

Affected Public: Individuals or Households.

Frequency: As required.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Mr. Frederick Licari.

Requests for copies of the information collection proposal should be sent to Mr. Licari at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: November 16, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–25460 Filed 11–21–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DOD–2018–OS–0065]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Acquisition and Sustainment, DoD.

ACTION: 30-day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by December 24, 2018.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Defense Logistics Agency Child and Youth Program; DLA Forms 1849, 1849–1, 1849–2, 1849–3, 1849–4, 1855, 1855–1, 1855–1A, 1855–1B, 1855–1C, 1855–1D (Parts I and II), 1855–1E, 1855–1F; OMB Control Number 0704–XXXX.

Type Request: Existing collection in use without an OMB Control Number.

Number of Respondents: 860.

Responses per Respondent: 14,017.

Annual Responses: 12,055.

Average Burden per Response: .08 hours.

Annual Burden Hours: 964.4.

Needs and Uses: The Department of Defense (DoD) requires the information in the proposed collection in support of Defense Logistics Agency (DLA) Child and Youth Programs (CYPs). This collection includes fourteen (14) DLA forms, some of which are used by all of the collection respondents and some of which are used under specific circumstances. The information collected is used for program planning, management, and health and safety purposes. More specifically, the information in the proposed collection allows CYP staff to provide safe, developmentally appropriate day care services and to ensure proper, effective response in the event of an emergency. Respondents include patrons enrolling their children in a CYP; these patrons may include active duty military, DoD civilian employees, or DoD contractors.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Mr. Frederick Licari.

Requests for copies of the information collection proposal should be sent to Mr. Licari at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: November 19, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–25505 Filed 11–21–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2018–OS–0036]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by December 24, 2018.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title: Associated Form; and OMB Number: Defense Sexual Assault Incident Database (DSAID); DD Forms 2965, 2910, and 2910–1; OMB Control Number 0704–0482.

Type of Request: Extension with change.

Number of Respondents: 730.

Responses per Respondent: 1.

Annual Responses: 730.

Average Burden per Response: 2.44 hours.

Annual Burden Hours: 1,780.

Needs and Uses: The information collection requirement is necessary to centralize case-level sexual assault data involving a member of the Armed Forces, in a manner consistent with

statute and DoD regulations for Restricted and Unrestricted reporting, as well as to facilitate reports to Congress on claims of retaliation in connection with an Unrestricted Report of sexual assault made by or against a member of the Armed Forces. Records may also be used as a management tool for statistical analysis, tracking, reporting, evaluating program effectiveness, conducting research, and case and business management. De-identified data may also be used to respond to mandated reporting requirements.

Affected Public: Individuals or Households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Mr. Frederick Licari.

Requests for copies of the information collection proposal should be sent to Mr. Licari at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: November 16, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–25445 Filed 11–21–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2018–OS–0093]

Proposed Collection; Comment Request

AGENCY: Under Secretary of Defense for Acquisition and Sustainment, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Logistics Agency (DLA) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 22, 2019.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal e-Rulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Logistics Agency Headquarters (DLA), ATTN: Ms. Nina Beshai, J62BK Information Operations, 8725 John Kingman Road, Fort Belvoir, VA 22060–6221, or call (571) 767–9810.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: DLA Police Center Records; DLA Form 635; OMB Control Number 0704–0514.

Needs and Uses: The DLA Police Center (POLC) system houses data of civilian and military personnel of DLA, contractor employees, and other persons who have committed or are suspected of having committed any criminal act (felony or misdemeanor), as well as any violations of laws, regulations, or ethical standards on DLA-controlled activities or facilities. The information is used by DLA police officers, DLA installation support offices, and the DLA Office of General Counsel (OGC) to monitor progress of cases and to develop non-personal statistic data on crime and criminal investigative support for the future. DLA OGC also uses data to review cases, determine appropriate legal action, and coordinate on all available remedies. Information is released to DLA managers who use the information to determine actions required to correct the causes of loss and to take appropriate action against DLA employees or contractors in cases of their involvement. Records are also used by DLA police to monitor the progress of incidents, identify crime-conducive conditions, and prepare crime vulnerability assessments.

Affected Public: Individuals or households; federal government.

Annual Burden Hours: 1,000 hours.

Number of Respondents: 2,000.

Responses per Respondent: 1.

Annual Responses: 2,000.

Average Burden per Response: 30 minutes.

Frequency: On occasion.

Dated: November 19, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–25533 Filed 11–21–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN–2018–HQ–0015]

Submission for OMB Review; Comment Request

AGENCY: Office of the Assistant Secretary of the Navy, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by December 24, 2018.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493, or *whs.mc-*

alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Department of the Navy (DON).

Reasonable Accommodations (RA) Tracker; SECNAV Form 12306/1T Confirmation of Reasonable Accommodation Request; OMB Control Number 0703–0063.

Type of Request: Revision.

Number of Respondents: 100.

Responses per Respondent: 1.

Annual Responses: 100.

Average Burden per Response: 20 minutes.

Annual Burden Hours: 33.

Needs and Uses: The information collection requirement is necessary to track, monitor, review, and process requests for reasonable accommodations applicants for employment. This information will be collected by DON EEO personnel involved in the Reasonable Accommodation process and data input into the Reasonable Accommodation Tracker (electronic information system) pursuant to Executive Order 13163. Official Reasonable Accommodation case files are secured with access granted on a strictly limited basis.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Mr. Frederick Licari.

Requests for copies of the information collection proposal should be sent to Mr. Licari at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: November 16, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–25474 Filed 11–21–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2018–ICCD–0081]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; International Resource Information System (IRIS)

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before December 24, 2018.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2018–ICCD–0081. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9086, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Sara Starke, 202–453–7681.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: International Resource Information System (IRIS).

OMB Control Number: 1840–0759.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Federal Government, Individuals or Households; Private Sector.

Total Estimated Number of Annual Responses: 6,596.

Total Estimated Number of Annual Burden Hours: 35,712.

Abstract: The International Resource Information System (IRIS) is an online performance reporting system for International and Foreign Language Education (IFLE) grantees. IFLE grantees are institutions of higher education, organizations and individuals funded under Title VI of the Higher Education Act of 1965, as amended (HEA) and/or the Mutual Educational and Cultural Exchange Act (Fulbright-Hays Act). Grantees under these programs enter budget and performance measure data for interim, annual and final performance reports via IRIS, as well as submit International Travel Approval Requests and Grant Activation Requests.

Dated: November 19, 2018.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2018–25485 Filed 11–21–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

International Energy Agency Meetings

AGENCY: Department of Energy.

ACTION: Notice of meetings.

SUMMARY: The Industry Advisory Board (IAB) to the International Energy Agency (IEA) will meet on November 27–29, 2018.

DATES: November 27–29, 2018.

ADDRESS: French Ministry for the Ecological and Inclusive Transition, Tour Séquoia, Place Carpeaux, La Défense, Paris, France; UIC–P Conference Centre, 16 rue Jean Rey, 75015, Paris, France.

FOR FURTHER INFORMATION CONTACT: Thomas Reilly, Assistant General Counsel for International and National Security Programs, Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–5000.

SUPPLEMENTARY INFORMATION: In accordance with section 252(c)(1)(A)(i) of the Energy Policy and Conservation Act (42 U.S.C. 6272(c)(1)(A)(i)) (EPCA), the following notice of meetings is provided:

A meeting involving members of the Industry Advisory Board (IAB) to the International Energy Agency (IEA) in connection with a workshop meeting of the IEA's Standing Group on Emergency Questions (SEQ) will be held at the French Ministry for the Ecological and Inclusive Transition, Tour Séquoia, Place Carpeaux, La Défense, Paris, France, on November 27, 2018. The purpose of the workshop meeting, which is a follow up from the workshop meeting held on September 18–19, 2018, is to discuss relevant key issues in order to establish a basis for drafting a proposal for possible improvements to the emergency oil stockholding requirement.

The agenda of the meeting is under the control of the IEA. It is expected that the IEA will adopt the following agenda:

Draft Agenda of the IEA's Workshop on the Review of the IEA Emergency Oil Stockholding Requirement

—Introduction by the Chairman
—Presentation by Secretariat:
—Overview of key considerations taken when developing different approaches
—Presentation and opportunity for clarification
—Overview of each approach option presented in background paper, followed by opportunity to ask questions for clarification

Discussion of Option 1

—Open floor discussion moderated by Chairman

Discussion of Option 2

—Open floor discussion moderated by Chairman

Discussion of Option 3

—Open floor discussion moderated by Chairman

Session 3—Reaching conclusion on the proposal for the SEQ and the GB

Wrap-Up and Next Steps

As provided in section 252(c)(1)(A)(ii) of the Energy Policy and Conservation Act (42 U.S.C. 6272(c)(1)(A)(ii)), Representatives of the Directorate-General for Competition of the European Commission and representatives of members of the IEA Group of Reporting Companies may attend the meeting as observers. The meeting will also be open to representatives of the Secretary of Energy, the Secretary of State, the Attorney General, and the Federal Trade Commission severally, to any United States Government employee designated by the Secretary of Energy, and to the representatives of Committees of the Congress.

A meeting of the Industry Advisory Board (IAB) to the International Energy Agency (IEA) will be held at the French Ministry for the Ecological and Inclusive Transition, Tour Séquoia, Place Carpeaux, La Défense, Paris, France, commencing at 9:30 a.m. on November 28, 2018. The purpose of this notice is to permit attendance by representatives of U.S. company members of the IAB at a meeting of the IEA's Standing Group on Emergency Questions (SEQ), which is scheduled to be held at the same location and time. The IAB will also hold a preparatory meeting among company representatives at the same location at 8:30 a.m. on November 28. The agenda for this preparatory meeting is to review the agenda for the SEQ meeting.

The agenda of the SEQ meeting is under the control of the SEQ. It is expected that the SEQ will adopt the following agenda:

Draft Agenda of the 155th Meeting of the SEQ

Closed SEQ Session—IEA Member Countries Only

1. Adoption of the Agenda
2. Approval of the Summary Record of the 154th Meeting
3. Status of Compliance with IEP Agreement Stockholding Obligations—Presentation by the Secretariat
4. The Future of Petrochemicals; IEA Report
5. Industry Advisory Board Update
6. Update on the Ministerial Mandates/Oil Stockholding System Review
7. Mid-term Review of the Slovak Republic

Open SEQ Session—Open to Association Countries

8. ERR of Ireland—Presentation by the Secretariat
9. ASEAN+6 Report—Presentation by the Secretariat
10. Mid-term Review of Hungary—Presentation by the Administration
11. Outreach—Presentation by the Secretariat
12. Oral Reports by Administrations:
Turkey; Stockholding obligation update:
Japan; Hokkaido black-out:
Belgium; Nuclear power plants:
The Netherlands; L-cal gas production:
Germany, Switzerland and France; stock releases due to low water level in Rhine
13. Input from Standing Groups & Committees for the 2019 IEA Ministerial
14. Other Business:
—ERR Programme
Schedule of upcoming SEQ & SOM Meetings:
—19–21 March 2019
—25–27 June 2019
—22–24 October 2019

Representatives of the Directorate-General for Competition of the European Commission and representatives of members of the IEA Group of Reporting Companies may attend the meeting as observers. The meeting will also be open to representatives of the Secretary of Energy, the Secretary of State, the Attorney General, and the Federal Trade Commission severally, to any United States Government employee designated by the Secretary of Energy, and to the representatives of Committees of the Congress.

A meeting of the Industry Advisory Board (IAB) to the International Energy Agency (IEA) will be held in the UIC–P Conference Centre, 16 rue Jean Rey, 75015, Paris, France, on November 29, 2018, commencing at 09:30 a.m. The purpose of this notice is to permit attendance by representatives of U.S. company members of the IAB at a joint meeting of the IEA's Standing Group on Emergency Questions (SEQ) and the IEA's Standing Group on the Oil Market (SOM), which is scheduled to be held at the same location and time.

The agenda of the meeting is under the control of the SEQ and the SOM. It is expected that the SEQ and the SOM will adopt the following agenda:

Draft Agenda of the Joint Session of the SEQ and the SOM

Start Meeting/Introduction

15. Adoption of the Agenda
16. Approval of Summary Record of 27 June 2018

17. Reports on Recent Oil Market and Policy Developments in IEA Countries
18. Update on the Current Oil Market Situation: Followed by Q&A
19. Presentation: ''Update on the implementation of the International Maritime Organisation's 2020 fuel specifications'' followed by Q&A
20. Presentation: On ''substitute Producer Economies'' followed by Q&A
21. Presentation: Long term oil market outlook—Chevron, followed by Q&A
22. Presentation: ''Uncertainty and Prosperity: A View from Unipec,'' followed by Q&A
23. Presentation: ''World Energy Investment 2018'' followed by Q&A
24. Presentation: ''Russian oil perspective'' followed by Q&A
25. Other Business:
—Tentative schedule of the next SOM meeting: 21 March 2019, Location TBC

Representatives of the Directorate-General for Competition of the European Commission and representatives of members of the IEA Group of Reporting Companies may attend the meeting as observers. The meeting will also be open to representatives of the Secretary of Energy, the Secretary of State, the Attorney General, and the Federal Trade Commission severally, to any United States Government employee designated by the Secretary of Energy, and to the representatives of Committees of the Congress.

Signed in Washington, DC, November 16, 2018.

Thomas Reilly,

Assistant General Counsel for International and National Security Programs.

[FR Doc. 2018–25526 Filed 11–21–18; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR19–7–000]

CITGO Petroleum Corporation v. Colonial Pipeline Company; Notice of Complaint

Take notice that on November 15, 2018, pursuant to sections 13(1), 15(1) and 15(7) of the Interstate Commerce Act (ICA),[1] Rules 211 and 214 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure,[2] and sections 343.2, 343.3, and 385.206 of the Commission's Procedural Rules Applicable to Oil Pipeline proceedings,[3] CITGO Petroleum Corporation (Complainant) filed a formal complaint against Colonial Pipeline Company (Respondent) alleging that the Respondent's untarriffed increase of a product loss allocation rate is unlawful under sections 6, 13, and 15 of the ICA, as more fully explained in the complaint.

The Complainant states that a copy of the complaint was served on the contacts for the Respondent listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on December 5, 2018.

Dated: November 15, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–25464 Filed 11–21–18; 8:45 am]

BILLING CODE 6717–01–P

[1] 49 App. U.S.C. 15(1) and 15(7) (1988).

[2] 18 CFR 385.211 and 385.214.

[3] 18 CFR 343.3.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2972–027]

City of Woonsocket; Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent Minor License.

b. *Project No.:* 2972–027.

c. *Date filed:* November 1, 2018.

d. *Applicant:* City of Woonsocket, Rhode Island (City).

e. *Name of Project:* Woonsocket Falls Project.

f. *Location:* On the Blackstone River in the City of Woonsocket, Providence County, Rhode Island. The project diverts water from the impoundment created by the U.S. Army Corps of Engineers' (Corps) Woonsocket Falls Dam; however, there are no federal or tribal lands within the project boundary.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Michael Debroisse, City of Woonsocket, Engineering, 169 Main Street, Woonsocket, RI 02895; (401) 767–9213.

i. *FERC Contact:* Patrick Crile, (202) 502–8042 or *Patrick.Crile@ferc.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See* 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. Deadline for filing additional study requests and requests for cooperating agency status: December 31, 2018.

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–2972–027.

m. The application is not ready for environmental analysis at this time.

n. The City electronically filed the application with the Commission after the close of business on October 31, 2018. Pursuant to 18 CFR 385.2001(a)(2), any document received after regular business hours is considered filed on the next regular business day. By this notice, the requirement under 18 CFR 16.20(c) to file the subsequent license application at least 24 months before the expiration of the existing license (*i.e.,* no later than October 31, 2018) is waived.

o. The Woonsocket Falls Project utilizes water from the impoundment created by the Corps' Woonsocket Falls Dam, and consists of: (1) A 14-foot-wide, 20.5-foot-high concrete intake structure located about 60 feet upstream of the Woonsocket Falls Dam and fitted with a 12-foot-wide, 18-foot-high steel trash rack having 3.5-inch clear bar spacing; (2) a 275-foot long, 12-foot-wide, 10-foot-high concrete penstock; (3) a 65-foot-long, 25-foot-wide, 20-foot-high concrete powerhouse containing one adjustable blade turbine-generator unit with an authorized capacity of 1,200 kilowatts; (4) a 50-foot-long, 12.5-foot-diameter steel draft tube; (5) an approximately 50-foot-long, 20-foot-wide, 15-foot-deep tailrace; (6) a 35-foot-long 4.16 kilovolt (kV) generator lead line, a 4.16/13.8-kV step-up transformer, a 1,200-foot-long, and a 13.8-kV transmission line connecting the project generator to the regional grid; and (7) appurtenant facilities.

The project bypasses approximately 360 feet of the Blackstone River and there is currently no required minimum instream flow for the bypassed reach. However, the City operates the project in a run-of-river (ROR) mode and voluntarily maintains a minimum flow of 20 cubic feet per second (cfs) over the crest of the dam to the bypassed reach using an automatic pond level controller. The Woonsocket Falls project has an average annual generation of approximately 4,580 megawatt-hours.

The City proposes to: (1) Continue operating the project in a ROR mode; (2) provide a year-round minimum flow of 20 cfs into the bypassed reach; (3) provide upstream eel passage at the project; and (4) implement targeted nighttime turbine shutdowns to facilitate downstream eel passage.

p. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

q. Procedural schedule and final amendments: The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Issue Deficiency Letter (if necessary)	January 2019.
Request Additional Information	January 2019.
Issue Acceptance Letter	April 2019.
Issue Scoping Document 1 for comments	May 2019.
Request Additional Information (if necessary)	July 2019.
Issue Scoping Document 2	August 2019.
Issue Notice of Ready for Environmental Analysis	August 2019.
Issue Notice of Availability of Environmental Assessment	February 2020.

Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: November 15, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–25472 Filed 11–21–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1235–017]

City of Radford; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for a subsequent license for the Municipal Hydroelectric Project, located on the Little River, near the City of Radford, in Montgomery and Pulaski Counties, Virginia, and has prepared an Environmental Assessment (EA) for the project.

The EA contains staff's analysis of the potential environmental impacts of the project and concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

A copy of the EA is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY).

You may also register online at *http://www.ferc.gov/docs-filing/*

esubscription.asp to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 30 days from the date of this notice.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–1235–017.

For further information, contact Allyson Conner at (202) 502–6082 or by email at *allyson.conner@ferc.gov.*

Dated: November 15, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–25465 Filed 11–21–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15–521–000]

Notice of Availability of the Draft Environmental Impact Statement for the Proposed Gulf LNG Liquefaction Project: Gulf LNG Liquefaction Company, LLC; Gulf LNG Energy, LLC; Gulf LNG Pipeline, LLC

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared a draft environmental impact statement (EIS) for the Gulf LNG Liquefaction Project, proposed by Gulf LNG Liquefaction Company, LLC; Gulf LNG Energy, LLC; and Gulf LNG Pipeline, LLC (GLP) (collectively referred to as Gulf LNG) in the above-referenced docket. Gulf LNG requests authorization pursuant to sections 3(a) and 7 of the *Natural Gas Act* (NGA) to construct and operate onshore liquefied natural gas (LNG) liquefaction and associated facilities to allow export of LNG, and to construct, own, operate, and maintain new interconnection and metering facilities for the existing Gulf LNG Pipeline in Jackson County, Mississippi. The proposed actions are referred to as the Gulf LNG Liquefaction Project (Project) and consist of the Gulf LNG Terminal Expansion (Terminal Expansion) and the GLP Pipeline Modifications.

The draft EIS assesses the potential environmental effects of construction and operation of the Gulf LNG Liquefaction Project in accordance with the requirements of the National Environmental Policy Act (NEPA). The FERC staff concludes that approval of the proposed Project, with the mitigation measures recommended in the EIS, would have some adverse environmental impacts; however, these impacts would be avoided or reduced to less-than-significant levels.

U.S. Army Corps of Engineers; U.S. Coast Guard; U.S. Department of Energy, Office of Fossil Energy; the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration; U.S. Fish and Wildlife Service; National Oceanic and Atmospheric Administration, National Marine Fisheries Service; and U.S. Environmental Protection Agency participated as cooperating agencies in the preparation of the EIS. In addition, the Mississippi Office of the Secretary of State has jurisdiction over the wetland mitigation property and, therefore, is assisting us as a cooperating agency. Cooperating agencies have jurisdiction by law or special expertise with respect to resources potentially affected by the proposal and participate in the NEPA analysis. Although the cooperating agencies provided input to the conclusions and recommendations presented in the draft EIS, the agencies will present their own conclusions and recommendations in their respective Records of Decision for the Project.

The draft EIS addresses the potential environmental effects of the construction and operation of the following proposed facilities:

- Feed gas pre-treatment facilities, including a mercury removal system, an acid gas removal system (to remove carbon dioxide and hydrogen sulfide), a molecular sieve dehydration system (to remove water), and a heavy hydrocarbon removal system (to remove natural gas liquids);
- two separate propane precooled mixed refrigerant liquefaction trains that liquefy natural gas, each with a nominal liquefaction capacity of 5 million metric tons per year (mtpy) and a maximum capacity of more than 5.4 mtpy of LNG;
- liquefaction facility utilities and associated systems, including two gas-fired turbine compressors per liquefaction train;
- storage facilities for condensate, ammonia and refrigerants;
- utilities systems, including instrument, plant air, and nitrogen;
- a truck loading/unloading facility to unload refrigerants and to load condensate produced during the gas liquefaction process;
- four flares (including one spare flare) in a single flare tower to incinerate excess gases associated with maintenance, startup/shutdown, and upset conditions during an emergency;
- two supply docks (North and South Supply Docks) designed to receive barges transporting materials and large equipment during construction, with one dock retained for use during operation;
- new in-tank LNG loading pumps in the existing LNG storage tanks to transfer LNG through the existing transfer lines to LNG marine carriers;
- new spill impoundment systems designed to contain LNG, refrigerants and other hazardous fluids;
- minor changes to piping at the existing berthing facility to permit bi-directional flow;
- a new concrete storm surge protection wall that connects to the existing storm surge protection wall near the southwest corner of the Terminal Expansion site and extends along the southern border of the Terminal Expansion site;
- a new earthen berm extending from the northeastern to the southeastern boundaries of the Terminal Expansion site, between the Terminal Expansion and the Bayou Casotte Dredged Material Management Site, and connecting to the new segments of the storm surge protection wall;
- six off-site construction support areas for use as staging and laydown areas, contractor yards, and parking;
- modifications to the existing metering stations at the existing Gulfstream Pipeline Company and Destin Pipeline Company interconnection facilities; [1] and
- modifications to the existing Gulf LNG Pipeline at the existing Terminal to provide a connection to the inlet of the LNG liquefaction pre-treatment facilities.

The Commission mailed a copy of the *Notice of Availability* to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes;

[1] Additionally, Transcontinental Gas Pipe Line Company, LLC (Transco) would construct modifications to the existing Transco/Florida Gas Transmission Company, LLC Interconnect. FERC would review this project under Transco's blanket certificate.

potentially affected landowners and other interested individuals and groups; and newspapers and libraries in the Project area. The draft EIS is only available in electronic format. It may be viewed and downloaded from the FERC's website (*www.ferc.gov*), on the Environmental Documents page (*https://www.ferc.gov/industries/gas/enviro/eis.asp*). In addition, the draft EIS may be accessed by using the eLibrary link on the FERC's website. Click on the eLibrary link (*https://www.ferc.gov/docs-filing/elibrary.asp*), click on General Search, and enter the docket number in the ''Docket Number'' field, excluding the last three digits (*i.e.* CP15–521–000). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Any person wishing to comment on the draft EIS may do so. Your comments should focus on draft EIS's disclosure and discussion of potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. To ensure consideration of your comments on the proposal in the final EIS, it is important that the Commission receive your comments on or before 5:00 p.m. Eastern Time on January 7, 2019.

For your convenience, there are four methods you can use to submit your comments to the Commission. The Commission will provide equal consideration to all comments received, whether filed in written form or provided verbally. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or *FercOnlineSupport@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the eComment feature on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. This is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the eFiling feature on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''*eRegister.*'' If you are filing a comment on a particular project, please select ''Comment on a Filing'' as the filing type; or

(3) You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the project docket number (CP15–521–000) with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426.

(4) In lieu of sending written or electronic comments, the Commission invites you to attend a public comment session its staff will conduct in the Project area to receive comments on the draft EIS, scheduled as follows:

Date and time	Location
Tuesday, December 18, 2018, 4:00–8:00 p.m. local time.	Pelican Landing Convention Center, 6217 Mississippi Highway 613, Moss Point, MS 39563, 228–474–1406.

The primary goal of this comment session is to have you identify the specific environmental issues and concerns with the draft EIS. Individual verbal comments will be taken on a one-on-one basis with a court reporter. This format is designed to receive the maximum amount of verbal comments, in a convenient way during the timeframe allotted.

The comment session is scheduled from 4:00 p.m. to 8:00 p.m. local time. You may arrive at any time after 4:00 p.m. There will not be a formal presentation by Commission staff when the session opens. If you wish to speak, the Commission staff will hand out numbers in the order of your arrival. Comments will be taken until 8:00 p.m. However, if no additional numbers have been handed out and all individuals who wish to provide comments have had an opportunity to do so, staff may conclude the session at 7:30 p.m. Please see appendix 1 for additional information on the session format and conduct.[2]

Your verbal comments will be recorded by the court reporter (with FERC staff or representative present) and become part of the public record for this proceeding. Transcripts will be publicly available on FERC's eLibrary system (see below for instructions on using eLibrary). If a significant number of people are interested in providing verbal comments in the one-on-one settings, a time limit of 5 minutes may be implemented for each commentor.

It is important to note that verbal comments hold the same weight as written or electronically submitted comments. Although there will not be a formal presentation, Commission staff will be available throughout the comment session to answer your questions about the environmental review process.

Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR part 385.214). Motions to intervene are more fully described at *http://www.ferc.gov/resources/guides/how-to/intervene.asp.* Only intervenors have the right to seek rehearing or judicial review of the Commission's decision. The Commission grants affected landowners and others with environmental concerns intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which no other party can adequately represent. Simply filing environmental comments will not give you intervenor status, but you do not need intervenor status to have your comments considered.

Questions?

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website (*www.ferc.gov*) using the eLibrary link. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription that allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the

[2] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary'' or from the Commission's Public Reference Room, 888 First Street NE, Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: November 15, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–25473 Filed 11–21–18; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2018–0690, FRL–9986–88–OLEM]

Agency Information Collection Activities; Proposed Collection; Comment Request; General Hazardous Waste Facility Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit the information collection request (ICR), General Hazardous Waste Facility (EPA ICR No. 1571.12, OMB Control No. 2050–0120) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA). Before doing so, the EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through April 30, 2019. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before January 22, 2019.

ADDRESSES: Submit your comments, referencing by Docket ID No. EPA–HQ–OLEM–2018–0690, online using *www.regulations.gov* (our preferred method), by email to *rcra-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Peggy Vyas, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 703–308–5477; fax number: 703–308–8433; email address: *vyas.peggy@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, the EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, the EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: Section 3004 of the Resource Conservation and Recovery Act (RCRA), as amended, requires the EPA to develop standards for hazardous waste treatment, storage, and disposal facilities (TSDFs) as may be necessary to protect human health and the environment. Subsections 3004(a)(1), (3), (4), (5), and (6) specify that these standards include, but not be limited to, the following requirements:

- Maintaining records of all hazardous wastes identified or listed under subtitle C that are treated, stored, or disposed of, and the manner in which such wastes were treated, stored, or disposed of;
- Operating methods, techniques, and practices for treatment, storage, or disposal of hazardous waste;
- Location, design, and construction of such hazardous waste treatment, disposal, or storage facilities;
- Contingency plans for effective action to minimize unanticipated damage from any treatment, storage, or disposal of any such hazardous waste; and
- Maintaining or operating such facilities and requiring such additional qualifications as to ownership, continuity of operation, training for personnel, and financial responsibility as may be necessary or desirable.

The regulations implementing these requirements are codified in 40 CFR parts 264 and 265. The collection of this information enables the EPA to properly determine whether owners/operators or hazardous waste treatment, storage, and disposal facilities meet the requirements of Section 3004(a) of RCRA.

Form Numbers: None.

Respondents/affected entities: Business and other for-profit, as well as State, Local, and Tribal governments.

Respondent's obligation to respond: Mandatory (RCRA section 3004).

Estimated number of respondents: 1,872.

Frequency of response: On occasion.

Total estimated burden: 672,417 hours per year. Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $41,749,044 (per year), includes $533,425 annualized capital or operation & maintenance costs and $41,225,619 annualized labor costs.

Changes in estimates: The burden hours are likely to stay substantially the same.

Dated: November 12, 2018.

Barnes Johnson,

Director, Office of Resource Conservation and Recovery.

[FR Doc. 2018–25547 Filed 11–21–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9042–5]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa/*.

Weekly receipt of Environmental Impact Statements

Filed 11/12/2018 Through 11/16/2018

Pursuant to 40 CFR 1506.9

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its

comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20180283, Final Supplement, NRC, LA, NUREG–1437, Supplement 59 Waterford Steam Electric Station, Unit 3 license renewal, Review Period Ends: 12/24/2018, Contact: Elaine Keegan 301–415–8517.

Dated: November 19, 2018.

Robert Tomiak,

Director, Office of Federal Activities.

[FR Doc. 2018–25590 Filed 11–21–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2018–0692, FRL–9986–86–OLEM]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generator Standards Applicable to Laboratories Owned by Eligible Academic Entities.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit the information collection request (ICR), Generator Standards Applicable to Laboratories Owned by Eligible Academic Entities (EPA ICR No. 2317.04, OMB Control No. 2050–0204) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*). Before doing so, the EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through April 30, 2019. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before January 22, 2019.

ADDRESSES: Submit your comments, referencing by Docket ID No. EPA–HQ–OLEM–2018–0692, online using *www.regulations.gov* (our preferred method), by email to *rcra-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Kristen Fitzgerald, (mail code 5304P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 703–308–8286; fax number: 703–308–0514; email address: *fitzgerald.kristen@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, the EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, the EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: Subpart K within 40 CFR Part 262 provides a flexible and protective set of regulations that address the specific nature of hazardous waste generation and accumulation in laboratories owned by colleges and universities, including teaching hospitals and non-profit research institutes that are either owned by or formally affiliated with a college or university. In addition, eligible academic entities have the discretion to determine the most appropriate and effective method of compliance with these requirements—by allowing them the choice of either managing their hazardous wastes in accordance with the alternative regulations as set forth in Subpart K, or remaining subject to the existing generator regulations.

Form Numbers: None.

Respondents/affected entities: Business and other for-profit, as well as State, Local, and Tribal governments.

Respondent's obligation to respond: Required to obtain or retain a benefit (Sections 2002, 3001, 3002, 3004 of RCRA).

Estimated number of respondents: 132.

Frequency of response: On occasion.

Total estimated burden: 35,813 hours per year. Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $1,806,663 (per year), which includes $1,667,976 in annualized labor and $138,687 in annualized capital or operation & maintenance costs.

Changes in estimates: The burden hours are likely to stay substantially the same.

Dated: November 12, 2018.

Barnes Johnson,

Director, Office of Resource Conservation and Recovery.

[FR Doc. 2018–25552 Filed 11–21–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9042–4]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–7156 or *https://www.epa.gov/nepa/*

Weekly receipt of Environmental Impact Statements Filed 11/12/2018 through 11/16/2018 Pursuant to 40 CFR 1506.9.

Notice:

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20180276, Draft, FERC, LA, The Plaquemines LNG and Gator

Express Pipeline Project, Comment Period Ends: 01/07/2019, Contact: Office of External Affairs 866–208–3372.

EIS No. 20180277, Draft, USFS, BLM, ID, Proposed Dairy Syncline Mine and Reclamation Plan, Comment Period Ends: 02/21/2019, Contact: Bill Stout 208–478–6367.

EIS No. 20180278, Draft, FERC, MS, Gulf LNG Liquefaction Project, Comment Period Ends: 01/07/2019, Contact: Office of External Affairs 866–208–3372.

EIS No. 20180279, Draft, BIA, MI, Little River Band of Ottawa Indians Trust Acquisition and Casino Project, Comment Period Ends: 01/07/2019, Contact: Scott Doig 612–725–4514.

EIS No. 20180280, Draft, FERC, FL, Eagle LNG Partners Jacksonville, LLC, Comment Period Ends: 01/07/2019, Contact: Office of External Affairs 866–208–3372.

EIS No. 20180281, Final, USFS, MT, The Flathead National Forest Land Management Plan and the NCDE Grizzly Bear Plan Amendments, Review Period Ends: 12/24/2018, Contact: Chip Weber 406–758–5204.

EIS No. 20180282, Final, USACE, IL, The Great Lakes and Mississippi River Interbasin Study—Brandon Road Integrated Feasibility Study and Environmental Impact Statement—Will County, Illinois, Review Period Ends: 12/24/2018, Contact: Andrew Leichty 309–794–5399.

Dated: November 19, 2018.

Robert Tomiak,

Director, Office of Federal Activities.

[FR Doc. 2018–25501 Filed 11–21–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2003–0073; FRL–9986–93–OAR]

Proposed Information Collection Request; Comment Request; Distribution of Offsite Consequence Analysis Information Under Section 112(r)(7)(H) of the Clean Air Act (CAA), as Amended—EPA No. 1981.07, OMB Control Number 2050–0172

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit an information collection request (ICR), Distribution of Offsite Consequence Analysis Information under Section 112(r)(7)(H) of the Clean Air Act (CAA), as amended—EPA No. 1981.07, OMB Control Number 2050–0172 to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through May 31, 2019. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before January 22, 2019.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OAR–2003–0073 referencing the Docket ID numbers provided for each item in the text, online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460 and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Wendy Hoffman, Office of Emergency Management, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–8794; email address: *hoffman.wendy@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: This ICR is the renewal of the ICR developed for the final rule, *Accidental Release Prevention Requirements; Risk Management Programs Under the Clean Air Act Section 112(r)(7); Distribution of Off-Site Consequence Analysis Information.* CAA section 112(r)(7) required EPA to promulgate reasonable regulations and appropriate guidance to provide for the prevention and detection of accidental releases and for responses to such releases. The regulations include requirements for submittal of a risk management plan (RMP) to EPA. The RMP includes information on offsite consequence analyses (OCA) as well as other elements of the risk management program.

On August 5, 1999, the President signed the Chemical Safety Information, Site Security, and Fuels Regulatory Relief Act (CSISSFRRA). The Act required the President to promulgate regulations on the distribution of OCA information (CAA section 112(r)(7)(H)(ii)). The President delegated to EPA and the Department of Justice (DOJ) the responsibility to promulgate regulations to govern the dissemination of OCA information to the public. The final rule was published on August 4, 2000 (65 FR 48108). The regulations imposed minimal information and recordkeeping requirements.

In accordance with the final rule, the federal government established 55 reading rooms at federal facilities geographically distributed across the United States and its territories. At these reading rooms, members of the public are able to read, but not mechanically copy or remove paper copies of OCA information for up to 10 stationary sources per calendar month. At these reading rooms, the members of the

public may also have access to OCA information that the Local Emergency Planning Committee (LEPC) in whose jurisdiction the person lives or works is authorized to provide.

The final rule also authorizes and encourages state and local government officials to have access to OCA information for their official use, and to provide members of the public with read-only access to OCA sections of RMPs for sources located within the jurisdiction of the LEPC where the person lives or works and for any other stationary sources with vulnerability zones extending into the LEPC's jurisdiction.

EPA also established a Vulnerable Zone Indicator System (VZIS) that informs any person located in any state whether an address specified by that person might be within the vulnerable zone of one or more stationary sources, according to the data reported in RMPs. The VZIS is available on the internet. Members of the public who do not have access to the internet are able to obtain the same information by regular mail request to the EPA.

Form numbers: None.

Respondents/affected entities: State and local agencies and the public.

Respondent's obligation to respond: Required to obtain or retain a benefit (40 CFR 1400).

Estimated number of respondents: 860 (total).

Frequency of response: As necessary.

Total estimated burden: 1,500 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $46,865 (per year), includes $620 annualized capital or operation & maintenance costs.

The Agency is requesting comments on the burden and costs estimated in the current ICR. EPA will revise the burden and costs, if necessary, prior to submitting the package to OMB for approval for this information collection.

Dated: November 14, 2018.

Reggie Cheatham,

Director, Office of Emergency Management.

[FR Doc. 2018–25555 Filed 11–21–18; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that at 10:29 a.m. on Tuesday, November 20, 2018, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters related to the Corporation's supervision, corporate, and resolution activities.

In calling the meeting, the Board determined, on motion of Director Martin J. Gruenberg, seconded by Director Mick Mulvaney (Acting Director, Consumer Financial Protection Bureau), and concurred in by Director Joseph M. Otting (Comptroller of the Currency), and Chairman Jelena McWilliams, that Corporation business required its consideration of the matters which were to be the subject of this meeting on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B).

Dated: November 20, 2018.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2018–25698 Filed 11–20–18; 4:15 pm]

BILLING CODE P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Submission for OMB Review; Comment Request (OMB No. 3064–0072)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to take this opportunity to comment on the renewal of the existing information collection described below (3064–0072). On August 16, 2018, the FDIC requested comment for 60 days on a proposal to renew the information collection described below. No comments were received. The FDIC hereby gives notice of its plan to submit to OMB a request to approve the renewal of this collection, and again invites comment on this renewal.

DATES: Comments must be submitted on or before December 24, 2018.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *https://www.FDIC.gov/regulations/laws/federal.*
- *Email: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.
- *Mail:* Jennifer Jones (202–898–6768), Counsel, MB–3105, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Jennifer Jones, Counsel, 202–898–6768, *jennjones@fdic.gov,* MB–3105, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: On August 16, 2018, the FDIC requested comment for 60 days on a proposal to renew the information collection described below. No comments were received. The FDIC hereby gives notice of its plan to submit to OMB a request to approve the renewal of this collection, and again invites comment on this renewal.

Proposal to renew the following currently approved collection of information:

1. *Title:* Acquisition Services Information Requirements.

OMB Number: 3064–0072.

Form Number: 3700/55 (Solicitation/Award); 1600/04 (Background Investigation Questionnaire for Contractor Personnel and Subcontractors); 1600/07 (Background Investigation Questionnaire for Contractors); 3700/12 (Integrity and Fitness Representations and Certifications); 3700/44 (Leasing Representations and Certifications); 3700/57 (Past Performance Questionnaire); 3700/04A (Contractor Representations and Certifications); and 3700/59 (Fair Inclusion of Minorities and Women).

Affected Public: Vendors of goods and services.

Burden Estimate:

SUMMARY OF ANNUAL BURDEN

	Type of burden	Obligation to respond	Estimated number of respondents	Estimated frequency of responses	Estimated time per response	Frequency of response	Total annual estimated burden (hours)
Request for Proposal and Price Quotation (includes Basic Safeguards)—Solicitation/Award (Form 3700/55).	Reporting	Required to Obtain or Retain Benefits.	656	1	6.55	On Occasion	4,297
Request for Information	Reporting	Voluntary	140	1	12.00	On Occasion	1,680
Background Investigation Questionnaire for Contractor Personnel and Subcontractors (Form 1600/04).	Reporting	Required to Obtain or Retain Benefits.	2,400	1	0.33	On Occasion	792
Background Investigation Questionnaire for Contractors (Form 1600/07).	Reporting	Required to Obtain or Retain Benefits.	200	1	0.5	On Occasion	100
Integrity and Fitness Representations and Certifications (Form 3700/12).	Reporting	Required to Obtain or Retain Benefits.	12	1	0.33	On Occasion	4
Leasing Representations and Certifications (Form 3700/44).	Reporting	Required to Obtain or Retain Benefits.	15	1	1	On Occasion	15
Past Performance Questionnaire (Form 3700/57).	Reporting	Required to Obtain or Retain Benefits.	984	1	0.75	On Occasion	738
Contractor Representations and Certifications (Form 3700/4A).	Reporting	Required to Obtain or Retain Benefits.	12	1	0.33	On Occasion	4
Fair Inclusion of Minorities and Women (Form 3700/59).	Reporting	Required to Obtain or Retain Benefits.	100	1	2	On Occasion	200
Total Hourly Burden							7,830

General Description of Collection:

This is a collection of information involving submission of information and various forms by contractors who desire to do business with the FDIC in connection with contract proposals submitted in response to FDIC solicitations.

In order to obtain competitive proposals and contracts from vendors interested in providing goods or services to the FDIC, the FDIC uses the Solicitation/Award request (Form 3700/55). This form is used in connection with a request for proposal and a request for price quotations.

In anticipation of a particular contract solicitation, the FDIC may first conduct market research to narrow down the list of potential contractors. This is done through a request for information (RFI). Following the RFI process, potential firms may be notified if they are to be included in the next phase of the acquisition process.

The FDIC Background Investigation Questionnaire for Contractor Personnel and Subcontractors (Form 1600/04), Background Investigation Questionnaire for Contractors (Form1600/07), Integrity and Fitness Representations and Certifications (Form 3700/12), and Leasing Representations and Certifications (Form 3700/44) are a result of the implementation of 12 CFR part 366. The FDIC adopted 12 CFR part 366 pursuant to Section 12(f)(3) and (4) of the Federal Deposit Insurance Act, 12 U.S.C. 1822(f)(3) and (4), and the rulemaking authority of the FDIC found at 12 U.S.C. 1819. Pursuant to those sections and consistent with the goals and purposes of titles 18 and 41 of the U.S. Code, the rule establishes the minimum standards of integrity and fitness that contractors, subcontractors, and employees of contractors and subcontractors must meet if they perform any service or function on behalf of the FDIC. This rule includes regulations governing conflicts of interest, ethical responsibility, and use of confidential information in accordance with 1822(f)(3); and the prohibitions and the submission of information in accordance with 1822(f)(4). This rule applies to a person who submits an offer to perform or performs, directly or indirectly, a contractual service or function on behalf of the FDIC.

In addition, the evaluation of an offeror's past performance under formal contracting procedures is a mandatory technical evaluation criterion in the FDIC's standard solicitation document. In support of the evaluation of the past performance criterion, the FDIC Past Performance Questionnaire (Form 3700/57) was developed to be submitted by other government agencies or commercial businesses who are doing business, or have done business, with the contractor that the FDIC is evaluating.

The FDIC Contractor Representations and Certifications form (Form 3700/4A) must be completed by any offeror that responds to a solicitation for an award over $100,000.

Finally, in connection with a contract proposal, the FDIC seeks a commitment from an FDIC contractor to ensure, to the maximum extent possible consistent with applicable law, the fair inclusion of minorities and women in its workforce and the workforces of its applicable subcontractors. The commitment is asserted by the FDIC Fair Inclusion of Minorities and Women form (Form 3700/59), which is a contract clause implementing Section 342(c)(2) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (12 U.S.C. 5452). The clause asserts the FDIC's right to request documentation from the contractor that demonstrates the contractor's good faith effort to include minorities and women in its workforce and subcontractors' workforces.

The annual burden for this information collection is estimated to be 7,830 hours. This represents an increase of 5,496 hours from the current burden estimate of 2,334 hours. This increase is not due to any new requirements imposed by the FDIC. Rather, it is due to FDIC's reassessment of the burden hours associated with the contracting

process and to better account for the burdens associated with requests for proposals and price quotations as well as RFIs.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, on November 19, 2018.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2018–25479 Filed 11–21–18; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request (OMB No. 3064–0093)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to take this opportunity to comment on the renewal of the existing information collection described below.

DATES: Comments must be submitted on or before January 22, 2019.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *https://www.FDIC.gov/regulations/laws/federal.*
- *Email: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.
- *Mail:* Manny Cabeza (202–898–3767), Counsel, MB–3007, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Manny Cabeza, Counsel, 202–898–3767, *mcabeza@fdic.gov,* MB–3007, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: Proposal to renew the following currently approved collection of information:

1. *Title:* Notices Required of Government Securities Dealers or Brokers.

OMB Number: 3064–0093.

Form Number: G–FIN; G–FINW; G–FIN4 & G–FIN5.

Affected Public: Insured state nonmember banks acting as government securities brokers and dealers.

Burden Estimate:

SUMMARY OF ANNUAL BURDEN

Information collection description	Type of burden	Obligation to respond	Estimated number of respondents	Estimated frequency of responses	Estimated time per response	Estimated annual burden (hours)
Notice by Financial Institutions of Government Securities Broker or Government Securities Dealer Activities (G–FIN).	Reporting	Mandatory	1	On Occasion	1 hour	1
Notice By Financial Institutions of Termination of Activities as a Government Securities Broker of Government Securities Dealer (G–FINW).	Reporting	Mandatory	1	On Occasion	15 minutes	.25
Disclosure Form for Person Associated with a Financial Institution Securities Broker or Dealer (G–FIN–4).	Reporting	Mandatory	1	On Occasion	2 hours	2
Uniform Termination Notice for Persons Associated With a Financial Institution Government Securities Broker of Dealer (G–FIN–5).	Reporting	Mandatory	5	On Occasion	2 hours	10

Total Estimated Annual Burden: 13.25 hours.

General Description of Collection

The Government Securities Act of 1986 requires all financial institutions acting as government securities brokers and dealers to notify their Federal regulatory agencies of their broker-dealer activities, unless exempted from the notice requirements by Treasury Department regulation.

The Form G–FIN and Form G–FINW are used by insured State nonmember banks that are government securities brokers or dealers to notify the FDIC of their status or that they have ceased to function as a government securities broker or dealer.

The Form G–FIN–4 is used by associated persons of insured State nonmember banks that are government securities brokers or dealers to provide certain information to the bank and to the FDIC concerning employment, residence, and statutory disqualification.

The Form G–FIN–5 is used by insured State nonmember banks that are government securities brokers or dealers to notify the FDIC that an associated person is no longer associated with the

government securities broker or dealer function of the bank.

There is no change in the method or substance of the collection. The overall reduction in burden hours (from 17 hours to 13.25 hours) is the result of economic fluctuation. In particular, the number of respondents has decreased from 17 to 8 while the hours per response and frequency of responses have remained the same.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, on November 19, 2018.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2018–25520 Filed 11–21–18; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors met in open session at 10:00 a.m. on Tuesday, November 20, 2018, to consider the following matters:

Summary Agenda

Disposition of minutes of previous Board of Directors' Meetings.

Memorandum and resolution re: Regulatory Capital Rule: Capital Simplification for Qualifying Community Banking Organizations.

Memorandum and resolution re: Notice of Proposed Rulemaking to Increase the Appraisal Threshold for Residential Real Estate Transactions, Implement the Residential Rural Exemption, and Require Appropriate Appraisal Review.

Memorandum and resolution re: Final Rule on Transferred OTS Regulations Regarding Fiduciary Powers of State Savings Associations and Consent Requirements for the Exercise of Trust Powers.

Memorandum and resolution re: Final Rule to Revise the FDIC's Regulations Concerning Inflation-Adjusted Maximum Civil Money Penalty Amounts.

Report of actions taken pursuant to authority delegated by the Board of Directors.

Discussion Agenda

Memorandum and resolution re: Notice of Proposed Rulemaking on Proposed Changes to Applicability Thresholds for Regulatory Capital Requirements and Liquidity Requirements.

In calling the meeting, the Board determined, on motion of Director Martin J. Gruenberg, seconded by Director Mick Mulvaney (Acting Director, Consumer Financial Protection Bureau), concurred in by Director Joseph Otting (Comptroller of the Currency), and Chairman Jelena McWilliams, that Corporation business required its consideration of the matters on less than seven days' notice to the public; and that no earlier notice of the meeting than that previously provided on November 14, 2018, was practicable.

The meeting was held in the Board Room located on the sixth floor of the FDIC Building located at 550 17th Street NW, Washington, DC.

Dated: November 20, 2018

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2018–25697 Filed 11–20–18; 4:15 pm]

BILLING CODE P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request (OMB No. 3064–0117; –0145; and –0152)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to take this opportunity to comment on the renewal of the existing information collections described below.

DATES: Comments must be submitted on or before January 22, 2019.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *https://www.FDIC.gov/regulations/laws/federal.*
- *Email: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.
- *Mail:* Manny Cabeza (202–898–3767), Counsel, MB–3007, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street NW building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Manny Cabeza, Counsel, 202–898–3767, *mcabeza@fdic.gov,* MB–3007, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

Proposal To Renew the Following Currently Approved Collections of Information

1. *Title:* Multi-to-Stock Conversion of State Savings Banks.

OMB Number: 3064–0117.

Form Number: None.

Affected Public: Insured state savings associations.

Burden Estimate:

SUMMARY OF ANNUAL BURDEN

	Type of burden	Obligation to respond	Estimated number of respondents	Estimated frequency of responses	Estimated time per response (hours)	Frequency of response	Total annual estimated burden (hours)
Multi-to-Stock Conversion of State Savings Bank.	Reporting	Mandatory	5	1	250 hours	On Occasion	1,250.
Total Hourly Burden							1,250 hours.

General Description of Collection

State savings associations must file a notice of intent to convert to stock form, and provide the FDIC with copies of documents filed with state and federal banking and/or securities regulators in connection with any proposed mutual-to-stock conversion.

There is no change in the method or substance of the collection. The overall reduction in burden hours is the result of economic fluctuation. In particular, the number of respondents has decreased while the hours per response and frequency of responses have remained the same.

2. *Title:* Notice Regarding Unauthorized Access to Customer Information.

OMB Number: 3064–0145.

Form Number: None.

Affected Public: Insured state nonmember banks.

Burden Estimate:

SUMMARY OF ANNUAL BURDEN

	Type of burden	Estimated number of respondents	Estimated time per response (hours)	Frequency of response	Total estimated annual burden hours
Implementation (One Time):					
Develop Policies and Procedures for Response Program.	Recordkeeping	2	24	1	48
Ongoing:					
Notice Regarding Unauthorized Access to Customer Information.	Third Party Disclosure	315	36 hours	On Occasion	11,340
Total Estimated Annual Burden.					11,388

General Description of Collection:

The Interagency Guidance on Response Programs for Unauthorized Access to Customer Information and Customer Notice describes the federal banking agencies' expectations regarding a response program, including customer notification procedures, that a financial institution should develop and apply under the circumstances described in the *Guidance* to address unauthorized access to or use of customer information that could result in substantial harm or inconvenience to a customer. The *Guidance* advises financial institutions when and how they might: (1) Develop notices to customers; (2) in certain circumstances defined in the *Guidance,* determine which customers should receive the notices and (3) send the notices to customers.

There is no change in the method or substance of the information collection. With respect to the third party disclosure requirements associated with providing notices regarding unauthorized access to customer information, the FDIC revised its estimate of the response time from 29 hours per response to 36 hours per response. The agency also revised its estimate of the number of annual respondents from 80 to 315 to reflect current industry trend data.

3. *Title:* Identity Theft Red Flags.

OMB Number: 3064–0152.

Form Number: None.

Affected Public: Insured state nonmember banks.

Burden Estimate:

SUMMARY OF ANNUAL BURDEN

	Type of burden	Obligation to respond	Estimated number of respondents	Estimated frequency of responses	Estimated time per response (hours)	Frequency of response	Total annual estimated burden (hours)
FACT Act Sections 114 and 315—Establish policies and Procedures.	Recordkeeping	Mandatory	3,575	1	16	On Occasion	57,200
FACT Act Section 315—Establish policies and Procedures.	Third-Party Disclosure.	Mandatory	3,575	1	4	On Occasion	14,300
Total Hourly Burden							71, 500

General Description of Collection

The regulation containing this information collection requirement is 12 CFR part 334, which implements sections 114 and 315 of the Fair and Accurate Credit Transactions Act of 2003 (FACT Act), Public Law 108–159 (2003).

FACT Act Section 114: Section 114 requires the Board of Governors of the Federal Reserve System, the Office of the Comptroller of the Currency and the FDIC (the Agencies) to jointly propose guidelines for financial institutions and creditors identifying patterns, practices, and specific forms of activity that indicate the possible existence of identity theft. In addition, each financial institution and creditor is required to establish reasonable policies and procedures to address the risk of identity theft that incorporate the guidelines. Credit card and debit card issuers must develop policies and procedures to assess the validity of a request for a change of address under certain circumstances. The information collections pursuant to section 114 require each financial institution and creditor to create an Identity Theft Prevention Program and report to the board of directors, a committee thereof, or senior management at least annually on compliance with the proposed regulations. In addition, staff must be trained to carry out the program. Each credit and debit card issuer is required to establish policies and procedures to assess the validity of a change of address request. The card issuer must notify the cardholder or use another means to assess the validity of the change of address.

FACT Act Section 315: Section 315 requires the Agencies to issue regulations providing guidance regarding reasonable policies and procedures that a user of consumer reports must employ when such a user receives a notice of address discrepancy from a consumer reporting agencies. Part 334 provides such guidance. Each user of consumer reports must develop reasonable policies and procedures that it will follow when it receives a notice of address discrepancy from a consumer reporting agency. A user of consumer reports must furnish an address that the user has reasonably confirmed to be accurate to the consumer reporting agency from which it receives a notice of address discrepancy.

There is no change in the method or substance of the information collection. The total estimated annual burden hours have increased because of the inclusion of the agency's estimate of third-party disclosure burden associated with the notices required by Section 315 of the FACT Act which were previously not included because the agencies had taken the position that the entities covered by the regulation were already furnishing addresses that they had reasonably confirmed to be accurate to consumer reporting agencies from which they receive a notice of address discrepancy as a usual and customary business practice. The above burden estimate now includes burden for the third-party disclosure requirements associated with Section 315 which resulted in an increase in estimated annual burden of 14, 300 hours. This increase was offset, in part, by a reduction in the estimated number of respondents from 4, 017 to 3,575 which resulted in a decrease in the estimated annual burden for the recordkeeping requirement associated with Sections 114 and 315 from 64, 272 hour to 57,200 hours. The net effect of the revision is an increase in estimated annual burden from 64,272 hours to 71,500 hours.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, on November 16, 2018.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2018–25425 Filed 11–21–18; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RETIREMENT THRIFT INVESTMENT

Agenda; Board Meeting

November 27, 2018, 8:30 a.m. (In-Person)

Open Session

1. Approval of the minutes for the October 22, 2018 Board Member Meeting
2. Monthly Reports
   (a) Participant Activity
   (b) Investment Performance
   (c) Legislative Report
3. Quarterly Reports
   (d) Metrics
4. Office of Participant Services Annual Report
5. Office of Enterprise Planning Annual Report
6. Withdrawal Project Update

Closed Session

Material covered by 5 U.S.C. (c)(4), (c)(6), and (c)(9)(B).

FOR FURTHER INFORMATION CONTACT: Kimberly Weaver, Director, Office of External Affairs, (202) 942–1640.

Dated: November 19, 2018.

Megan G. Grumbine,

General Counsel, Federal Retirement Thrift Investment Board.

[FR Doc. 2018–25543 Filed 11–21–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Phase II Evaluation Activities for Implementing a Next Generation Evaluation Agenda for the Chafee Foster Care Independence Program—Extension

OMB No.: 0970–0489.

Description: The Administration for Children and Families (ACF), Office of Planning Research and Evaluation (OPRE) is proposing an extension of a currently approved information collection (OMB no. 1970–0489). The information collection activities are part of the Phase II Evaluation Activities for Implementing a Next Generation Evaluation Agenda for the Chafee Foster Care Independence Program (now known as the Chafee Foster Care Program for the Successful Transition to Adulthood). The purpose of the extension is to continue the ongoing information collection, which consists of site visits by staff from the Urban Institute and Chapin Hall at the University of Chicago to conduct formative evaluations of programs serving transition-age foster youth. The evaluations include preliminary visits to discuss the evaluation process with program administrators and site visits to each program to speak with program leaders, partners and key stakeholders, front-line staff, and participants. These formative evaluations will determine programs' readiness for more rigorous evaluation in the future. The activities and products from this project will help

ACF to fulfill the ongoing legislative mandate for program evaluation specified in the Foster Care Independence Act of 1999.

Respondents: Semi-structured interviews will be held with program leaders, partners and stakeholders, and front-line staff as well as young adults being served by the programs.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Outreach email for discussion with program administrators and staff	16	8	1	8	64
Outreach email for Focus Group Recruiters	12	6	1	8	48
Discussion Guide for program leaders	48	24	4	1	96
Discussion Guide for program partners and stakeholders	60	30	2	1	60
Discussion Guide for program front-line staff	104	52	1	1	52
Focus Group Guide for program participants	160	80	1	2	160
Compilation and Submission of Administrative Data Files	48	24	2	12	576

Estimated Total Annual Burden Hours: 1,056.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2018–25548 Filed 11–21–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1262]

Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the issuance of vouchers as well as the approval of products redeeming a voucher. FDA has determined that AJOVY (fremanezumab-vfrm), approved September 14, 2018, meets the redemption criteria.

FOR FURTHER INFORMATION CONTACT: Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4061, Fax: 301–796–9858, email: *althea.cuff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that AJOVY (fremanezumab-vfrm), approved September 14, 2018, meets the redemption criteria.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about AJOVY (fremanezumab-vfrm) go to the ''*Drugs@FDA*'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: November 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–25480 Filed 11–21–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Request for Information; A Notice by the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council) requests information from the general public and stakeholders related to efforts and strategies to combat Antibiotic Resistance (AR). Given the evolution of AR and the long-term nature of the problem, the Secretary of Health and Human Services (HHS) tasked the Advisory Council with identifying significant areas that have emerged since the release of the National Action Plan (NAP) for Combatting Antibiotic-Resistant Bacteria (CARB) in 2015. To aid in the process of developing its response to the Secretary's task, the Advisory Council has posted this Request for Information (RFI) to hear from a wide range of stakeholders and sectors relevant to the overall CARB effort. This RFI offers the opportunity for the public, including interested individuals, organizations, associations, industries, and others, to provide their input on new priority

areas within each of the five goals of the NAP that should be considered by the United States Government (USG) for 2020–2025.

Responses to the RFI must be received by 11:59 p.m. on January 7, 2019 to be considered. The questions in the RFI are available through an online form on the Advisory Council's web page at *www.hhs.gov/ash/carb.* Individuals unable to submit their answers using the online platform should send an email to *CARB@hhs.gov,* indicating ''RFI Response'' in the subject line, along with the corresponding goal number(s) for which they are responding.

DATES AND TIMES: Comments must be received by 11:59 p.m. on January 7, 2019 to be considered.

ADDRESSES: Individuals are encouraged to submit their responses through one of the following methods. Utilization of the online form available on *www.hhs.gov/ash/carb* is the preferred method of submission. Should you choose to send in your responses via email, please be sure to include ''RFI Response'' along with the corresponding goal number(s) in the subject line. Responses should not include information of a confidential nature, such as sensitive personal information or proprietary information. Responses to this notice are not offers and cannot be accepted by the federal government to form a binding contract or issue a grant. Please be aware that your comments will not be posted publicly, however they may be made available to the public, in part or in full, subject to applicable laws and regulations.

- *Online Form: www.hhs.gov/ash/carb.* Online submissions will receive an automatic confirmation acknowledging receipt of your response, but you will not receive individualized feedback on any suggestions.
- *Email: CARB@hhs.gov.* Please indicate ''RFI Response'' and the corresponding goal number(s) in the subject line of your email.
- All submissions will receive an electronic confirmation acknowledging receipt of your response, but you will not receive individualized feedback on any suggestions.

FOR FURTHER INFORMATION CONTACT: Dr. Jomana Musmar, Acting Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Room 715H, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. Phone: (202) 690–5566; email: *CARB@hhs.gov.*

SUPPLEMENTARY INFORMATION: Under Executive Order 13676, dated September 18, 2014, authority was given to the Secretary of Health and Human Services (HHS) to establish the Advisory Council, in consultation with the Secretaries of Defense and Agriculture. Activities of the Advisory Council are governed by the provisions of Public Law 92–463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The Advisory Council will provide advice, information, and recommendations to the Secretary of HHS regarding programs and policies intended to support and evaluate the implementation of Executive Order 13676, including the National Strategy for CARB and the Action Plan (NAP). The Advisory Council shall function solely for advisory purposes.

In carrying out its mission, the Advisory Council will provide advice, information, and recommendations to the Secretary regarding programs and policies intended to preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating AR and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat AR.

Background: Antibiotic Resistance (AR) poses a significant threat to our Nation's public health, economy, and national security. The Centers for Disease Control and Prevention (CDC) estimates that every year more than two million people in the United States (U.S.) contract infections that are resistant to antibiotics, and at least 23,000 people die as a result. The United States exceeds $20 billion in direct health care costs, and loses $35 billion in indirect costs due to loss of productivity associated with antibiotic-resistant infections. By 2050, drug-resistant bacterial infections worldwide are estimated to result in greater than 10 million deaths yearly and cost up to $100 trillion in losses to the world economy. Drug-resistant infections also complicate the U.S. medical response to chemical, biological, radiological, or nuclear emergencies, and the global spread of AR makes our deployed service members particularly vulnerable.

In response to the AR threat, the USG developed the National Strategy for Combating Antibiotic-Resistant Bacteria (CARB) in 2014. The Strategy takes a One Health approach to combating antibiotic resistance based on the persistence of AR within our global environment and the recognition that integrated multi-sectoral action is needed to prevent the emergence and spread of AR. In 2015, the U.S. government issued the corresponding National Action Plan (NAP) for CARB, providing a five-year roadmap (2015–2020) to guide the Nation in implementing the following five goals outlined in the Strategy:

1. Slow the emergence of resistant bacteria and prevent the spread of resistant infections;
2. Strengthen national One Health surveillance efforts to combat resistance;
3. Advance development and use of rapid and innovative diagnostic tests for identification and characterization of resistant bacteria;
4. Accelerate basic and applied research and development for new antibiotics and other therapeutics, including vaccines; and
5. Improve international collaboration and capacities for antibiotic resistance prevention, surveillance, control and antibiotic research and development.

The U.S. government has made meaningful progress towards these goals; however, since the issuance of the NAP in 2015, the domestic and international landscape has changed with continued unparalleled advancement and innovation in technology and the life sciences. Additional action is needed and opportunities exist to continue this progress beyond 2020. As such, the U.S. Government will issue a second iteration of the NAP that will guide action on AR for the period of 2020–2025. The development of this draft will involve the U.S. Government's careful consideration of progress to date on the current NAP, including barriers to progress in certain areas and new developments across sectors, at home and abroad.

Request for Information: To inform the Advisory Council's deliberation on recommended priorities to consider in the USG's process of developing the next NAP (2020–2025), please review the five goals in the current NAP, and provide the following information:

- In the context of the existing five goals, on what new priorities should the

federal government focus in the next NAP for CARB—that are not already included in the current plan—and why are they the most important? Your response can cover a range of priority areas for human, animal, and environmental health, including surveillance, research and development, stewardship practices, infection prevention and control practices, and/or other areas for consideration.

In preparing your response, please be sure to:

○ Consider how your response fits into the existing One Health paradigm, and how your proposed priority should be further pursued by the U.S. Government;

○ Provide an answer that is feasible and actionable by the U.S. Government;

○ Limit your responses to no more than two priorities for each of the five goals (a maximum of 10 can be submitted);

○ Summarize your response for each priority area in 250 words or less, including its scientific justification;

○ Indicate whether your response is relevant domestically, internationally, or both;

○ Indicate the domain(s) to which your response applies—human, animal, and/or environmental health;

○ Include citations to support your response (references must be in the form of an active link or citation; we will not accept attachments. Peer-reviewed citations and journal links are highly encouraged.

Response to this RFI is voluntary. Responders are free to address any or all of the goals listed in the NAP. Please note that the USG will not pay for response preparation or for the use of any information contained in the response. The answers provided in this RFI must not include any confidential or proprietary data. Responses to this notice are not offers and cannot be accepted by the USG to form a binding contract or issue a grant. Please be aware that your comments will not be posted publicly, however, they may be made available to the public, in part or in full, subject to applicable laws and regulations.

More information can be found at *www.hhs.gov/ash/carb.*

Dated: November 13, 2018.

Jomana F. Musmar,

Acting Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria Committee Manager.

[FR Doc. 2018–25435 Filed 11–21–18; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council). The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is required for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or send in their public comment via email should send an email to *CARB@hhs.gov.* Registration information is available on the website *http://www.hhs.gov/ash/carb/* and must be completed by January 23, 2019; all in-person attendees must pre-register by this date. Additional information about registering for the meeting and providing public comment can be obtained at *http://www.hhs.gov/ash/carb/* on the Meetings page.

DATES: The meeting is scheduled to be held on January 30, 2019, from 9:00 a.m. to 5:00 p.m. and January 31, 2019, from 9:00 a.m. to 5:00 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the website for the Advisory Council at *http://www.hhs.gov/ash/carb/* when this information becomes available. Pre-registration for attending the meeting in person is required to be completed no later than January 23, 2019; public attendance at the meeting is limited to the available space.

ADDRESSES: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Great Hall, 200 Independence Avenue SW, Washington, DC 20201.

The meeting can also be accessed through a live webcast on the day of the meeting. For more information, visit *http://www.hhs.gov/ash/carb/.*

FOR FURTHER INFORMATION CONTACT: Dr. Jomana Musmar, Acting Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Room 715H, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. Phone: (202) 690–5566; email: *CARB@hhs.gov.*

SUPPLEMENTARY INFORMATION: Under Executive Order 13676, dated September 18, 2014, authority was given to the Secretary of HHS to establish the Advisory Council, in consultation with the Secretaries of Defense and Agriculture. Activities of the Advisory Council are governed by the provisions of Public Law 92–463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The Advisory Council will provide advice, information, and recommendations to the Secretary of HHS regarding programs and policies intended to support and evaluate the implementation of Executive Order 13676, including the National Strategy for Combating Antibiotic-Resistant Bacteria and the National Action Plan for Combating Antibiotic-Resistant Bacteria. The Advisory Council shall function solely for advisory purposes.

In carrying out its mission, the Advisory Council will provide advice, information, and recommendations to the Secretary regarding programs and policies intended to preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat antibiotic resistance.

The public meeting will be dedicated to hosting stakeholders to explore priority areas that have emerged since the original National Action Plan on Combating Antibiotic Resistant Bacteria was launched in 2015. The meeting agenda will be posted on the Advisory Council website at *http://www.hhs.gov/ash/carb/* when it has been finalized. All agenda items are tentative and subject to change.

Public attendance at the meeting is limited to the available space. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Advisory Council at the address/telephone number listed above at least one week prior to the meeting. For those unable to attend in person, a live webcast will be available. More information on registration and accessing the webcast can be found at *http://www.hhs.gov/ash/carb/.*

Members of the public will have the opportunity to provide comments prior to the Advisory Council meeting by emailing *CARB@hhs.gov.* Public comments should be sent in by midnight January 23, 2019, and should be limited to no more than one page. All public comments received prior to January 23, 2019, will be provided to Advisory Council members; comments are limited to five minutes per speaker.

Dated: November 16, 2018.

Tammy R. Beckham,

Acting Director, National Vaccine Program Office.

[FR Doc. 2018–25439 Filed 11–21–18; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; NIDA Research Education Program for Clinical Researchers and Clinicians (R25).

Date: November 27, 2018.

Time: 10:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Julia Berzhanskaya, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, Room 4234, MSC 9550, Bethesda, MD 20892, 301–827–5840, *julia.berzhanskaya@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Multi-Site Studies for System-Level Implementation of Substance Use Prevention and Treatment Services (R01; R34).

Date: November 27, 2018.

Time: 1:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Julia Berzhanskaya, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, Room 4234, MSC 9550, Bethesda, MD 20892, 301–827–5840, *julia.berzhanskaya@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Workshops on the Use of Adolescent Brain Cognitive Development (ABCD) Data (R25 Clinical Trial Not Allowed).

Date: November 29, 2018.

Time: 10:00 a.m. to 11:30 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Julia Berzhanskaya, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, Room 4234, MSC 9550, Bethesda, MD 20892, 301–827–5840, *julia.berzhanskaya@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Mechanism for Time-Sensitive Drug Abuse Research (R21 Clinical Trial Optional).

Date: December 5, 2018.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Hiromi Ono, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 4238, MSC 9550, Bethesda, MD 20892, 301–827–5820, *hiromi.ono@nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Advancing Exceptional Research on HIV/AIDS and Substance Abuse (R01, Clinical Trial Optional).

Date: December 13, 2018.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Gerald L. McLaughlin, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Blvd., Room 4238, MSC 9550, Bethesda, MD 20892–9550, 301–827–5819, *gm145a@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: November 16, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–25427 Filed 11–21–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Pharmacokinetic Analysis Resource Center (8947).

Date: January 8, 2019.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive

Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Lyle Furr, Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4227, MSC 9550, 6001 Executive Boulevard, Bethesda, MD 20892–9550, (301) 827–5702, *lf33c.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: November 16, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–25426 Filed 11–21–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Informatics Methodology and Secondary Analyses for Immunology Data in ImmPort.

Date: December 14, 2018.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Paul A. Amstad, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G41, 5601 Fishers Lane, Bethesda, MD 20892–7616, 240–669–5067, *pamstad@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 16, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–25428 Filed 11–21–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning the opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Substance Abuse Prevention and Treatment Block Grant Synar Report Format, FFY 2020–2022—(OMB No. 0930–0222)—Extension

Section 1926 of the Public Health Service Act [42 U.S.C. 300x–26] stipulates that Substance Abuse Prevention and Treatment Block Grant (SABG) funding agreements for alcohol and drug abuse programs for fiscal year 1994 and subsequent fiscal years require states to have in effect a law stating that it is unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18. This section further requires that states conduct annual, random, unannounced inspections to ensure compliance with the law; that the state submit annually a report describing the results of the inspections, the activities carried out by the state to enforce the required law, the success the state has achieved in reducing the availability of tobacco products to individuals under the age of 18, and the strategies to be utilized by the state for enforcing such law during the fiscal year for which the grant is sought.

Before making an award to a state under the SABG, the Secretary must make a determination that the state has maintained compliance with these requirements. If a determination is made that the state is not in compliance, penalties shall be applied. Penalties ranged from 10 percent of the Block Grant in applicable year 1 (FFY 1997 SABG Applications) to 40 percent in applicable year 4 (FFY 2000 SABG Applications) and subsequent years. Respondents include the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, Palau, Micronesia, and the Marshall Islands. Red Lake Indian Tribe is not subject to tobacco requirements.

Regulations that implement this legislation are at 45 CFR 96.130, are approved by OMB under control number 0930–0163, and require that each state submit an annual Synar report to the Secretary describing their progress in complying with section 1926 of the PHS Act. The Synar report, due December 31 following the fiscal year for which the state is reporting, describes the results of the inspections and the activities carried out by the state to enforce the required law; the success the state has achieved in reducing the availability of tobacco products to individuals under the age of 18; and the strategies to be utilized by the state for enforcing such law during the fiscal year for which the grant is sought. SAMHSA's Center for Substance Abuse Prevention will request an extension of OMB approval of the current report format associated with section 1926 (42 U.S.C. 300x–26) to 2022. Extending OMB approval of the current report format will continue to facilitate consistent, credible, and efficient monitoring of Synar compliance across the states.

ANNUAL REPORTING BURDEN

45 CFR citation	Number of respondents [1]	Responses per respondents	Total number of responses	Hours per response	Total hour burden
Annual Report (Section 1—States and Territories) 96.130(e)(1–3)	59	1	59	15	885
State Plan (Section II—States and Territories) 96.130(e)(4,5)96.130(g)	59	1	59	3	177
Total	59		118		1,062

[1] Red Lake Indian Tribe is not subject to tobacco requirements.

Send comments to Summer King, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57–B, Rockville, Maryland 20857, OR email a copy to *summer.king@samhsa.hhs.gov.* Written comments should be received by January 22, 2019.

Summer King,

Statistician.

[FR Doc. 2018–25560 Filed 11–21–18; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer at (240) 276–1243.

Project: Minority AIDS Initiative-Management Reporting Tools (MAI–MRTs)—(OMB No. 0930–0357)—Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention (CSAP) is requesting from the Office of Management and Budget (OMB) approval for the revision of Minority AIDS Initiative (MAI) monitoring tools, which includes both youth and adult questionnaires as well as the quarterly progress report. This revision includes the inclusion of new cohorts, substantial revisions to the youth and adult questionnaires, updates to the data used to estimate response rates and expected numbers of participants by service duration (see Table 1 below).

The cohorts of grantees funded by the MAI and included in this clearance request are:

- Capacity Building Initiative (CBI) 2015
- Capacity Building Initiative (CBI) 2016
- Capacity Building Initiative (CBI) 2017
- Capacity Building Initiative (CBI) 2018
- Prevention Navigators 2017
- Secretary's Minority AIDS Initiative Fund (SMAIF) 2018

The target population for the MAI grantees will be at-risk minority adolescents and young adults. All MAI grantees are expected to report their monitoring data using SAMHSA's Strategic Prevention Framework (SPF) to target minority populations, as well as other high risk groups residing in communities of color with high prevalence of Substance Abuse and HIV/AIDS. The primary objectives of the monitoring tools include:

- Assess the success of the MAI in reducing risk factors and increasing protective factors associated with the transmission of the Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), and other sexually-transmitted diseases (STD).
- Measure the effectiveness of evidence-based programs and infrastructure development activities such as: Outreach and training, mobilization of key stakeholders, substance abuse and HIV/AIDS counseling and education, testing, referrals to appropriate medical treatment and/or other intervention strategies (*i.e.,* cultural enrichment activities, educational and vocational resources, social marketing campaigns, and computer-based curricula).
- Investigate intervention types and features that yield the best outcomes for specific population groups.
- Assess the extent to which access to health care was enhanced for population groups and individuals vulnerable to behavioral health disparities residing in communities targeted by funded interventions.
- Assess the process of adopting and implementing the SPF with the target populations.

Revisions to the monitoring tools include the following:

Quarterly Progress Report (QPR)

- Removed Numbers Served, HIV Testing, VH Testing, VH Vaccination, and Referrals for Services Not Funded by MAI funds from the Implementation Section. These data will be collected via the participant level
- Added opioid items to lists for targeted outcome measures, name of direct services list, indirect services—environmental strategy list and environmental strategy purpose
- Added Promising Approaches and Innovations Section (2 questions)
- Added upload screen for Final Evaluation Report (for closeout grantees only) tool

The following two tools have been added to this data collection, but were approved under OMB No. 0930–0347 with the exception of the new items listed below. Questions removed were non-essential.

Adult Questionnaire

- Aligned questions with the Center for Substance Abuse Treatment (CSAT)/ Center for Mental Health Service (CMHS) tools & the Rapid HIV Hepatitis Form, where possible
- Removed some demographic questions related to language, education, employment status, health, military details, and relationship status
- Removed some knowledge & attitude questions about peer behavior & how they feel about it, sex refusal skills, & HIV knowledge
- Removed some behavior questions related to other tobacco products, electronic vapor products, synthetic marijuana, mental health, and experience with alcohol use
- Added opioid drug questions
- Added questions to capture details on the intervention and the referrals to

the record management section (completed by grantee staff)

Youth Questionnaire

In addition to all items listed above, on the youth questionnaire, SAMHSA also removed non-essential questions related to:

- Interest in school & feelings about ethnic identity
- Relationships with parents or guardians
- Friend substance abuse and sexual behavior
- Exposure to prevention education messages

The following two tools have been deleted from this data collection:

- Indirect Service Outcomes (ISO)
- HIV Testing Retrospective Reporting Tool

Revision made per the 60-day comment period:

(1) Ask about cigarettes and other tobacco products separately. (See questions 26 in the adult questionnaire and 23 in the youth questionnaire for the revisions)

(2) Include brand examples in the help text of the questionnaires to clarify what types of vapor products may be included. (See question 24 in the youth questionnaire and question 27 in the adult questionnaire for the revisions)

TABLE 1—ESTIMATES OF ANNUALIZED HOUR BURDEN

Type of respondent activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Quarterly Progress Report	155	4	620	4	2,480
Adult questionnaire	12,000	2	24,000	.20	4,800
Youth questionnaire	3,000	2	6,000	.20	600
Total	15,155		30,620		7,880

Written comments and recommendations concerning the proposed information collection should be sent by December 24, 2018 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2018–25559 Filed 11–21–18; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2018–0279]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0044

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval for reinstatement, without change, of the following collection of information: 1625–0044, Outer Continental Shelf Activities—Title 33 CFR Subchapter N. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before December 24, 2018.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2018–0279] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* Alternatively, you may submit comments to OIRA using one of the following means:

(1) *Email: dhsdeskofficer@omb.eop.gov.*

(2) *Mail:* OIRA, 725 17th Street NW, Washington, DC 20503, attention Desk Officer for the Coast Guard.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr Ave. SE, Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine

whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG–2018–0279], and must be received by December 24, 2018.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

OIRA posts its decisions on ICRs online at *https://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0044.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (83 FR 45645, September 10, 2018) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments. Accordingly, no changes have been made to the Collections.

Information Collection Request

Title: Outer Continental Shelf Activities—Title 33 CFR Subchapter N.

OMB Control Number: 1625–0044.

Summary: The Outer Continental Shelf Lands Act, as amended, authorizes the Coast Guard to promulgate and enforce regulations promoting the safety of life and property on OCS facilities. These regulations are located in 33 CFR chapter I subchapter N.

Need: The information is needed to ensure compliance with the safety regulations related to OCS activities. The regulations contain reporting and recordkeeping requirements for annual inspections of fixed OCS facilities, employee citizenship records, station bills, and emergency evacuation plans.

Forms: CG–5432, Fixed OCS Facility Inspection Report.

Respondents: Operators of facilities and vessels engaged in activities on the OCS.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 8,441 hours to 9,582 hours a year due to an increase in the estimated annual number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: November 15, 2018.

James D. Roppel,

U.S. Coast Guard, Acting Chief, Office of Information Management.

[FR Doc. 2018–25481 Filed 11–21–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2018–0002; Internal Agency Docket No. FEMA–B–1861]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before February 21, 2019.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location *https://www.fema.gov/preliminaryfloodhazarddata* and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1861, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and are used to calculate the appropriate flood insurance premium

rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://www.floodsrp.org/pdfs/srp_overview.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location *https://www.fema.gov/preliminaryfloodhazarddata* and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

David I. Maurstad,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Lincoln County, Georgia and Incorporated Areas Project: 17–04–4564S Preliminary Date: March 14, 2018	
City of Lincolnton	City Hall, 125 North Peachtree Street, Lincolnton, GA 30817.
Unincorporated Areas of Lincoln	Lincoln County Courthouse, 210 Humphrey Street, Lincolnton, GA 30817.
Bandera County, Texas and Incorporated Areas Project: 14–06–1699S Preliminary Date: June 29, 2018	
City of Bandera	City Hall, 511 Main Street, Bandera, TX 78003.
Unincorporated Areas of Bandera County	Bandera County Engineer's Office, 502 11th Street, Bandera, TX 78003.
Kendall County, Texas and Incorporated Areas Project: 14–06–1699S Preliminary Date: June 29, 2018	
Unincorporated Areas of Kendall County	Kendall County Courthouse, 201 East San Antonio Avenue, Suite 101, Boerne, TX 78006.
Kerr County, Texas and Incorporated Areas Project: 14–06–1699S Preliminary Date: June 29, 2018	
Unincorporated Areas of Kerr County	Kerr County Engineering Office, 3766 State Highway 27, Kerrville, TX 78028.
Medina County, Texas and Incorporated Areas Project: 14–06–1699S Preliminary Date: June 29, 2018	
City of Castroville	City Hall, 1209 Fiorella Street, Castroville, TX 78009.
Unincorporated Areas of Medina County	Medina County Environmental Health Group, 925 Avenue Y, Hondo, TX 78861.

[FR Doc. 2018–25546 Filed 11–21–18; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2018–0002; Internal Agency Docket No. FEMA–B–1866]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The

FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

David I. Maurstad,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Connecticut: Fairfield.	Town of Newtown (18–01–0540P).	The Honorable Dan Rosenthal, First Selectman, Town of Newtown Board of Selectmen, 3 Primrose Street, Newtown, CT 06470.	Town Hall, 3 Primrose Street, Newtown, CT 06470.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 19, 2019	090011
Delaware: Kent	City of Dover (18–03–1850P).	The Honorable Robin R. Christiansen, Mayor, City of Dover, P.O. Box 475, Dover, DE 19903.	Department of Planning and Inspections, 15 Loockerman Plaza, Dover, DE 19901.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 29, 2019	100006
Florida:						
Collier	City of Marco Island (18–04–4433P).	The Honorable Jared Grifoni, Chairman, City of Marco Island Council, 50 Bald Eagle Drive, Marco Island, FL 34145.	Building Department, 50 Bald Eagle Drive, Marco Island, FL 34145.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 1, 2019	120426
Miami-Dade	City of Miami (18–04–4671P).	The Honorable Francis Suarez, Mayor, City of Miami, 3500 Pan American Drive, Miami, FL 33133.	Building Department, 444 Southwest 2nd Avenue, 4th Floor, Miami, FL 33130.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 13, 2019	120650
Monroe	City of Layton (18–04–5816P).	The Honorable Norman S. Anderson, Mayor, City of Layton, P.O. Box 778, Long Key, FL 33001.	Building Department, 68280 Overseas Highway, Long Key, FL 33001.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 8, 2019	120169
Monroe	City of Layton (18–04–5890P).	The Honorable Norman S. Anderson, Mayor, City of Layton, P.O. Box 778, Long Key, FL 33001.	Building Department, 68280 Overseas Highway, Long Key, FL 33001.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 14, 2019	120169

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Monroe	Unincorporated areas of Monroe County (18–04–5923P).	The Honorable David Rice, Mayor, Monroe County Board of Commissioners, 9400 Overseas Highway, Suite 210, Marathon, FL 33050.	Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 19, 2019	125129
Monroe	Village of Islamorada (18–04–5780P).	The Honorable Chris Sante, Mayor, Village of Islamorada, 86800 Overseas Highway, Islamorada, FL 33036.	Planning and Development Department, 86800 Overseas Highway, Islamorada, FL 33036.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 7, 2019	120424
Monroe	Village of Islamorada (18–04–6933P).	The Honorable Chris Sante, Mayor, Village of Islamorada, 86800 Overseas Highway, Islamorada, FL 33036.	Planning and Development Department, 86800 Overseas Highway, Islamorada, FL 33036.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 19, 2019	120424
Orange	City of Orlando (18–04–3956P).	The Honorable Buddy W. Dyer, Mayor, City of Orlando, P.O. Box 4990, Orlando, FL 32802.	Public Works Department, Engineering Division, 400 South Orange Avenue, 8th Floor, Orlando, FL 32801.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 1, 2019	120186
Osceola	City of St. Cloud (18–04–5710P).	Mr. Bill Sturgeon, Manager, City of St. Cloud, 1300 9th Street, St. Cloud, FL 34769.	Public Services Department, 1300 9th Street, St. Cloud, FL 34769.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 7, 2019	120191
Pinellas	Town of Indian Shores (18–04–5445P).	The Honorable Patrick Soranno, Mayor, Town of Indian Shores, 19305 Gulf Boulevard, Indian Shores, FL 33785.	Building Department, 19305 Gulf Boulevard, Indian Shores, FL 33785.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 11, 2019	125118
Polk	Unincorporated areas of Polk County (18–04–6600P).	The Honorable R. Todd Dantzler, Chairman, Polk County Board of Commissioners, 330 West Church Street, Bartow, FL 33831.	Polk County Floodplain Department, 330 West Church Street, Bartow, FL 33831.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 14, 2019	120261
Louisiana:						
Lafayette	Unincorporated areas of Lafayette Parish (18–06–3630P).	The Honorable Joel Robideaux, Mayor-President, Lafayette Consolidated Government, P.O. Box 4017–C, Lafayette, LA 70502.	Lafayette Parish, Department of Planning and Development, 220 West Willow Street, Building B, Lafayette, LA 70501.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 1, 2019	220101
Morehouse	Unincorporated areas of Morehouse Parish (18–06–2764P).	The Honorable Terry Matthews, President, Morehouse Parish Police Jury, 125 East Madison Avenue, Bastrop, LA 71220.	Morehouse Parish Police Jury, 125 East Madison Avenue, Bastrop, LA 71220.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 11, 2019	220367
Maine: York	City of Saco (18–01–0986P).	The Honorable Marston D. Lovell, Mayor, City of Saco, 300 Main Street, Saco, ME 04072.	City Hall, 300 Main Street, Saco, ME 04072.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 4, 2019	230155
New Mexico:						
Bernalillo	City of Albuquerque (18–06–1222P).	The Honorable Timothy M. Keller, Mayor, City of Albuquerque, P.O. Box 1293, Albuquerque, NM 87103.	Planning Department, 600 2nd Street Northwest, Albuquerque, NM 87102.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 11, 2019	350002
Bernalillo	City of Albuquerque (18–06–1705P).	The Honorable Timothy M. Keller, Mayor, City of Albuquerque, P.O. Box 1293, Albuquerque, NM 87103.	Planning Department, 600 2nd Street Northwest, Albuquerque, NM 87102.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 8, 2019	350002
North Carolina: Franklin.	Unincorporated areas of Franklin County (18–04–5161P).	Ms. Angela L. Harris, Manager, Franklin County, 113 Market Street, Louisburg, NC 27549.	Franklin County Planning and Inspections Department, 215 East Nash Street, Louisburg, NC 27549.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 1, 2019	370377
North Dakota: Stark.	City of Dickinson (18–08–0776P).	The Honorable Scott Decker, Mayor, City of Dickinson, 99 2nd Street East, Dickinson, ND 58601.	City Hall, 99 2nd Street East, Dickinson, ND 58601.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 20, 2019	380117
Oklahoma:						
Pottawatomie	City of McLoud (17–06–1163P).	The Honorable Stan Jackson, Mayor, City of McLoud, P.O. Box 300, McLoud, OK 74851.	Pottawatomie County Commissioner's Office, 14101 Acme Road, Shawnee, OK 74801.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 30, 2019	400398

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Pottawatomie	Unincorporated areas of Pottawatomie County (17–06–1163P).	The Honorable John G. Canavan, Jr., Pottawatomie County Judge, 325 North Broadway Avenue, Shawnee, OK 74801.	Pottawatomie County Commissioner's Office, 14101 Acme Road, Shawnee, OK 74801.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 30, 2019	400496
South Carolina: York.	Unincorporated areas of York County (18–04–1779P).	The Honorable Britt Blackwell, Chairman, York County Council, P.O. Box 66, York, SC 29745.	York County Heckle Complex, 1070 Heckle Boulevard, Suite 107, York, SC 29732.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 11, 2019	450193
Texas:						
Bexar	Unincorporated areas of Bexar County (18–06–1356P).	The Honorable Nelson W. Wolff, Bexar County Judge, 101 West Nueva, 10th Floor, San Antonio, TX 78205.	Bexar County Department of Public Works, 233 North Pecos, Suite 420, San Antonio, TX 78207.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 28, 2019	480035
Bexar	Unincorporated areas of Bexar County (18–06–1991P).	The Honorable Nelson W. Wolff, Bexar County Judge, 101 West Nueva, 10th Floor, San Antonio, TX 78205.	Bexar County Department of Public Works, 233 North Pecos, Suite 420, San Antonio, TX 78207.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 28, 2019	480035
Denton	City of Justin (18–06–1570P).	The Honorable David Wilson, Mayor, City of Justin, P.O. Box 129, Justin, TX 76247.	Planning and Zoning Department, 415 North College Avenue, Justin, TX 76247.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 7, 2019	480778
Denton	Unincorporated areas of Denton County (18–06–1570P).	The Honorable Mary Horn, Denton County Judge, 110 West Hickory Street, 2nd Floor, Denton, TX 76201.	Denton County Public Works, Engineering Department, 1505 East McKinney Street, Suite 175, Denton, TX 76209.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 7, 2019	480774
Harris	City of Baytown (18–06–2955P).	The Honorable Stephen DonCarlos, Mayor, City of Baytown, P.O. Box 424, Baytown, TX 77522.	Engineering Department, 2123 Market Street, Baytown, TX 77522.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 22, 2019	485456
Harris	Unincorporated areas of Harris County (18–06–0277P).	The Honorable Edward M. Emmett, Harris County Judge, 1001 Preston Street, Suite 911, Houston, TX 77002.	Harris County Permits Office, 10555 Northwest Freeway, Suite 120, Houston, TX 77092.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 28, 2019	480287
Harris	Unincorporated areas of Harris County (18–06–2955P).	The Honorable Edward M. Emmett, Harris County Judge, 1001 Preston Street, Suite 911, Houston, TX 77002.	Harris County Permits Office, 10555 Northwest Freeway, Suite 120, Houston, TX 77092.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 22, 2019	480287
Travis	City of Pflugerville (18–06–0800P).	The Honorable Victor Gonzales, Mayor, City of Pflugerville, P.O. Box 589, Pflugerville, TX 78691.	Development Services Center, 201–B East Pecan Street, Pflugerville, TX 78691.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 11, 2019	481028
Travis	Unincorporated areas of Travis County (18–06–0800P).	The Honorable Sarah Eckhardt, Travis County Judge, P.O. Box 1748, Austin, TX 78767.	Travis County Transportation and Natural Resources Division, 700 Lavaca Street, Suite 540, Austin, TX 78701.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 11, 2019	481026
Utah: Washington	City of St. George (18–08–0374P).	The Honorable Jonathan T. Pike, Mayor, City of St. George, 175 East 200 North St., George, UT 84770.	City Hall, 175 East 200 North St., George, UT 84770.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 4, 2019	490177

[FR Doc. 2018–25545 Filed 11–21–18; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4400–DR; Docket ID FEMA–2018–0001]

Georgia; Amendment No. 5 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Georgia (FEMA–4400–DR), dated October 14, 2018, and related determinations.

DATES: This amendment was issued November 7, 2018.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Georgia is hereby amended to

include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of October 14, 2018.

Montgomery and Telfair Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018–25527 Filed 11–21–18; 8:45 am]

BILLING CODE 9111–11–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4399–DR; Docket ID FEMA–2018–0001]

Florida; Amendment No. 7 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Florida (FEMA–4399–DR), dated October 11, 2018, and related determinations.

DATES: This amendment was issued November 15, 2018.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Florida is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of October 11, 2018.

Okaloosa and Walton Counties for Public Assistance.

Jefferson and Madison Counties for Public Assistance [Categories C–G] (already designated for debris removal and emergency protective measures [Categories A and B], including direct federal assistance under the Public Assistance program).

Franklin, Holmes, Leon, Taylor, Wakulla, and Washington Counties for Public Assistance [Categories C–G] (already designated for Individual Assistance and assistance for debris removal and emergency protective measures [Categories A and B], including direct federal assistance under the Public Assistance program).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018–25562 Filed 11–21–18; 8:45 am]

BILLING CODE 9111–11–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2018–0002; Internal Agency Docket No. FEMA–B–1864]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before February 21, 2019.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location *https://www.fema.gov/preliminaryfloodhazarddata* and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1864, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov*; or visit the FEMA Map Information eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or

pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://www.floodsrp.org/pdfs/srp_overview.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location *https://www.fema.gov/preliminaryfloodhazarddata* and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

David I. Maurstad,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Maricopa County, Arizona and Incorporated Areas Project: 17–09–0411S Preliminary Date: March 16, 2018	
City of Avondale	City Hall, 11465 West Civic Center Drive, Development and Engineering Services Department, Suite 120, Avondale, AZ 85323.
City of Buckeye	Engineering Department, 530 East Monroe Avenue, Buckeye, AZ 85326.
City of Goodyear	Engineering Department, 14455 West Van Buren Street, Goodyear, AZ 85338.
City of Phoenix	Street Transportation Department, 200 West Washington Street, 5th Floor, Phoenix, AZ 85003.
Town of Gila Bend	Town Hall, 644 West Pima Street, Gila Bend, AZ 85337.
Unincorporated Areas of Maricopa County	Flood Control District of Maricopa County, 2801 West Durango Street, Phoenix, AZ 85009.
Cerro Gordo County, Iowa and Incorporated Areas Project: 16–07–2144S Preliminary Date: May 3, 2018	
City of Clear Lake	Public Works Office, 1419 2nd Avenue South, Clear Lake, IA 50428.
City of Dougherty	City Hall, 81 East Patrick Street, Doughtery, IA 50433.
City of Mason City	City Hall, 10 1st Street Northwest, Mason City, IA 50401.
City of Meservey	City Hall, 428 1st Steet, Meservey, IA 50457.
City of Plymouth	City Hall, 616 Broad Street, Plymouth, IA 50464.
City of Rock Falls	City Hall, 3 South Nottingham Street, Suite 100, Rock Falls, IA 50467.
City of Rockwell	City Hall, 114 3rd Street North, Rockwell, IA 50469.
City of Swaledale	City Hall, 506 Main Street, Swaledale, IA 50477.
City of Thornton	City Hall, 404 Main Street, Thornton, IA 50479.
City of Ventura	City Hall, 101 Sena Street, Ventura, IA 50482.
Unincorporated Areas of Cerro Gordo County	Cerro Gordo County Courthouse, 220 North Washington Avenue, Mason City, IA 50401.

[FR Doc. 2018–25525 Filed 11–21–18; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4400–DR; Docket ID FEMA–2018–0001]

Georgia; Amendment No. 6 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Georgia (FEMA–4400–DR), dated October 14, 2018, and related determinations.

DATES: This amendment was issued November 15, 2018.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency

Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Georgia is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of October 14, 2018.

Hancock and Tattnall Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018–25531 Filed 11–21–18; 8:45 am]

BILLING CODE 9111–11–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2018–0002; Internal Agency Docket No. FEMA–B–1863]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

David I. Maurstad,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Colorado:						

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Denver	City and County of Denver (18–08–1060P).	The Honorable Michael Hancock, Mayor, City and County of Denver, 1437 Bannock Street, Room 350, Denver, CO 80202.	Department of Public Works, 201 West Colfax Avenue, Denver, CO 80202.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 11, 2019	080046
Denver	City of Fountain (17–08–0467P).	The Honorable Gabriel Ortega, Mayor, City of Fountain, 116 South Main Street, Fountain, CO 80817.	Pikes Peak Regional Development Center, 2880 International Circle, Colorado Springs, CO 80910.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 15, 2019	080061
El Paso	Unincorporated areas of El Paso County (17–08–0467P).	The Honorable Darryl Glenn, President, El Paso County Board of Commissioners, 200 South Cascade Avenue, Suite 100, Colorado Springs, CO 80903.	Pikes Peak Regional Development Center, 2880 International Circle, Colorado Springs, CO 80910.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 15, 2019	080059
Connecticut:						
New Haven	City of New Haven (18–01–1588P).	The Honorable Toni N. Harp, Mayor, City of New Haven, 165 Church Street, New Haven, CT 06510.	Planning Department, 165 Church Street, 5th Floor, New Haven, CT 06510.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 18, 2019	090084
Tolland	Town of Mansfield (18–01–0807P).	Mr. Derrik M. Kennedy, Manager, Town of Mansfield, 4 South Eagleville Road, Mansfield, CT 06268.	Town Hall, 4 South Eagleville Road, Mansfield, CT 06268.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 11, 2019	090128
Delaware:						
Kent	Town of Camden (18–03–0719P).	The Honorable Justin T. King, Mayor, Town of Camden, 1783 Friends Way, Camden, DE 19934.	Land Use Department, 1783 Friends Way, Camden, DE 19934.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 9, 2019	100003
Kent	Unincorporated areas of Kent County (18–03–0719P).	The Honorable P. Brooks Banta, President and First District Commissioner, Kent County Levy Court, 555 Bay Road, Dover, DE 19901.	Kent County Inspections and Enforcement Department, 555 Bay Road, Dover, DE 19901.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 9, 2019	100001
Florida:						
Lee	Town of Fort Myers Beach (18–04–4850P).	The Honorable Tracey Gore, Mayor, Town of Fort Myers Beach, 2525 Estero Boulevard, Fort Myers Beach, FL 33931.	Community Development Department, 2525 Estero Boulevard, Fort Myers Beach, FL 33931.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 31, 2019	120673
Lee	Unincorporated areas of Lee County (18–04–5442P).	Mr. Roger Desjarlais, Manager, Lee County, 2120 Main Street, Fort Myers, FL 33901.	Lee County Building Department, 1500 Main Street, Fort Myers, FL 33901.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 17, 2019	125124
Miami-Dade	City of Doral (18–04–3562P).	The Honorable Juan C. Bermudez, Mayor, City of Doral, 8401 NW 53rd Terrace, 2nd Floor, Doral, FL 33166.	City Hall, 8401 Northwest 53rd Terrace, Doral, FL 33166.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 31, 2019	120041
Monroe	City of Marathon (18–04–5518P).	The Honorable Michelle Coldiron, Mayor, City of Marathon, 9805 Overseas Highway, Marathon, FL 33050.	Planning Department, 9805 Overseas Highway, Marathon, FL 33050.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 23, 2019	120681
Monroe	Unincorporated areas of Monroe County (18–04–4672P).	The Honorable David Rice, Mayor, Monroe County Board of Commissioners, 9400 Overseas Highway, Suite 210, Marathon, FL 33050.	Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 28, 2019	125129
Monroe	Unincorporated areas of Monroe County (18–04–5414P).	The Honorable David Rice, Mayor, Monroe County Board of Commissioners, 9400 Overseas Highway, Suite 210, Marathon, FL 33050.	Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 16, 2019	125129
Monroe	Unincorporated areas of Monroe County (18–04–5417P).	The Honorable David Rice, Mayor, Monroe County Board of Commissioners, 9400 Overseas Highway, Suite 210, Marathon, FL 33050.	Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 16, 2019	125129

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Monroe	Village of Islamorada (18–04–5481P).	The Honorable Chris Sante, Mayor, Village of Islamorada, 86800 Overseas Highway, Islamorada, FL 33036.	Planning and Development Department, 86800 Overseas Highway, Islamorada, FL 33036.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 2, 2019	120424
Pinellas	City of St. Petersburg (18–04–5337P).	The Honorable Rick Kriseman, Mayor, City of St. Petersburg, 175 5th Street North, St. Petersburg, FL 33701.	Construction Services and Permitting Department, 1 4th Street North, St. Petersburg, FL 33701.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 28, 2019	125148
Polk	Unincorporated areas of Polk County (18–04–1818P).	The Honorable R. Todd Dantzler, Chairman, Polk County Board of Commissioners, 330 West Church Street, Bartow, FL 33831.	Polk County Floodplain Department, 330 West Church Street, Bartow, FL 33831.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 24, 2019	120261
Georgia: Henry	Unincorporated areas of Henry County (18–04–3824P).	The Honorable June Wood, Chair, Henry County Board of Commissioners, 140 Henry Parkway, McDonough, GA 30253.	Henry County Stormwater Department, 347 Phillips Drive, McDonough, GA 30253.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 31, 2019	130468
Maine: Knox	Town of Owls Head (18–01–1542P).	The Honorable Thomas Von Malder, Chairman, Town of Owls Head Board of Selectmen, 224 Ash Point Drive, Owls Head, ME 04854.	Building Department, 224 Ash Point Drive, Owls Head, ME 04854.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 11, 2019	230075
Massachusetts: Essex.	Town of Rockport (18–01–1042P).	The Honorable Sarah J. Wilkinson, Chair, Town of Rockport Board of Selectmen, 34 Broadway, Rockport, MA 01966.	Department of Inspection Services, 34 Broadway, Rockport, MA 01966.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 9, 2019	250100
Mississippi: Warren	City of Vicksburg (18–04–5020P).	The Honorable George E. Flaggs, Jr., Mayor, City of Vicksburg, 1401 Walnut Street, Vicksburg, MS 39180.	Inspections Department, 819 South Street, Vicksburg, MS 39180.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 2, 2019	280176
Nevada: Clark	Unincorporated areas of Clark County (18–09–0813P).	The Honorable Steve Sisolak, Chairman, Clark County Board of Commissioners, 500 South Grand Central Parkway, Las Vegas, NV 89155.	Clark County Public Works Department, 500 South Grand Central Parkway, Las Vegas, NV 89155.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 25, 2019	320003
New Mexico: Bernalillo.	Unincorporated areas of Bernalillo County (18–06–2313P).	The Honorable Steven Michael Quezada, Chairman, Bernalillo County Board of Commissioners, 1 Civic Plaza Northwest, Albuquerque, NM 87102.	Bernalillo County Public Works Division, 2400 Broadway Boulevard Southeast, Albuquerque, NM 87102.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 14, 2019	350001
North Carolina:						
Alleghany	Town of Sparta (18–04–0634P).	The Honorable Wes Brinegar, Mayor, Town of Sparta, P.O. Box 99, Sparta, NC 28675.	Town Hall, 304 South Main Street, Sparta, NC 28675.	*https://msc.fema.gov/portal/advanceSearch.*	Dec. 6, 2018	370005
Warren	Unincorporated areas of Warren County (18–04–2099P).	The Honorable Victor Hunt, Chairman, Warren County Board of Commissioners, 602 West Ridgeway Street, Warrenton, NC 27589.	Planning, Zoning & Code Enforcement Office, 542 West Ridgeway Street, Warrenton, NC 27589.	*https://msc.fema.gov/portal/advanceSearch.*	Dec. 27, 2018	370396
South Dakota:						
Stanley	City of Fort Pierre (18–08–0148P).	The Honorable Gloria Hanson, Mayor, City of Fort Pierre, P.O. Box 700, Fort Pierre, SD 57532.	Department of Public Works, 08 East 2nd Avenue, Fort Pierre, SD 57532.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 25, 2019	465419
Stanley	Unincorporated areas of Stanley County (18–08–0148P).	The Honorable Dana Iversen, Chair, Stanley County Commission, P.O. Box 595, Fort Pierre, SD 57532.	Stanley County Department of Public Works, 08 East 2nd Avenue, Fort Pierre, SD 57532.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 25, 2019	460287
Texas:						
Bell	City of Temple (18–06–1765P).	The Honorable Tim Davis, Mayor, City of Temple, 2 North Main Street, Suite 103, Temple, TX 76501.	Department of Public Works, Engineering Division, 3210 East Avenue H, Building A, Suite 107, Temple, TX 76501.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 9, 2019	480034
Bell	Unincorporated areas of Bell County (18–06–1765P).	The Honorable Jon H. Burrows, Bell County Judge, P.O. Box 768, Belton, TX 76513.	Bell County Engineering Department, 206 North Main Street, Belton, TX 76513.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 9, 2019	480706

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Bexar	City of Universal City (18–06–1420P).	The Honorable John Williams, Mayor, City of Universal City, 2150 Universal City Boulevard, Universal City, TX 78148.	Stormwater Department, 2150 Universal City Boulevard, Universal City, TX 78148.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 14, 2019	480049
Bexar	Unincorporated areas of Bexar County (18–06–1812P).	The Honorable Nelson W. Wolff, Bexar County Judge, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205.	Bexar County Public Works Department, 233 North Pecos-La Trinidad Street, Suite 420, San Antonio, TX 78207.	*https://msc.fema.gov/portal/advanceSearch.*	Dec. 24, 2018	480035
Collin	City of Allen (18–06–1943P).	Mr. Peter H. Vargas, Manager, City of Allen, 305 Century Parkway, Allen, TX 75013.	Engineering and Traffic Department, 305 Century Parkway, Allen, TX 75013.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 7, 2019	480131
Collin	City of Plano (18–06–1563P).	The Honorable Harry LaRosiliere, Mayor, City of Plano, 1520 K Avenue, Plano, TX 75074.	Engineering Department, 1520 K Avenue, Plano, TX 75074.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 18, 2019	480140
Collin	City of Plano (18–06–1943P).	The Honorable Harry LaRosiliere, Mayor, City of Plano, 1520 K Avenue, Plano, TX 75074.	Engineering Department, 1520 K Avenue, Plano, TX 75074.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 7, 2019	480140
Tarrant	City of Fort Worth (18–06–1064P).	The Honorable Betsy Price, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	Transportation and Public Works Department, 200 Texas Street, Fort Worth, TX 76102.	*https://msc.fema.gov/portal/advanceSearch.*	Dec. 28, 2018	480596
Tarrant	City of Kennedale (18–06–3137X).	The Honorable Brian Johnson, Mayor, City of Kennedale, 405 Municipal Drive, Kennedale, TX 76060.	Planning and Development Department, 405 Municipal Drive, Kennedale, TX 76060.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 3, 2019	480603
Webb	City of Laredo (17–06–3048P).	The Honorable Pete Saenz, Mayor, City of Laredo, 1110 Houston Street, 3rd Floor, Laredo, TX 78040.	Planning and Zoning Department, 1120 San Bernardo Avenue, Laredo, TX 78050.	*https://msc.fema.gov/portal/advanceSearch.*	Jan. 14, 2019	480651

[FR Doc. 2018–25551 Filed 11–21–18; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2018–0065]

Notice of the President's National Infrastructure Advisory Council Meeting

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: Announcement of meeting; request for comments.

SUMMARY: The National Protection and Programs Directorate (NPPD) announces a public meeting of the President's National Infrastructure Advisory Council (NIAC). To facilitate public participation, NPPD invites public comment on the agenda items to be considered by the NIAC at the meeting, a draft report on catastrophic power outages, and the associated briefing materials for the report.

DATES:

Meeting Registration: Individual registration to attend the meeting in person must be received no later than 5 p.m. EST on December 5, 2018.

Written Comments: Written comments must be received no later than 12 p.m. EST on December 12, 2018.

Meeting: The meeting will be held on Thursday, December 13, 2018 from 10 a.m.–1 p.m. EST.

ADDRESSES: The NIAC meeting will be held at the Eisenhower Executive Office Building, 1650 Pennsylvania Ave. NW, Washington, DC 20502.

Public Comments: Written comments may be submitted on the issues to be considered by the NIAC as described in the **SUPPLEMENTARY INFORMATION** section below and the briefing materials for the meeting. The draft report and associated briefing materials will be made publicly available at *https://www.dhs.gov/national-infrastructure-advisory-council* on Friday, December 7, 2018.

Comments identified by docket number ''DHS–2018–0065'' may be submitted by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting written comments.
- *Email: NIAC@hq.dhs.gov.* Include docket number DHS–2018–0065 in the subject line of the message.
- *Fax:* 703–235–9707, ATTN: Ginger K. Norris.
- *Mail:* Ginger K. Norris, Designated Federal Officer, National Infrastructure Advisory Council, National Protection and Programs Directorate, Department of Homeland Security, 245 Murray Lane, Mail Stop 0612, Arlington, VA 20598–0612.

Instructions: All submissions received must include the agency name and docket number for this notice. All written comments received will be posted without alteration at *www.regulations.gov,* including any personal information provided. For detailed instructions on sending comments and additional information on participating in the upcoming NIAC meeting, see the ''PUBLIC PARTICIPATION'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket and comments received by the NIAC, go to *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Ginger K. Norris, 202–441–5885, *ginger.norris@hq.dhs.gov.*

SUPPLEMENTARY INFORMATION: The NIAC is established under Section 10 of E.O. 13231 issued on October 16, 2001. Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. Appendix (Pub. L. 92–463). The NIAC shall provide the President, through the Secretary of Homeland Security, with advice on the security and resilience of the Nation's critical infrastructure sectors.

The NIAC will meet in an open meeting on December 13, 2018 to

receive remarks from DHS leadership and other senior Federal officials regarding their report on Catastrophic Power Outages. Additionally, the NIAC will deliberate and vote on their final recommendations for this current report as tasked by the National Security Council.

Agenda

I. Opening of Meeting

II. Roll Call of Members

III. Opening Remarks and Introductions

IV. Approval of June 2018 Meeting Minutes

V. Public Comment Catastrophic Power Outage Report

VI. Catastrophic Power Outage Report Deliberations

VII. Discussion of New NIAC Business

VIII. Closing Remarks

IX. Adjournment

Public Participation

Meeting Registration Information

Due to limited seating, requests to attend in person will be accepted and processed in the order in which they are received. Individuals may register to attend the NIAC meeting by sending an email to *NIAC@hq.dhs.gov.* For those who cannot attend in person, the meeting's proceedings will also be available via webcast at *www.whitehouse.gov/live.*

Public Comment

While this meeting is open to the public, participation in NIAC deliberations are limited to council members. A public comment period will be held during the meeting from approximately 10:30 a.m.–10:45 a.m. EST. Speakers who wish to comment on the draft catastrophic power outage report must register in advance and can do so by emailing *NIAC@hq.dhs.gov* no later than Wednesday, December 12, 2018, at 5 p.m. EST. Speakers are requested to limit their comments to three minutes. Please note that the public comment period may end before the time indicated, following the last call for comments.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact *NIAC@hq.dhs.gov* as soon as possible.

Dated: November 16, 2018.

Ginger K. Norris,

Designated Federal Officer, National Infrastructure Advisory Council, National Protection and Programs Directorate, Department of Homeland Security.

[FR Doc. 2018–25524 Filed 11–21–18; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6128–N–01]

Notice of Certain Operating Cost Adjustment Factors for 2019

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: This notice establishes operating cost adjustment factors (OCAFs) for project-based assistance contracts issued under Section 8 of the United States Housing Act of 1937 and renewed under the Multifamily Assisted Housing Reform and Affordability Act of 1997 (MAHRA) for eligible multifamily housing projects having an anniversary date on or after February 11, 2019. OCAFs are annual factors used to adjust Section 8 rents renewed under section 515 or section 524 of MAHRA.

DATES: *Applicability Date:* February 11, 2019.

FOR FURTHER INFORMATION CONTACT: Carissa Janis, Program Analyst, Office of Asset Management and Portfolio Oversight, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; telephone number 202–402–2487 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. OCAFs

Section 514(e)(2) and section 524(c)(1) of MAHRA (42 U.S.C. 1437f note) require HUD to establish guidelines for the development of OCAFs for rent adjustments. Sections 524(a)(4)(C)(i), 524(b)(1)(A), and 524(b)(3)(A) of MAHRA, all of which prescribe the use of the OCAF in the calculation of renewal rents, contain similar language. HUD has therefore used a single methodology for establishing OCAFs, which vary among states and territories.

MAHRA gives HUD broad discretion in setting OCAFs, referring, for example, in sections 524(a)(4)(C)(i), 524(b)(1)(A), 524(b)(3)(A) and 524(c)(1) simply to ''an operating cost adjustment factor established by the Secretary.'' The sole limitation to this grant of authority is a specific requirement in each of the foregoing provisions that application of an OCAF ''shall not result in a negative adjustment.'' Contract rents are adjusted by applying the OCAF to that portion of the rent attributable to operating expenses exclusive of debt service.

The OCAFs provided in this notice are applicable to eligible projects having a contract anniversary date of February 11, 2019 or after and were calculated using the same method as those published in HUD's 2018 OCAF notice published on November 2, 2017 (82 FR 50888). Specifically, OCAFs are calculated as the sum of weighted component cost changes for wages, employee benefits, property taxes, insurance, supplies and equipment, fuel oil, electricity, natural gas, and water/sewer/trash using publicly available indices. The weights used in the OCAF calculations for each of the nine cost component groupings are set using current percentages attributable to each of the nine expense categories. These weights are calculated in the same manner as in the November 2, 2017 notice. Average expense proportions were calculated using three years of audited Annual Financial Statements from projects covered by OCAFs. The expenditure percentages for these nine categories have been found to be very stable over time but using three years of data increases their stability. The nine cost component weights were calculated at the state level, which is the lowest level of geographical aggregation with enough projects to permit statistical analysis. These data were not available for the Western Pacific Islands, so data for Hawaii were used as the best available indicator of OCAFs for these areas.

The best current price data sources for the nine cost categories were used in calculating annual change factors. State-level data for fuel oil, electricity, and natural gas from Department of Energy surveys are relatively current and continue to be used. Data on changes in employee benefits, insurance, property taxes, and water/sewer/trash costs are only available at the national level. The data sources for the nine cost indicators selected used were as follows:

- *Labor Costs:* First quarter, 2018 Bureau of Labor Statistics (BLS) ECI, Private Industry Wages and Salaries, All Workers (Series ID CIU2020000000000I) at the national level and Private Industry Benefits, All Workers (Series ID CIU2030000000000I) at the national level.

• *Property Taxes:* Census Quarterly Summary of State and Local Government Tax Revenue—Table 1 *http://www2.census.gov/govs/qtax/20172018/q1t1.xlshttp://www2.census.gov/govs/qtax/2017/q1t1.xls.* 12-month property taxes are computed as the total of four quarters of tax receipts for the period from April through March. Total 12-month taxes are then divided by the number of occupied housing units to arrive at average 12-month tax per housing unit. The number of occupied housing units is taken from the estimates program at the Bureau of the Census. *http://www.census.gov/housing/hvs/data/histtab8.xlsx.*

• *Goods, Supplies, Equipment:* May 2017 to May 2018 Bureau of Labor Statistics (BLS) Consumer Price Index, All Items Less Food, Energy and Shelter (Series ID CUUR0000SA0L12E) at the national level.

• *Insurance:* May 2017 to May 2018 Bureau of Labor Statistic (BLS) Consumer Price Index, Tenants and Household Insurance Index (Series ID CUUR0000SEHD) at the national level.

• *Fuel Oil:* October 2017–March 2018 U.S. Weekly Heating Oil and Propane Prices report. Average weekly residential heating oil prices in cents per gallon excluding taxes for the period from October 2, 2017 through the week of March 26, 2018 are compared to the average from October 3, 2016 through the week of March 27, 2017. For the States with insufficient fuel oil consumption to have separate estimates, the relevant regional Petroleum Administration for Defense Districts (PADD) change between these two periods is used; if there is no regional PADD estimate, the U.S. change between these two periods is used. *http://www.eia.gov/dnav/pet/pet_pri_wfr_a_EPD2F_prs_dpgal_w.htm.*

• *Electricity:* Energy Information Agency, February 2018 ''Electric Power Monthly'' report, Table 5.6.B. *http://www.eia.gov/electricity/monthly/epm_table_grapher.cfm?t=epmt_5_06_b.*

• *Natural Gas:* Energy Information Agency, Natural Gas, Residential Energy Price, 2016–2017 annual prices in dollars per 1,000 cubic feet at the state level. Due to EIA data quality standards several states were missing data for one or two months in 2017; in these cases, data for these missing months were estimated using data from the surrounding months in 2017 and the relationship between that same month and the surrounding months in 2016. *http://www.eia.gov/dnav/ng/ng_pri_sum_a_EPG0_PRS_DMcf_a.htm.*

• *Water and Sewer:* May 2017 to May 2018 Consumer Price Index, All Urban Consumers, Water and Sewer and Trash Collection Services (Series ID CUUR0000SEHG) at the national level.

The sum of the nine cost component percentage weights equals 100 percent of operating costs for purposes of OCAF calculations. To calculate the OCAFs, state-level cost component weights developed from AFS data are multiplied by the selected inflation factors. For instance, if wages in Virginia comprised 50 percent of total operating cost expenses and increased by 4 percent from 2017 to 2018 the wage increase component of the Virginia OCAF for 2019 would be 2.0 percent (50% * 4%). This 2.0 percent would then be added to the increases for the other eight expense categories to calculate the 2019 OCAF for Virginia. For states where the calculated OCAF is less than zero, the OCAF is floored at zero. The OCAFs for 2019 are included as an Appendix to this Notice.

II. MAHRA OCAF Procedures

Sections 514 and 515 of MAHRA, as amended, created the Mark-to-Market program to reduce the cost of federal housing assistance, to enhance HUD's administration of such assistance, and to ensure the continued affordability of units in certain multifamily housing projects. Section 524 of MAHRA authorizes renewal of Section 8 project-based assistance contracts for projects without restructuring plans under the Mark-to-Market program, including projects that are not eligible for a restructuring plan and those for which the owner does not request such a plan. Renewals must be at rents not exceeding comparable market rents except for certain projects. As an example, for Section 8 Moderate Rehabilitation projects, other than single room occupancy projects (SROs) under the McKinney-Vento Homeless Assistance Act (42 U.S.C. 11301 *et seq.*), that are eligible for renewal under section 524(b)(3) of MAHRA, the renewal rents are required to be set at the lesser of: (1) The existing rents under the expiring contract, as adjusted by the OCAF; (2) fair market rents (less any amounts allowed for tenant-purchased utilities); or (3) comparable market rents for the market area.

III. Findings and Certifications

Environmental Impact

This notice sets forth rate determinations and related external administrative requirements and procedures that do not constitute a development decision affecting the physical condition of specific project areas or building sites. Accordingly, under 24 CFR 50.19(c)(6), this notice is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Paperwork Reduction Act

This notice does not impact the information collection requirements already submitted to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). In accordance with the Paperwork Reduction Act, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a currently valid OMB control number.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number for this program is 14.195.

Dated: November 14, 2018.

Brian D. Montgomery,

Assistant Secretary for Housing, Federal Housing Commissioner.

Appendix

OPERATING COST ADJUSTMENT FACTORS FOR 2019

State	OCAF (%)
Alabama	2.9
Alaska	3.5
Arizona	2.7
Arkansas	2.8
California	2.9
Colorado	2.7
Connecticut	3.1
Delaware	2.6
District of Columbia	3.0
Florida	2.9
Georgia	2.9
Hawaii	3.2
Idaho	2.7
Illinois	3.1
Indiana	2.8
Iowa	3.2
Kansas	2.6
Kentucky	2.7
Louisiana	2.6
Maine	3.0
Maryland	2.7
Massachusetts	2.8
Michigan	2.7
Minnesota	3.0
Mississippi	3.0
Missouri	2.6
Montana	2.6
Nebraska	3.0
Nevada	2.7
New Hampshire	3.2
New Jersey	3.1
New Mexico	3.2
New York	3.1
North Carolina	2.6
North Dakota	2.8

OPERATING COST ADJUSTMENT FACTORS FOR 2019—Continued

State	OCAF (%)
Ohio	2.7
Oklahoma	2.7
Oregon	2.6
Pacific Islands	3.2
Pennsylvania	2.9
Puerto Rico	2.6
Rhode Island	2.5
South Carolina	2.7
South Dakota	2.8
Tennessee	2.7
Texas	2.9
Utah	2.6
Vermont	0.9
Virgin Islands	2.5
Virginia	2.6
Washington	2.7
West Virginia	2.6
Wisconsin	3.0
Wyoming	2.7
U.S	2.9

[FR Doc. 2018–25440 Filed 11–21–18; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–ES–2018–N145; MO# 300030113; OMB Control Number 1018–0119]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Policy for Evaluation of Conservation Efforts When Making Listing Decisions (PECE)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service, are proposing to renew an information collection with revisions.

DATES: Interested persons are invited to submit comments on or before December 24, 2018.

ADDRESSES: Send written comments on this information collection request (ICR) to the Office of Management and Budget's Desk Officer for the Department of the Interior by email at *OIRA_Submission@omb.eop.gov;* or via facsimile to (202) 395–5806. Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or by email to *Info_Coll@fws.gov.* Please reference OMB Control Number 1018–0119 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on February 28, 2018 (83 FR 8698). The following comments were received:

Comment 1: Letter dated April 30, 2018, from Myles P. Culhane, Assistant General Counsel, Occidental Petroleum Corporation. Received via email on April 30, 2018.

Occidental Petroleum Corporation provided comments on whether PECE is necessary to the proper functions of the Service, whether we will use the information in a timely manner, and how to enhance the information being collected. They stated that PECE is very important to encourage voluntary conservation efforts prior to listing decisions such that listing may not be necessary. They offered three suggestions to improve information collection in the context of specific listing decisions:

(1) Ensure that we are collecting the right types of information by considering what will be useful in predicting future conservation actions and results, and articulating the factors we think will inform such predictions,

(2) Ensure that we have the ability to update our listing decisions up until the last minute regarding current information about conservation efforts, and

(3) Ensure that PECE analyses are cumulative and include all qualifying conservation efforts together rather than in isolation.

FWS Response to Comment 1: The Service appreciates this comment and does consider the best available scientific and commercial information received through the public comment period, information solicitation, or other means related to conservation efforts when making listing determinations. The Service maintains that in every proposed or final listing decision, we articulate the species' needs, the threats to the species and its response to those threats, and any actions that may ameliorate or exacerbate those threats. Each particular situation is unique, but in the Service's final PECE, we articulated the non-exhaustive list of criteria that we would use to evaluate each conservation effort that did not have a track record of implementation or effectiveness. The Service is required to consider best available scientific and commercial information in making listing decisions, including information on conservation efforts that do not have a track record of implementation or effectiveness. The Service evaluates the certainty of implementation and effectiveness by considering the criteria in the PECE, and those efforts that meet the PECE standard of sufficiently certain to be implemented and effective are then evaluated in the status assessment for the species. The Service understands that stakeholders want a transparent and flexible process, and the Service is open to communication and collaboration with these stakeholders which will encourage conservation of species.

Comment 2: Letter dated April 27, 2018, from Steve Wright, General Manager, Public Utility District No. 1 of Chelan County, WA. Received via email on May, 7, 2018.

Chelan Public Utility District No. 1 commented that it finds PECE useful because it encourages aggregation of information about conservation efforts, which can provide notice to permit applicants and other entities possibly affected by a listing, both of the listing and the efforts. It can also encourage entities to participate in conservation efforts, which can be meaningful for species. It finds that encouraging conservation efforts is consistent with the ESA and benefits species.

FWS Response to Comment 2: The Service appreciates the District's comments about the utility and benefits of PECE.

We are again soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the Service; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Service enhance the quality, utility, and clarity of the

information to be collected; and (5) how might the Service minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: Section 4 of the Endangered Species Act (ESA; 16 U.S.C. 1531 *et seq.*) outlines the process by which we can list a species as a threatened species or an endangered species. When we consider whether to list a species, the ESA requires us to take into account the efforts made by any State or any political subdivision of a State to protect such species. We also take into account the efforts made by other entities. States or other entities often formalize conservation efforts in conservation agreements, conservation plans, management plans, or similar documents. The conservation efforts recommended or described in such documents could prevent some species from becoming so imperiled that they meet the definition of a threatened species or an endangered species under the ESA.

The Policy for Evaluation of Conservation Efforts When Making Listing Decisions (PECE) (68 FR 15100, March 28, 2003) encourages the development of conservation agreements or plans and provides certainty about the standard that an individual conservation effort must meet in order for us to consider whether it is likely to make a difference in a species' status. PECE applies to ''formalized conservation efforts'' that have not been implemented or have been implemented but have not yet demonstrated if they are effective at the time of a listing decision.

Under PECE, formalized conservation efforts are defined as conservation efforts (specific actions, activities, or programs designed to eliminate or reduce threats or otherwise improve the status of a species) identified in a conservation agreement, conservation plan, management plan, or similar document. To assist us in evaluating a formalized conservation effort under PECE, we collect information such as conservation plans, monitoring results, and progress reports. The development of any agreement or plan is voluntary. There is no requirement that the individual conservation efforts included in such documents be designed to meet the standard in PECE. The PECE policy is posted on our Candidate Conservation website at *http://www.fws.gov/endangered/esa-library/pdf/PECE-final.pdf.*

We are not reporting an increase in burden with this renewal, although we revised the collection to include burden for individuals, businesses, and not-for-profit organizations who may develop agreements/plans or may agree to implement certain conservation efforts identified in a State agreement or plan. Previously, we reported all burden estimates as government, although it was possible to receive submissions from individuals and private sector respondents. This submission breaks their burden out separately, with a placeholder of one submission for each category, to account for the rare occasion that we may receive a submission from these additional respondent categories.

Title of Collection: Policy for Evaluation of Conservation Efforts When Making Listing Decisions (PECE).

OMB Control Number: 1018–0119.

Form Number: None.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: Primarily State, local, or Tribal governments. However, individuals, businesses, and not-for-profit organizations could develop agreements/plans or may agree to implement certain conservation efforts identified in a State agreement or plan.

Respondent's Obligation: Required to Obtain or Retain a Benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

Activity	Estimated number of annual respondents	Average number of submissions each	Estimated number of annual responses	Completion time per response (hours)	Estimated annual burden hours
PECE—Reporting					
Individuals	1	1	1	120	120
Private Sector	1	1	1	120	120
Government	5	1	5	120	600
PECE—Monitoring					
Individuals	1	1	1	600	600
Private Sector	1	1	1	600	600
Government	5	1	5	600	3,000
PECE—Development of Conservation Plan/Agreement (One-Time Burden)					
Individuals	1	1	1	2,000	2,000
Private Sector	1	1	1	2,000	2,000
Government	2	1	2	2,000	4,000
Totals	18	.....	18	.....	13,040

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: November 16, 2018.

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2018–25454 Filed 11–21–18; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX19EE000101100]

Public Meeting of the National Geospatial Advisory Committee

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the U.S. Geological Survey (USGS) is publishing this notice to announce that a Federal Advisory Committee meeting of the National Geospatial Advisory Committee will take place.

DATES: The meeting will be held on Thursday, December 6, 2018 from 1:00 p.m. to 4:30 p.m. (Eastern Standard Time).

ADDRESSES: The meeting will be held via web conference and teleconference. Send your comments to Group Federal Officer by email to *gs-faca-mail@usgs.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. John Mahoney, Federal Geographic Data Committee, U.S. Geological Survey, 909 First Avenue, Suite 800, Seattle, WA 98104; by email at *jmahoney@usgs.gov;* or by telephone at (206) 220–4621.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552B, as amended), and 41 CFR 102–3.140 and 102–3.150.

Purpose of the Meeting: The National Geospatial Advisory Committee (NGAC) provides advice and recommendations related to management of Federal and national geospatial programs, the development of the National Spatial Data Infrastructure (NSDI), and the implementation of Office of Management and Budget Circular A–16. The NGAC reviews and comments on geospatial policy and management issues and provides a forum to convey views representative of non-federal stakeholders in the geospatial community. The NGAC meeting is one of the primary ways that the FGDC collaborates with its broad network of partners. Additional information about the NGAC meeting is available at: *www.fgdc.gov/ngac.*

Agenda Topics:

—FGDC Update

—Geospatial Data as Services

—Cultural and Historical Geospatial Resources

—Geospatial Infrastructure

—NSDI Strategic Plan

—Landsat Advisory Group

Meeting Accessibility/Special Accommodations: The webinar meeting is open to the public from 1:00 p.m. to 4:30 p.m. on December 6, 2018. Members of the public wishing to attend the meeting should contact Ms. Lucia Foulkes by email at *lfoulkes@usgs.gov* to register no later than Monday, December 3, 2018. Webinar/conference line instructions will be provided to registered attendees prior to the meeting. Individuals requiring special accommodations to access the public meeting should contact Ms. Lucia Foulkes at the email stated above or by telephone at 703–648–4142 no later than Friday, November 30, 2018 so that appropriate arrangements can be made.

Public Disclosure of Comments: Time will be allowed at the meeting for any individual or organization wishing to make formal oral comments. To allow for full consideration of information by the NGAC members at the meeting, written comments must be provided to Ms. Lucia Foulkes, Federal Geographic Data Committee, U.S. Geological Survey, 12201 Sunrise Valley Drive, MS–590, Reston, VA 20192; by email at *lfoulkes@usgs.gov;* or by telephone at 703–648–4142, no later than Monday, December 3, 2018. Any written comments received will be provided to the NGAC members.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

James Sayer,

Federal Advisory Committee, GPO, Information Management and Delivery, USGS.

[FR Doc. 2018–25561 Filed 11–21–18; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/A0A501010.999900 253G; OMB Control Number 1076–NEW]

Agency Information Collection Activities; Human Capital Management Strengths and Needs Assessment

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Indian Education (BIE) are proposing a new information collection to gain an understanding of processes and practices within BIE schools.

DATES: Interested persons are invited to submit comments on or before January 22, 2019.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to The Bureau of Indian Education, 1011 Indian School Road NW, Suite 332, Albuquerque, NM 87104; or by email to Veronica Lane, *Veronica.Lane@bie.edu.* Please reference OMB Control Number 1076–NEW in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Veronica Lane by email at *Veronica.Lane@bie.edu,* or by telephone at 505–563–5279.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following

issues: (1) Is the collection necessary to the proper functions of the BIE; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the BIE enhance the quality, utility, and clarity of the information to be collected; and (5) how might the BIE minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The purpose of the Human Capital Management Strengths and Needs Assessment process is to gain an understanding of processes and practices within BIE schools in five areas including: Hiring, retention, staff support and development, learning environment, school culture and community engagement. Information will be collected from school staff members, residential staff members, school board members, and parents through online surveys. The goal of collecting this information is to capture the perspective of stakeholders when considering a school's strengths and areas of improvement in relation to human capital functions. The BIE will use the information collected from this process to provide targeted individualized support to schools and to inform institutional change and improvement in areas including but not limited to hiring, professional development, and retention.

Title of Collection: Human Capital Management Strengths and Needs Assessment.

OMB Control Number: 1076–NEW.

Form Number: None.

Type of Review: New.

Respondents/Affected Public: School staff, residential staff, parents, and school board members affiliated with Bureau-funded schools.

Total Estimated Number of Annual Respondents: 380.

Total Estimated Number of Annual Responses: 380.

Estimated Completion Time per Response: Varies from 10 to 40 minutes depending on role of respondent.

Total Estimated Number of Annual Burden Hours: 148 hours.

Respondent's Obligation: Required to Obtain a Benefit.

Frequency of Collection: Annually.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Elizabeth K. Appel,

Director, Office of Regulatory Affairs and Collaborative Action, Indian Affairs.

[FR Doc. 2018–25482 Filed 11–21–18; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/A0A501010.999900 253G]

Proposed Finding Against Federal Acknowledgment of the Southern Sierra Miwuk Nation

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Department of the Interior (Department) gives notice that the Assistant Secretary–Indian Affairs (AS–IA) proposes to determine that the petitioner, Southern Sierra Miwuk Nation (SSM), is not an Indian Tribe within the meaning of Federal law. This notice is based on a determination that SSM does not meet one of the seven mandatory criteria for a government-to-government relationship with the United States. This proposed finding is based on only one criterion.

DATES: Comments on this proposed finding (PF) are due on or before May 22, 2019. We must receive any request for a technical assistance meeting by January 22, 2019. *See* the **SUPPLEMENTARY INFORMATION** section of this notice for more information about these dates.

ADDRESSES: Please address comments on the PF or requests for a copy of the report to the Department of the Interior, Office of the Assistant Secretary–Indian Affairs, Attn: Office of Federal Acknowledgment, 1849 C Street NW, MS–4071 MIB, Washington, DC 20240. Parties who make comments on the PF must also provide a copy of their comments to the petitioner.

FOR FURTHER INFORMATION CONTACT: R. Lee Fleming, Director, Office of Federal Acknowledgment (OFA), (202) 513–7650.

SUPPLEMENTARY INFORMATION: Pursuant to 25 CFR 83.10(h), the Department gives notice that the AS–IA proposes to determine that the Southern Sierra Miwuk Nation (SSM, Petitioner #82), c/o William H. Leonard, 4630 Ben Hur Road, Mariposa, California 95338, is not an Indian Tribe within the meaning of the Federal law. This notice is based on a preliminary finding that the petitioner fails to satisfy one of the seven mandatory criteria for acknowledgement set forth in 25 CFR 83.7(a) through (g), and thus, does not meet the requirements for a government-to-government relationship with the United States.

The Department received a letter of intent from the petitioner under the name ''American Indian Council of Mariposa County'' (AICMC) on April 24, 1982, and designated it Petitioner #82. The petitioner submitted a narrative and partial documentation on April 19, 1984. The Department replied with an ''obvious deficiency'' (OD) review letter on May 1, 1985. The petitioner responded with documentation on December 12, 1986. At the request of the petitioner, the Department sent a second OD review letter on April 11, 1988. The Department received the petitioner's response on January 16, 1998. The Department then placed Petitioner #82 on the ''Ready, Waiting for Active Consideration'' list.

Active consideration began on November 1, 2010, after which the Department asked for an updated membership list and any other materials within 60 days (70 FR 16514). The petitioner requested an ''extension of time to submit documentation,'' and the Department received the petitioner's submission on February 8, 2011, containing documentation, meeting minutes, membership list, articles, newspapers, and governing documents.

During review of Petitioner #82's documented petition, OFA identified technical issues with the petitioner's membership files that needed to be resolved in order to complete the review for the PF. For this reason, the AS–IA extended the original due date for issuance of the PF, from November 1, 2011 to April 30, 2012. During further review, additional technical issues with the petitioner's membership vital records arose, and the AS–IA found good cause to suspend the issuance of the PF under 83.10(g).

On July 31, 2015, the Department issued a final rule that revised the acknowledgment regulations and provided the petitioner the opportunity to choose to complete the evaluation either under the revised 2015 regulations or under the 1994 regulations (80 FR 37862–37895). Petitioner #82 decided to continue with the review of its petition under the 1994 regulations. Active consideration resumed, with the AS–IA ultimately extending the deadline for this PF to November 16, 2018.

Criterion 83.7(b) requires that ''a predominant portion of the petitioning group comprises a distinct community and has existed as a community from historical times until the present.'' Section 83.1 defines ''Community'' as: Any group of people which can demonstrate that consistent interactions and significant social relationships exist within its membership and that its members are differentiated from and identified as distinct from nonmembers.. *Community* must be understood in the context of the history, geography, culture and social organization of the group.'' The definition of ''the present'' is tailored to each petitioner's unique history. For this petitioner, ''the present'' is defined as 1982 (the year when the petitioner submitted its Letter of Intent) to 2011 (the year when the petitioner submitted supplemental membership information).

Evidence in the record shows involvement by some members of the petitioner in group activities, but not by a predominant portion of the membership. Events sponsored by the formal organization are attended by some of the petitioner's members, but also by non-Indians and non-Miwok Indians (some of whom may be closely related to the petitioner but who are enrolled in federally recognized Tribes). Participation in these activities appears to include some members from various families, but it is unclear to what extent this participation represents a cross-section of the entire membership. The record contains very little information regarding how often members interact with each other outside of the functions organized by the group's leadership. The materials and interviews contained few descriptions of members from multiple families socializing at birthday parties, baby showers, graduations, anniversaries, or other events not sponsored by the group's governing body. There is also little to no discussion in the interviews or in any of the documents in the record of members informally looking after each other's children, taking in other members if they were rendered homeless, helping other members to secure employment, or aiding other members in times of sickness or financial hardship.

The evidence in the record is insufficient to demonstrate that Petitioner #82 meets the criterion 83.7(b), one of the seven mandatory criteria of the regulations for a determination that the petitioning group is an Indian Tribe. In accordance with the regulations, the failure to meet all seven criteria requires a determination that the petitioning group is not an Indian Tribe within the meaning of Federal law. *See* 25 CFR 83.6(d) and 25 CFR 83.10(m). Therefore, the Department proposes to decline to acknowledge Petitioner #82 as an Indian Tribe.

According to the AS–IA OFA; Guidance and Direction Regarding Internal Procedures of May 23, 2008:

> If during the evaluation of a petition on active consideration it becomes apparent that the petitioner fails on one criterion, or more, under the reasonable likelihood of the validity of the facts standard, OFA may prepare a proposed finding or final determination not to acknowledge the group on the failed criterion or criteria alone, setting forth the evidence, reasoning, and analyses that form the basis for the proposed decision. (73 FR 30146–30148)

The burden of providing sufficient evidence under the criteria in the regulations rests with the petitioner (25 CFR 83.5(c)). Because Petitioner #82 has not met criterion § 83.(b) as a distinct community, it is not necessary, at this time, for the Department to make conclusions regarding the other six mandatory criteria.

Additionally, due to the fact that the petitioner fails to meet the requirements of 83.7(b) (''the present''), the Department considers it unnecessary to conduct an analysis whether a predominant portion of the group comprised a distinct community and existed as a community from historical times. If additional evidence is provided after the PF is published, the Department may find it necessary to conduct an analysis of community from historical times to the present.

The PF is based on the evidence currently in the record. Additional evidence may be submitted during the comment period that follows publication of this finding. If new evidence provided during the comment period results in a reversal of this conclusion, the AS–IA will issue an amended PF evaluating all seven criteria. (73 FR 30146–30148)

Publication of this notice of the PF in the **Federal Register** initiates a 180-day comment period during which the petitioner and interested and informed parties may submit arguments and evidence to support or rebut the evidence relied upon in the PF. Comments on the PF should be addressed to both the petitioner and the Federal Government as required by 25 CFR 83.10(i) and as instructed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The regulations, 25 CFR 83.10(k), provide the petitioner a minimum of 60 days to respond to any submissions on the PF received from interested and informed parties during the comment period. After expiration of the comment and response periods described above, the Department will consult with the petitioner and interested parties to determine an equitable timeframe for consideration of written arguments and evidence. The Department will notify the petitioner and interested parties of the date such consideration begins. After consideration of the written arguments and evidence rebutting or supporting the PF and the petitioner's response to the comments of interested parties, the AS–IA will either issue an amended proposed finding or make a final determination regarding the petitioner's status. The Department will publish a summary of this determination in the **Federal Register**.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal information from public review, we cannot guarantee that we will be able to do so.

Dated: November 16, 2018.

Tara Sweeney,

Assistant Secretary, Indian Affairs.

[FR Doc. 2018–25487 Filed 11–21–18; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

DEPARTMENT OF AGRICULTURE

Forest Service

[17XL LLIDI00000.L71220000.EO0000. LVTFDX508300 241A 4500117783]

Notice of Availability of Draft Environmental Impact Statement for the Proposed Dairy Syncline Mine and Reclamation Plan, Caribou County, Idaho

AGENCY: Bureau of Land Management, Interior. United States Forest Service, Agriculture.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969 (NEPA), as amended, and the Federal Land Policy Management Act of 1976, as amended, the Bureau of Land Management (BLM) and the Forest Service (USFS) Caribou-Targhee National Forest, have prepared a Draft Environmental Impact Statement (EIS) for the proposed Dairy Syncline Phosphate Mine Project (Project), and by this Notice announce the opening of the comment period.

DATES: To ensure consideration, the Agencies must receive written comments on the Dairy Syncline Mine Project Draft EIS by February 21, 2019. The BLM will announce any future public meetings and any other public involvement activities at least 15 days in advance on our ePlanning website, *https://go.usa.gov/xUjcA.* We may also use other means such as public notices, media news releases, and/or mailings.

ADDRESSES: The public may submit comments related to the Dairy Syncline Mine Project Draft EIS by any of the following methods:

- *website: https://go.usa.gov/xUjcA.*
- *Email: blm_id_dairysynclineeis@blm.gov.*
- *Mail:* Dairy Syncline Mine Draft EIS, c/o Stantec Consulting Services Inc., 3995 South 700 East, Suite 300, Salt Lake City, Utah 84107.

Please reference ''Dairy Syncline Mine Draft EIS'' on all correspondence. CD–ROM and print copies of the Dairy Syncline Mine Draft EIS are available in the BLM Pocatello Field Office at the following address: 4350 Cliffs Drive, Pocatello, ID 83204. In addition, an electronic copy of the Draft EIS is available online at:

- BLM Land Use Planning and NEPA Register: *https://go.usa.gov/xUjcA.*
- Caribou-Targhee National Forest Current and Recent Projects *http://www.fs.usda.gov/projects/ctnf/landmanagement/projects.*

FOR FURTHER INFORMATION CONTACT: Bill Stout, BLM Pocatello Field Office, 4350 Cliffs Drive, Pocatello, ID 83204; phone 208–236–6367; email: *jwstout@blm.gov;* fax 208–478–6376. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 800–877–8339 to contact Mr. Stout. The FRS is available 24 hours a day, 7 days a week, to leave a message or question for Mr. Stout. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The BLM, as the Federal mineral lease administrator, is the lead agency, and the USFS is the co-lead agency for preparation of the Draft EIS, which includes several alternatives. The Idaho Department of Environmental Quality, the Idaho Department of Lands, the U.S. Army Corps of Engineers, and the Idaho Governor's Office of Energy and Mineral Resources are cooperating agencies. J.R. Simplot Company (Simplot) submitted a proposed Mine and Reclamation Plan application for agency consideration to extract phosphate rock from the Dairy Syncline leases (IDI–28115 and IDI–0258) located approximately 14 miles east of Soda Springs, in southeastern Caribou County, Idaho. Simplot submitted its original Dairy Syncline Mine and Reclamation Plan (M&RP) in 2008 and a revised M&RP was submitted in 2013.

The proposal would disturb a total of 2,830 acres as described in the Draft EIS. In one of the alternatives and in order to accommodate the proposed tailings pond, the BLM is considering acceptance of a land donation and offering a land sale, and the USFS is considering a land exchange and acceptance of a land donation. The BLM further describes these two land tenure adjustments in the Draft EIS. The BLM land tenure adjustment would require an amendment to the current Pocatello Resource Management Plan and the land exchange would require a Forest Plan Amendment.

In addition, the BLM and USFS propose seven enlargements (lease modifications) to the existing leases in order to maximize recovery of the leased phosphate resource. Further, eight USFS Special Use Authorizations would be necessary.

The Draft EIS analyzes numerous action alternatives, including an alternate access route, reduced BLM and USFS land tenure adjustments, and an alternative to reduce impacts to water resources. The agency Preferred Alternative is a modified form of the Proposed Action, which includes reducing the size of land tenure adjustments and adopting elements of the selective waste rock handling alternative. The modifications made to the Proposed Action (resulting in the Preferred Alternative) would result in a net gain of Federal land acreage and the fewest impacts to surface and groundwater of all the action alternatives.

A Notice of Intent to prepare this EIS was published in the **Federal Register** on April 13, 2010 (75 FR 18875), initiating a 30-day public scoping period during which the BLM accepted written public comments on the Proposed Action. The scoping process identified concerns involving impacts to water resources and watersheds from potentially elevated levels of selenium and other contaminants in mine waste rock. Other potential effects and/or cumulative effects identified and addressed in the Draft EIS include potential impacts to minerals, paleontology, air quality, climate, soils, vegetation, wildlife, fisheries, grazing, recreation, roadless areas, visual resources, transportation, socioeconomics, tribal treaty rights, and wetlands .

To facilitate an understanding of the project and commenting on the Draft EIS, the lead agencies plan to hold public meetings in Soda Springs, Georgetown, and Pocatello, Idaho. Meetings will be announced as previously described and will be in the open-house format, with displays explaining the Project and a forum for commenting on the Project. Written and electronic comments regarding the Draft EIS should be submitted by February 21, 2019.

The portions of the Project related to USFS decisions are subject to the USFS objection process. Due to the need for a Revised Forest Plan amendment, this proposed Project is subject to the predecisional administrative review process described in 36 CFR 218 subparts A and B and 36 CFR 219 subpart B. Only those who provide comments during this comment period or who have previously submitted specific written comments on the Proposed Action, either during scoping or other designated opportunities for public comment, will be eligible as objectors (see 36 CFR 218.5 (a) and 219.53 (a)).

Before including your phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time.

While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authorities: 42 U.S.C. 4321 *et seq.;* 40 CFR 1500 through 1508; 43 CFR 46; 43 U.S.C. 1701; 43 CFR 3590.

Peter J. Ditton,

State Director, Idaho Bureau of Land Management (Acting).

Mel Bolling,

Forest Supervisor, Caribou-Targhee National Forest.

[FR Doc. 2018–25509 Filed 11–21–18; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–PWR–KAHO–26895; PPPWKAHOS0, PPMPSPD1Z.YM0000]

Na Hoa Pili O Kaloko-Honokohau National Historical Park Advisory Commission Notice of Public Meeting

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the National Park Service (NPS) is hereby giving notice that the Na Hoa Pili O Kaloko-Honokohau National Historical Park Advisory Commission (Commission) will meet as indicated below.

DATES: The Commission will meet on Friday, December 7, 2018, from 9:30 a.m. to 2:30 p.m., with a public comment period at 1:00 p.m. (Hawaii Standard Time).

ADDRESSES: The meeting will be held at the Kaloko-Honokohau National Historical Park Kaloko Picnic area. The Kaloko-Honokohau National Historical Park is located in Kailua Kona, Hawaii 96740.

FOR FURTHER INFORMATION CONTACT: Jeff Zimpfer, Environmental Protection Specialist, Kaloko-Honokohau National Historical Park, 73–4786 Kanalani Street, #14, Kailua Kona, Hawaii 96740, telephone (808) 329–6881, ext. 1500, or email *jeff_zimpfer@nps.gov.*

SUPPLEMENTARY INFORMATION: The park was established by section 505(a) of Public Law 95–625, November 10, 1978, and the Commission was established by section 505(f) of that same law. The Commission was re-established by Title VII, Subtitle E, section 7401 of Public Law 111–11, the Omnibus Public Land Management Act of 2009, March 30, 2009. The Commission's current termination date is December 31, 2018.

The purpose of the Commission is to advise the Director of the National Park Service with respect to the historical, archeological, cultural, and interpretive programs of the park. The Commission is to afford particular emphasis to the quality of traditional native Hawaiian cultural practices demonstrated in the park.

Agenda: The Commission meeting will discuss the following:

1. Approval of Agenda
2. Chairman's Report
3. Superintendent's Report
4. Subcommittee Reports
5. Commission Recommendations

a. In absence of the Commission, what cultural center activities should the NPS and the community focus on in the short-term, medium term, and long-term to carry out the mission of the Park?

b. In the absence of the Commission, how should the NPS engage with the community for insights, feedback, and suggestions to ensure the park's mission is fulfilled as detailed in the park's enabling legislation?

6. Public Comments

All meetings are open to the public. Interested persons may make oral/written presentations to the Commission or file written statements. Such requests should be made to the Superintendent at least seven days prior to the meetings.

Public Disclosure of Information: Before including your address, telephone number, email address, or other personal identifying information in your comments, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. Appendix 2.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2018–25540 Filed 11–21–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NERO–GATE–26866; PPNEGATEB0, PPMVSCS1Z.Y00000]

Gateway National Recreation Area Fort Hancock 21st Century Advisory Committee Notice of Public Meeting

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the National Park Service (NPS) is hereby giving notice that the Gateway National Recreation Area Fort Hancock 21st Century Advisory Committee will meet as indicated below.

DATES: The meeting will take place on Friday, December 7, 2018 from 9:00 a.m. until 3:00 p.m., with a public comment period at 11:30 a.m. (Eastern).

ADDRESSES: The meeting will be held at the Northeast Fisheries Science Center James J. Howard Marine Sciences Laboratory, 74 Magruder Road, Sandy Hook Highlands, New Jersey 07732.

FOR FURTHER INFORMATION CONTACT: Daphne Yun, Acting Public Affairs Officer, Gateway National Recreation Area, 210 New York Avenue, Staten Island, New York 10305, or by telephone (718) 815–3651, or by email *daphne_yun@nps.gov.*

SUPPLEMENTARY INFORMATION: The Committee was established on April 18, 2012, by authority of the Secretary of the Interior (Secretary) under 54 U.S.C. 100906, and is regulated by the Federal Advisory Committee Act. The Committee provides advice to the Secretary, through the Director of the National Park Service, on matters relating to the Fort Hancock Historic District of Gateway National Recreation Area. All meetings are open to the public.

Purpose of the Meeting: The agenda will include an update on the leasing program, and a general park update.

The Committee website, *https://www.forthancock21.org,* includes summaries from all prior meetings. Interested persons may present, either orally or through written comments, information for the Committee to consider during the public meeting. Written comments will be accepted prior to, during, or after the meeting.

Due to time constraints during the meeting, the Committee is not able to read written public comments submitted into the record. Individuals or groups requesting to make oral comments at the public Committee meeting will be limited to no more than five minutes per speaker. All comments will be made part of the public record and will be electronically distributed to all Committee members.

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your written comments, you should be aware that your entire comment including your personal identifying information will be publicly available. While you can ask us in your comment to withhold your personal identifying information

from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. Appendix 2.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2018–25541 Filed 11–21–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NRSS–BRD–; PPWONRADB0PPMRSNR1Y.NM0000]; OMB Control Number 1024–0275]

Agency Information Collection Activities; Using Web and Mobile-Based Applications During NPS Citizen Science Events

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection request; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing to renew an information collection with revisions.

DATES: Interested persons are invited to submit comments on or before January 22, 2019.

ADDRESSES: Send your comments on this Information Collection Request (ICR) by mail to Phadrea Ponds, Acting, Information Collection Clearance Officer, National Park Service, 1201 Oakridge Drive, Fort Collins, CO 80525 (mail); or *phadrea_ponds@nps.gov* (email). Please reference Information Collection Request 1024– 0275 in the subject line.

FOR FURTHER INFORMATION CONTACT: To request additional information about this IC, contact Kriston Barnes, Natural Resource Stewardship and Science Directorate, National Park Service, 1201 Oakridge Dr., Suite 200, Fort Collins, CO 80525 (mail); *kriston_barnes@nps.gov* (email); or: 970–658–6013 (phone).

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed information collection request (ICR) that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the NPS; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the NPS enhance the quality, utility, and clarity of the information to be collected; and (5) how might the NPS minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this IC. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The NPS is authorized by the National Park Service Protection Interpretation and research in System (54 U.S.C. 100701) to collect this information. The NPS is requesting approval to use mobile and web-based applications (*e.g.,* iNaturalist, eBird, etc) as a means to collect natural history observational information from park visitors during citizen science events. The information will be used to substantiate the occurrence of plant, wildlife and invertebrate species within NPS units during these events. By using citizen science applications, this information will be immediately available to all parks and others interested in species identification and advancing the knowledge of the natural world. Using mobile and web-based applications will enable parks to increase the number of natural history observation records that will contribute to greater understanding of the biodiversity within the park systems.

Title of Collection: Using web and mobile-based applications during NPS Citizen Science events.

OMB Control Number: 1024–0275.

Form Number: None.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: General public, individual households, and non-federal scientists.

Total Estimated Number of Annual Respondents: 5,000.

Total Estimated Number of Annual Responses: 2,500 (2,000 public and 500 non-federal scientists.

Estimated Completion Time per Response: 50 minutes.

Total Estimated Number of Annual Burden Hours: 2,083 hours.

Respondent's Obligation: Voluntary.

Frequency of Collection: One time.

Total Estimated Annual Non-Hour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

Phadrea D. Ponds,

Acting, NPS Information Collections Clearance Officer, National Park Service.

[FR Doc. 2018–25430 Filed 11–21–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–CR–NR–NHL–FR00000038; PPWOCRADI0, PCU00RP14.50000; OMB Control Number 1024–0276]

Agency Information Collection Activities; National Historic Landmarks Nomination Form

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection request; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before January 22, 2019.

ADDRESSES: Send comments on this Information Collection Request (ICR) to Phadrea D. Ponds, Information Collection Clearance Officer, National Park Service, 1201 Oakridge Drive, Fort Collins, CO 80525; or by email to *phadrea_ponds@nps.gov.* Please reference OMB Control Number 1024–0276 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Patty Henry by email at *patty_henry@nps.gov,* or by telephone at 202–354–2216.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the

general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed information collection request (ICR) that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the NPS, (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the NPS enhance the quality, utility, and clarity of the information to be collected; and (5) how might the NPS minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The NPS is authorized by Historic Sites Act of 1935 (54 U.S.C. 320101 *et seq.*); 36 CFR part 65; the National Historic Preservation Act of 1966 (54 U.S.C. 300101 *et seq.*) to collect this information on behalf of the Secretary of the Interior. In accordance with the law and 36 CFR part 65, private citizens, businesses, and organizations; Federal agencies (FPO); State and local public agencies; State Historic Preservation Officers (SHPOs); territories; and Indian tribes (THPO) may submit nominations for National Historic Landmark (NHL) designation.

All interested parties must inquire by letter or email about the eligibility of properties to be considered for NHL designation. The inquiry will include the name and location of property, brief historical summary of property, and brief description of property. If determined eligible for consideration the respondent will use NPS Form 10–934 (National Historic Landmarks Nomination Form) to nominate a property. The form is used to collect the following information: (1) Name and location of property; (2) significance data related to the property; (3) any withholding of sensitive information; (4) geographical data; (5) significance statement and discussion about the property; (6) property description and statement of integrity; (7) major bibliographic references; and (8) name, organization, address, phone number, and email of the person completing the form.

Title of Collection: National Historic Landmarks Nomination Form.

OMB Control Number: 1024–0276.

Form Number: NPS Form 10–934.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Private individuals; state, tribal and local governments; businesses; educational institutions; and nonprofit organizations

Total Estimated Number of Annual Respondents: 30.

Total Estimated Number of Annual Responses: 10,320.

Estimated Completion Time per Response: Varies from 239 hours to 520 hours, depending on respondent and/or activity.

Total Estimated Number of Annual Burden Hours: 10,320.

Respondent's Obligation: Required to obtain or retain benefits.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

Requirement	Annual number of responses	Total annual burden hours
Letter of Inquiry:		
Individuals	3	6
Private Sector	7	14
Government	10	20
Nominations	30	10,320
Totals	50	10,360

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea D. Ponds,

Acting, NPS Information Collection Clearance Officer, National Park Service.

[FR Doc. 2018–25431 Filed 11–21–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR03042000, 18XR0680A1, RX.18786000.1501100; OMB Control Number 1006–0015]

Agency Information Collection Activities; Diversions, Return Flow, and Consumptive Use of Colorado River Water in the Lower Colorado River Basin

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Reclamation (Reclamation), are proposing to renew an information collection with revisions.

DATES: Interested persons are invited to submit comments on or before January 22, 2019.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Mr. Paul Matuska, Bureau of Reclamation, Boulder Canyon Operations Office, Water Accounting and Verification Group, LC–4200, P.O. Box 61470, Boulder City, NV 89006; or by email to *pmatuska@usbr.gov.* Please reference OMB Control Number 1006–0015 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about

this ICR, contact Paul Matuska by email at *pmatuska@usbr.gov,* or by telephone at 702–293–8164.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of Reclamation; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might Reclamation enhance the quality, utility, and clarity of the information to be collected; and (5) how might Reclamation minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Bureau of Reclamation delivers Colorado River water to water users for diversion and beneficial consumptive use in the States of Arizona, California, and Nevada. The Consolidated Decree of the United States Supreme Court in the case of *Arizona* v. *California, et al.,* entered March 27, 2006 (547 U.S. 150 (2006)), requires the Secretary of the Interior to prepare and maintain complete, detailed, and accurate records of diversions of water, return flow, and consumptive use and make these records available at least annually. The information collected ensures that a State or a water user within a State does not exceed its authorized use of Colorado River water. Water users are obligated by provisions in their water delivery contracts to provide Reclamation information on diversions and return flows. Reclamation determines the consumptive use by subtracting return flow from diversions or by other engineering means.

Title of Collection: Diversions, Return Flow, and Consumptive Use of Colorado River Water in the Lower Colorado River Basin.

OMB Control Number: 1006–0015.

Form Number: LC–2A, LC–2B, Custom Forms.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: The respondents will include the Lower Basin States (Arizona, California, and Nevada), local and tribal entities, water districts, and individuals that use Colorado River water.

Total Estimated Number of Annual Respondents: 53.

Total Estimated Number of Annual Responses: 306.

Estimated Completion Time per Response: See table.

Total Estimated Number of Annual Burden Hours: 51 hours.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Monthly, annually, or otherwise as stipulated by the entity's water delivery contract with the Secretary of the Interior.

Total Estimated Annual Non-hour Burden Cost: 0.

Monthly/annual	Form No.	Number of respondents	Minutes/ response	Number responses/ respondent	Total hours/ year	Total responses/ year
Annual	LC–72A	1	10	1	0.17	1
Annual	LC–72B	12	10	1	2	12
Monthly	Custom Forms	23	10	12	46	276
Annual	Custom Forms	17	10	1	2.8	17
Total		53			51	306

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: October 26, 2018.

Terrance J. Fulp,

Regional Director, Lower Colorado Region.

[FR Doc. 2018–25498 Filed 11–21–18; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1053]

Certain Two-Way Radio Equipment and Systems, Related Software and Components Thereof; Commission Decision To Affirm-in-Part, Modify-in-Part, Reverse-in-Part, and Strike Certain Portions of a Final Initial Determination Finding a Violation of Section 337; Issuance of Limited Exclusion Order and Cease and Desist Orders; and Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to affirm-in-part, modify-in-part, reverse-in-part, and strike certain portions of a final initial determination (''ID'') of the presiding administrative law judge (''ALJ''). Accordingly, the Commission has determined that a violation of section 337 has occurred in the above-captioned investigation, and has issued a limited exclusion order directed against infringing two-way radio products and cease and desist orders directed against two domestic respondents found in violation. The Commission has terminated the investigation.

FOR FURTHER INFORMATION CONTACT: Clint Gerdine, Esq., Office of the General Counsel, U.S. International

Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–2310. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on May 3, 2017, based on a complaint filed on behalf of Motorola Solutions, Inc. (''Motorola'') of Chicago, Illinois. 82 FR 20635–36. The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, by reason of infringement of certain claims of U.S. Patent Nos.: 8,116,284 (''the '284 patent''); 7,369,869 (''the '869 patent''); 7,729,701 (''the '701 patent''); 8,279,991 (''the '991 patent''); 9,099,972 (''the '972 patent''); 8,032,169 (''the '169 patent''); and 6,591,111 (''the '111 patent''). The Commission's Notice of Investigation named as respondents Hytera Communications Corp. Ltd. of Shenzhen, China; Hytera America, Inc. (''Hytera America'') of Miramar, Florida; and Hytera Communications America (West), Inc. (''Hytera Communications America'') of Irvine, California (collectively, ''Hytera''). The Office of Unfair Import Investigations is not participating in the investigation. *Id.*

On September 18, 2017, the Commission issued notice of its determination not to review an ID (Order No. 10) terminating the investigation as to: (1) Claims 2, 5, 10, and 16 of the '284 patent; (2) claims 2–3, 8, 12, 14–15, 20, 22–24, and 30 of the '169 patent; (3) claims 5, 8, 11–14, 18, and 22 of the '869 patent; (4) claims 3, 5, 8–10, 15, and 17–18 of the '701 patent; (5) claim 3 of the '972 patent; and (6) claims 3–5, 8–10, and 14 of the '111 patent. On October 17, 2017, the Commission issued notice of its determination not to review an ID (Order No. 16) terminating the investigation as to claim 10 of the '869 patent. On November 14, 2017, the Commission issued notice of its determination not to review an ID (Order No. 19) terminating the investigation as to: (1) Claims 1, 4, 12, and 18 of the '284 patent; (2) claims 4, 13, 16, and 25 of the '169 patent; (3) claims 3–4, 9, 19–20, and 23–24 of the '869 patent; (4) claims 2, 4, and 14 of the '701 patent; (5) claims 4 and 8 of the '972 patent; (6) claims 6 and 12 of the '111 patent; and (7) claim 19 of the '991 patent for the purposes of satisfying the technical prong of the domestic industry requirement.

On December 4, 2017, the Commission issued notice of its determination not to review an ID (Order No. 21) terminating the investigation as to claims 5 and 18 of the '169 patent. On January 3, 2018, the Commission issued notice of its determination not to review an ID (Order No. 23) terminating the investigation as to: (1) The '111 and '169 patents; (2) claims 2 and 7 of the '869 patent; and (3) claims 7–8 and 19 of the '284 patent. On the same date, the Commission issued notice of its determination not to review an ID (Order No. 24) terminating the investigation as to claim 1 of the '701 patent. On February 6, 2018, the Commission issued notice of its determination not to review an ID (Order No. 31) terminating the investigation as to the following patent claims: (1) Claim 13 of the '701 patent; (2) claim 6 of the '284 patent; and (3) claim 1 of the '972 patent. On February 26, 2018, the Commission issued notice of its determination not to review an ID (Order No. 40) terminating the investigation as to the '972 patent.

On January 26, 2018, the ALJ issued Order No. 38 which granted Motorola's motion *in limine* to preclude Hytera's licensing defense. On May 18, 2018, the ALJ issued Order No. 47, which granted-in-part Motorola's motion to strike certain portions of Hytera's expert testimony at the evidentiary hearing. On July 3, 2018, the ALJ issued her final ID and recommended determination (''RD'') on remedy and bonding in one document. The ID finds that Hytera's accused products infringe claims 1, 6, 17, and 21 of the '869 patent; claims 1 and 11 of the '701 patent; and claims 7–8 of the '991 patent. The ID also finds that Hytera's accused legacy products literally infringe claims 9 and 13–15 of the '284 patent and that Hytera's accused redesigned products infringe these claims under the doctrine of equivalents. The ID also finds that Hytera induced infringement of and contributorily infringed all of the claims of the asserted patents. As part of the ID's finding of indirect infringement, the ID applied an adverse inference against Hytera for certain of its witnesses' invocation of their Fifth Amendment right against self-incrimination. The ID also finds that Motorola satisfies the domestic industry requirement with respect to the '869, '701, and '991 patents, but that its domestic products do not satisfy the technical prong of the domestic industry requirement with respect to the '284 patent. Accordingly, the ID finds a violation of section 337 with respect to the '869, '701, and '991 patents. The RD recommended the issuance of limited exclusion orders directed against Hytera's infringing products and cease and desist orders directed against two domestic Hytera respondents.

On July 17, 2018, Motorola and Hytera petitioned for review of the final ID. Hytera's petition for review included a petition for review of Order Nos. 38 and 47. On July 25, 2018, Motorola and Hytera each filed a response in opposition to the other party's petition for review. On August 6 and 7, 2018, respectively, Hytera and Motorola filed statements on the public interest. On August 10, 2018, the Commission received statements on the public interest from interested non-parties.

On September 4, 2018, the Commission issued notice of its determination to review the following: (1) Order No. 38's finding that Hytera's licensing defense is precluded; (2) Order No. 47's finding that certain expert testimony from Hytera at the evidentiary hearing is stricken; (3) the ID's finding that Hytera's accused redesigned products infringe claims 9 and 13–15 of the '284 patent under the doctrine of equivalents; (4) the ID's application of an adverse inference against Hytera as part of the finding of indirect infringement; and (5) the ID's finding that insufficient record evidence exists to make a conclusive determination as to whether any redesigned products infringe the '701 patent and ID's lack of an express finding on this issue with respect to the '869 or '991 patent. The Commission determined not to review the remainder of the final ID. The determinations made in the final ID that were not reviewed became final determinations of the Commission by operation of rule. *See* 19 CFR 210.43(h)(2). The Commission also (1) requested the parties to respond to certain questions concerning the issues under review; and (2) requested written submissions on the issues of remedy, the public interest, and bonding from the parties, interested government agencies, and interested non-parties, including requesting the parties to respond to certain questions concerning the public interest. 83 FR 45679–81 (Sept. 10, 2018).

On September 18 and 25, 2018, respectively, complainant and respondents each filed a brief and a reply brief on all issues for which the Commission requested written submissions. The Commission also received written submissions on the public interest from interested non-parties on September 18, 2018.

Having reviewed the record in this investigation, including the final ID and the parties' written submissions, the Commission has determined to affirm-in-part, reverse-in-part, modify-in-part, and strike certain portions of the final ID's findings under review. Specifically, the Commission has: (1) Reversed the ID's finding that Hytera's accused redesigned products infringe claims 9 and 13–15 of the '284 patent under the doctrine of equivalents; (2) struck the first and second sentences of the fourth paragraph on page 8 in Order No. 38, and struck the third sentence of this paragraph ''There is no analysis'' and substituted ''There is no analysis in Dr. Akl's Report,'' and struck the second sentence of the first full paragraph on page 9 of Order No. 38; (3) affirmed Order No. 47 and supplemented and clarified its reasoning; (4) took no position on the ID's drawing of an adverse inference against Hytera as part of its finding of indirect infringement; and (5) found that Hytera's redesigned products do not infringe the '701, '869, or '991 patents. Accordingly, the Commission has found that there is a violation of section 337 with respect to the '991, '869, and '701 patents.

Having found a violation of section 337 as to these patents, the Commission has made its determination on the issues of remedy, the public interest, and bonding. The Commission has determined that the appropriate form of relief is (1) a limited exclusion order prohibiting the unlicensed entry of two-way radio equipment and systems, related software and components thereof that infringe one or more of claims 1, 6, 17, and 21 of the '869 patent; claims 1 and 11 of the '701 patent; and claims 7–8 of the '991 patent, which are manufactured abroad by or on behalf of, or are imported by or on behalf of, Hytera, or any of its affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns; and (2) cease and desist orders prohibiting Hytera America or Hytera Communications America from conducting any of the following activities in the United States: Importing, selling, marketing, advertising, distributing, offering for sale, transferring (except for exportation), and soliciting U.S. agents or distributors for two-way radio equipment and systems, related software and components thereof that infringe one or more of claims 1, 6, 17, and 21 of the '869 patent; claims 1 and 11 of the '701 patent; and claims 7–8 of the '991 patent.

The Commission further determined that the public interest factors enumerated in section 337(d)(1) and (f)(1) (19 U.S.C. 1337(d)(1), (f)(1)) do not preclude issuance of the limited exclusion order or cease and desist orders. Finally, the Commission determined that a bond of 44 percent of the entered value of the covered products is required to permit temporary importation during the period of Presidential review (19 U.S.C. 1337(j)). The Commission has also issued an opinion explaining the basis for the Commission's action. The Commission's order and opinion were delivered to the President and to the United States Trade Representative on the day of their issuance. The investigation is terminated.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in part 210 of the Commission's Rules of Practice and Procedure, 19 CFR part 210.

By order of the Commission.

Issued: November 16, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018–25463 Filed 11–21–18; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. TA–131–044 and TPA–105–005]

U.S.-EU Trade Agreement: Advice on the Probable Economic Effect of Providing Duty-Free Treatment for Currently Dutiable Imports; Institution of Investigation and Scheduling of Hearing

AGENCY: United States International Trade Commission.

ACTION: Notice of investigation and scheduling of a public hearing.

SUMMARY: Following receipt on November 9, 2018, of a request from the United States Trade Representative (USTR) for a report containing advice and an assessment, the Commission instituted Investigation Nos. TA–131–044 and TPA–105–005, *U.S.-EU Trade Agreement: Advice on the Probable Economic Effect of Providing Duty-free Treatment for Currently Dutiable Imports.*

DATES: December 6, 2018: Deadline for filing requests to appear at the public hearing.

December 10, 2018: Deadline for filing prehearing briefs and statements.

December 18, 2018: Public hearing.

January 4, 2019: Deadline for filing post-hearing briefs and submissions.

January 4, 2019: Deadline for filing all other written statements.

March 19, 2019: Transmittal of Commission report to the USTR.

ADDRESSES: All Commission offices, including the Commission's hearing rooms, are located in the U.S. International Trade Commission Building, 500 E Street SW, Washington, DC. All written submissions should be addressed to the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Project Leader Diana Friedman (202–205–3433 or *diana.friedman@usitc.gov*) or Deputy Project Leader Mary Roop (202–708–2277 or *mary.roop@usitc.gov*) for information specific to this investigation. For information on the legal aspects of this investigation, contact William Gearhart of the Commission's Office of the General Counsel (202–205–3091 or *william.gearhart@usitc.gov*). The media should contact Margaret O'Laughlin, Office of External Relations (202–205–1819 or *margaret.olaughlin@usitc.gov*). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its website (*https://www.usitc.gov*). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

SUPPLEMENTARY INFORMATION:

Background: In his letter of November 8, 2018, the USTR requested that the Commission provide certain advice under section 131 of the Trade Act of 1974 (19 U.S.C. 2151) and an assessment under section 105(a)(2)(B)(i)(III) of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 (19 U.S.C. 4204(a)(2)(B)(i)(III)) with respect to the effects of providing duty-free treatment for imports of products from the EU.

More specifically, the USTR, under authority delegated by the President and

pursuant to section 131 of the Trade Act of 1974, requested that the Commission provide a report containing its advice as to the probable economic effect of providing duty-free treatment for imports of currently dutiable products from the EU on (i) industries in the United States producing like or directly competitive products, and (ii) consumers. The USTR asked that the Commission's analysis consider each article in chapters 1 through 97 of the *Harmonized Tariff Schedule of the United States* (HTS) for which U.S. tariffs will remain, taking into account implementation of U.S. commitments in the World Trade Organization. The USTR asked that the advice be based on the HTS in effect during 2018 and trade data for 2017.

In addition, the USTR requested that the Commission prepare an assessment, as described in section 105(a)(2)(B)(i)(III) of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015, of the probable economic effects of eliminating tariffs on imports from the EU of those agricultural products described in the list attached to the USTR's request letter on (i) industries in the United States producing the products concerned, and (ii) the U.S. economy as a whole. The USTR's request letter and list of agricultural products are posted on the Commission's website at *https://www.usitc.gov.*

For the purposes of these analyses, the USTR requested that the Commission assume that the United Kingdom will no longer be a Member State of the EU. The USTR indicated that those sections of the Commission's report that relate to the advice and assessment of probable economic effects will be classified. The USTR also indicated that he considers the Commission's report to be an interagency memorandum that will contain pre-decisional advice and be subject to the deliberative process privilege. As requested, the Commission will provide its report to USTR as soon as possible, which is March 19, 2019.

Public Hearing: A public hearing in connection with this investigation will be held at the U.S. International Trade Commission Building, 500 E Street SW, Washington, DC, beginning at 9:30 a.m. on Tuesday, December 18, 2018. Requests to appear at the public hearing should be filed with the Secretary no later than 5:15 p.m., Thursday, December 6, 2018, in accordance with the requirements in the ''Written Submissions'' section below. All prehearing briefs and statements should be filed not later than 5:15 p.m., Monday, December 10, 2018, and all post-hearing briefs and statements should be filed not later than 5:15 p.m., Friday, January 4, 2019. For further information, call 202–205–2000.

Written Submissions: In lieu of or in addition to participating in the hearing, interested parties are invited to file written submissions concerning this investigation. All written submissions should be addressed to the Secretary, and should be received not later than 5:15 p.m., January 4, 2019. All written submissions must conform to the provisions of section 201.8 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.8). Section 201.8 and the Commission's Handbook on Filing Procedures require that interested parties file documents electronically on or before the filing deadline and submit eight (8) true paper copies by 12:00 p.m. Eastern Time on the next business day. In the event that confidential treatment of a document is requested, interested parties must file, at the same time as the eight paper copies, at least four (4) additional true paper copies in which the confidential information must be deleted (see the following paragraphs for further information regarding confidential business information). Persons with questions regarding electronic filing should contact the Office of the Secretary, Docket Services Division (202–205–1802).

Confidential Business Information: Any submissions that contain confidential business information must also conform to the requirements of section 201.6 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the ''confidential'' or ''non-confidential'' version, and that the confidential business information is clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available for inspection by interested parties.

The Commission may include some or all of the confidential business information submitted in the course of this investigation in the report it sends to the USTR. Additionally, all information, including confidential business information, submitted in this investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel (a) for cybersecurity purposes or (b) in monitoring user activity on U.S. government classified networks. The Commission will not otherwise disclose any confidential business information in a way that would reveal the operations of the firm supplying the information.

Summaries of Written Submissions: Persons wishing to have a summary of their position included in the report should include a summary with their written submission and should mark the summary as having been provided for that purpose. The summary should be clearly marked as ''summary'' at the top of the page. The summary may not exceed 500 words, should be in MS Word format or a format that can be easily converted to MS Word, and should not include any confidential business information. The summary will be published as provided if it meets these requirements and is germane to the subject matter of the investigation. The Commission will list the name of the organization furnishing the summary and will include a link to the Commission's Electronic Document Information System (EDIS) where the full written submission can be found.

By order of the Commission.
Issued: November 20, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018–25677 Filed 11–21–18; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of the Federal Unemployment Tax Act (FUTA) Credit Reduction Applicable in 2018

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: Sections 3302(c)(2)(A) and 3302(d)(3) of the FUTA provide that employers in a State that has outstanding advances under Title XII of the Social Security Act on January 1 of two or more consecutive years are subject to a reduction in credits otherwise available against the FUTA tax for the calendar year in which the most recent such January 1 occurs, if advances remain on November 10 of that year. Further, Section 3302(c)(2)(C) of FUTA provides for an additional credit reduction for a year if a State has outstanding advances on five or more

consecutive January firsts and has a balance on November 10 for such years. Section 3302(c)(2)(C) also provides for waiver of this additional credit reduction and substitution of the credit reduction provided in Section 3302(c)(2)(B) if a state meets certain conditions.

California and the United States Virgin Islands were potentially liable for the additional credit reduction under Section 3302(c)(2)(C) of FUTA and applied for the available waiver. It has been determined that each one met all of the criteria of the section necessary to qualify for the waiver of the additional credit reduction. Further, the additional credit reduction of Section 3302(c)(2)(B) is zero for California and the Virgin Islands for 2018. California repaid its outstanding advances prior to November 10, 2018; hence there will be no FUTA credit reduction for the State's employers. Employers in the Virgin Islands will have no additional credit reduction applied for calendar year 2018. However, as a result of having outstanding advances on each January 1 of 2010 through 2018 as well as on November 10, 2018, employers in the Virgin Islands are subject to a FUTA credit reduction of 2.4 percent in 2018.

Molly E. Conway,

Acting Assistant Secretary, Employment and Training Administration.

[FR Doc. 2018–25456 Filed 11–21–18; 8:45 am]

BILLING CODE 4510–FW–P

LEGAL SERVICES CORPORATION

Request for Letters of Intent To Apply for 2019 Pro Bono Innovation Fund Grants

AGENCY: Legal Services Corporation.

ACTION: Notice.

SUMMARY: The Legal Services Corporation (LSC) issues this Notice describing the conditions for submitting a Letters of Intent (LOI) to Apply for 2019 Pro Bono Innovation Fund grants. This notice and application information are posted at *www.lsc.gov/pbifgrants.*

DATES: Letters of Intent must be submitted by Wednesday, January 23, 2019 by 11:59 p.m. Eastern Time.

ADDRESSES: Letters of Intent must be submitted electronically through *http://lscgrants.lsc.gov.*

FOR FURTHER INFORMATION CONTACT: For more information about current Pro Bono Innovation Fund projects, please contact Mytrang Nguyen, Program Counsel, (202) 295–1564 or *nguyenm@lsc.gov.* For general questions about the Pro Bono Innovation Fund application process, please email *probonoinnovation@lsc.gov.* For technical questions or issues with the LSC Grants online application system, please email *techsupport@lsc.gov.*

SUPPLEMENTARY INFORMATION: The Legal Services Corporation (LSC) issues this Notice describing the conditions for submitting a Letter of Intent to Apply (LOI) for 2019 Pro Bono Innovation Fund grants. This notice and application information are posted at *www.lsc.gov/pbifgrants.*

I. Introduction

Since 2014, Congress has provided an annual appropriation to LSC ''for a Pro Bono Innovation Fund.'' *See, e.g.,* Consolidated Appropriations Act, 2017, Public Law 115–31, 131 Stat. 135 (2017). LSC requested these funds for grants to ''develop, test, and replicate innovative pro bono efforts that can enable LSC grantees to expand clients' access to high quality legal assistance.'' LSC Budget Request, Fiscal Year 2014 at 26 (2013). The grants must involve innovations that are either ''new ideas'' or ''new applications of existing best practices.'' *Id.* Each grant would ''either serve as a model for other legal services providers to follow or effectively replicate a prior innovation. *Id.* The Senate Appropriations Committee explained that these funds ''will support innovative projects that promote and enhance pro bono initiatives throughout the Nation,'' and the House Appropriations Committee directed LSC ''to increase the involvement of private attorneys in the delivery of legal services to [LSC-eligible] clients.'' Senate Report 114–239 at 123 (2016), House Report 113–448 at 85 (2014).

LSC sought these funds based on the 2012 recommendation of the LSC Pro Bono Task Force. Since its inception, the Pro Bono Innovation Fund has advanced LSC's goal of increasing the quantity and quality of legal services by funding projects that more efficiently and effectively involve pro bono volunteers in serving the critical unmet legal needs of LSC-eligible clients. In 2017, LSC built on these successes by creating three funding categories to better focus on innovations serving unmet and well-defined client needs (Project Grants), on building comprehensive and effective pro bono programs through new applications of existing best practices (Transformation Grants), and on providing continued development support for the most promising innovations (Sustainability Grants).

II. Funding Opportunities Information

A. Eligible Applicants

To be eligible for the Pro Bono Innovation Fund's Project, Sustainability, and Transformation grants, Applicants must be current grantees of LSC Basic Field-General, Basic Field-Migrant, or Basic Field-Native American grants. In addition, Sustainability Grant Applicants must also be a former or current Pro Bono Innovation Fund grantee from the FY17 grant making cycle.

B. Pro Bono Innovation Fund Purpose and Key Goals

Pro Bono Innovation Fund grants develop, test, and replicate innovative pro bono efforts that can enable LSC grantees to use pro bono volunteers to serve larger numbers of low-income clients and improve the quality and effectiveness of the services provided. The key goals of the Pro Bono Innovation Fund are to:

1. Address gaps in the delivery of legal services to low-income people;
2. Engage more lawyers and other volunteers in pro bono service;
3. Develop, test, and replicate innovative pro bono efforts.

C. Funding Opportunities

1. Project Grants

The goal of Pro Bono Innovation Fund *Project Grants* is to leverage volunteers to meet a critical, unmet and well-defined client need. Consistent with the key goals of the Pro Bono Innovation Fund, applicants are encouraged to focus on engaging volunteers to increase free civil legal aid for low-income Americans by proposing new, replicable ideas. Applicants are strongly encouraged to research prior successful Pro Bono Innovation Fund projects and Sustainability Grants to replicate, adapt, or create enhancements to prior effective pro bono projects. LSC will be particularly receptive to applications that propose to replicate projects LSC has previously funded with ''Sustainability'' Grants. Our Sustainability Grants have included:

- Community-based partnerships, like the Medical-Legal Partnership of Community Legal Aid, Inc. (MA) or the school-based clinic of Legal Aid of West Virginia, Inc., that work with law firms to provide legal services where clients are located;
- Court-based partnerships, like those at Legal Action of Wisconsin, Inc., and Legal Services Law Line of Vermont, Inc., that use pro bono volunteers to provide same-day, in-court representation and legal assistance;

• An ''emeritus'' project at The Legal Aid Society of Cleveland (LASC) that provides transitioning and retired attorneys with varied and substantive opportunities to support the LASC's advocates and clients;

• A neighborhood-based project at Legal Aid of Western Missouri that engages transactional attorneys to assist clients in distressed and underserved communities.

Project Grants can be either 18 or 24 months.

2. Transformation Grants

The goal of Pro Bono Innovation Fund *Transformation Grants* is to support LSC grantees in comprehensive assessment and restructuring of pro bono programs through new applications of existing best practices in pro bono delivery. Each *Transformation Grant* will support a rigorous and extensive assessment of an LSC grantee's pro bono program, the identification of best practices in pro bono delivery that are best suited to that grantee's needs and circumstances, and the development and implementation of short- and long-term improvements to organizational policies, management, and operations. *Transformation Grants* are 24 months and targeted towards LSC grantees whose leadership is committed to restructuring an entire pro bono program and incorporating pro bono best practices into core, high-priority client services with an urgency to create a high-impact pro bono program. This funding opportunity is open to all LSC grantees, but is primarily intended for LSC grantees who have been unsuccessful applying for *Project Grants* or who have never applied for a Pro Bono Innovation Fund grant in the past.

3. Sustainability Grants

Pro Bono Innovation Fund *Sustainability Grants* are available to current or former Pro Bono Innovation Fund grantees who were funded in FY 2017. The goal of *Sustainability Grants* is to support further development of the most promising and replicable Pro Bono Innovation Fund projects with an additional 24 months of funding so grantees can leverage new sources of revenue for the project, collect meaningful data to demonstrate the project's results and outcomes for clients and volunteers, and quantify the return on LSC's investment of Pro Bono Innovation Fund dollars. Applicants for *Sustainability Grants* will be required to propose an ambitious match requirement, tied to realistic goals that reduce the Pro Bono Innovation Fund contribution to the project over the grant term.

D. Available Funds for FY 2019

The availability of funds for Pro Bono Innovation Fund grants for FY 2019 depends on LSC's appropriation. LSC is currently operating under a Continuing Resolution for FY 2019 which funds the federal government through December 7, 2018. The Continuing Resolution maintains funding at $410 million. Pro Bono Innovation Fund grant decisions for FY 2019 will be made in the summer of 2019. LSC anticipates knowing the total amount available for Pro Bono Innovation Fund grants before August.

In FY 2018, LSC received an appropriation of $4.5 million, of which $4.25 million was available for direct grants to support Pro Bono Innovation Fund projects. In 2018, fifteen Pro Bono Innovation Fund applications received funding with a median funding amount of $293,650. There is no maximum amount for Pro Bono Innovation Fund requests that are within the total funding available.

LSC will not designate fixed or estimated amounts for the three different funding categories and will make grant awards for the three categories within the total amount of funding available.

E. Project and Grant Term

Pro Bono Innovation Fund grant awards will cover an 18- to 24-month period. Applicants for *Project Grants* can apply for either an 18- or a 24-month grant. Applicants for *Transformation Grants* and *Sustainability Grants* apply for a 24-month grant only. Applicants' proposals should cover the full term for which a grant award is requested. The grant term is expected to commence on October 1, 2019.

III. Grant Application Process and Letter of Intent To Apply Instructions

A. Pro Bono Innovation Fund Grant Application Process

LSC is committed to reviewing all Pro Bono Innovation Fund grant applications in a timely and thorough manner. Applicants must first submit a Letter of Intent (LOI) to Apply for Funding to LSC by January 23, 2019 to be considered for a grant. After review by LSC Staff, LSC's President makes the final decision on which applicants will be asked to submit a detailed, full application due to LSC in April. Applicants will be notified of invitations to full application by February 2019. Once LSC has received a full application from a selected applicant, the application will undergo a rigorous review by LSC staff and external subject matter experts. LSC's President makes the final decision on funding for the Pro Bono Innovation Fund.

B. Late or Incomplete Applications

LSC may consider an LOI after the deadline, but only if the Applicant has submitted an email to *probonoinnovation@lsc.gov* explaining the circumstances that caused the delay prior to the applicable deadline. Communication with LSC staff, including assigned Program Liaisons, is not a substitute for sending an explanatory email to *probonoinnovation@lsc.gov.* At its discretion, LSC may consider incomplete applications. LSC will determine the admissibility of late or incomplete applications on a case-by-case basis.

C. Letters of Intent To Apply for Funding Requirements and Format

The LOI should succinctly summarize the information requested for the category of funding the applicant seeks. A complete LOI consists of: (1) A narrative that responds to the questions for the funding category; and (2) a budget form. Applicants must submit the LOI electronically using the LSC Grants online system found at *http://lscgrants.lsc.gov.* The system will be live for applicants in mid-December 2018.

The LOI narrative should be a Word or PDF document submitted in the LSC Grants system. *The narrative must not exceed 5 double-spaced pages or approximately 1,300 words in Times New Roman, 12-point font.* The LOI narrative must be paginated. The budget form is an online form that is submitted in LSC Grants. Applicants who do not follow the above formatting requirements for the *Narrative* submission may be subject to scoring penalties.

Applicants may submit multiple LOIs under the same or different funding category. If applying for multiple grants, applicants should submit a separate LOI in LSC Grants for each funding request.

1. Project Grants

The LOI Narrative for *Project Grants* should respond to the following questions.

a. *Project Description.* Please provide a brief description of the proposed project that includes:

• The specific client need and challenge or opportunity in the pro bono delivery system that the project will address.

• The goals and objectives of the project, the activities that make up the project, and how those activities will

link to and achieve the stated goals and objectives.

• Strong indication of volunteer interest in and support for the project.

• The expected impact of the project. This should include a brief explanation of the changes and outcomes that will be created as a result of the project.

• The proposed strategies that are innovative or the best practices being replicated, including a brief discussion of how these strategies or best practices were identified.

b. *Project Staff, Organizational Capacity, and Project Partners.* Please briefly identify and describe the project team and project partners including:

• The qualifications and relevant experience of the proposed project team, any proposed partner organizations, and your organization.

• The role of your organization's executive management in the design and implementation of the project.

c. *Budget and Timeline.* Please state whether you are proposing an 18- or 24-month project and provide the following information about the estimated project costs:

• Estimated total project cost. This includes the estimate for the Pro Bono Innovation Fund requested amount and other in-kind or cash contributions to support the project. Your narrative should provide a breakdown of the major project expenses including, but not limited to, personnel, project expenses, contracts or sub-grants, etc., and how each expense supports the project design.

• For expenses related to personnel, please indicate how many and which positions will be fully or partially funded by the proposed grant.

• A list of any anticipated contributions, both in-kind and monetary, from all partners involved in the project.

• A list of key partners who will receive Pro Bono Innovation Fund funding, including their roles and the estimated dollar amount or percent of budget assigned to each partner.

2. Transformation Grants

The LOI Narrative for *Transformation Grants* should respond to the following questions.

a. *Transformation Strategy:* Please explain why you are seeking a Transformation Grant for your pro bono program. In your response, please include:

• An honest assessment of the challenges with your organization's current pro bono efforts that inhibit your ability to test, develop, and replicate innovations, and the reasons for them.

• At least three specific and important improvements to your organization's pro bono program that you would like to achieve in the first year of a two-year Transformation Grant.

b. *Guiding Coalition:* Please describe the core team who would be responsible for the pro bono transformation effort in your organization. In your response, please state:

• The qualifications and relevant experience of each proposed team member.

• Whether a majority of your executive and senior managers agree that your organization's pro bono program needs significant improvements.

• The role your organization's executive director and/or senior managers would play in a pro bono transformation effort.

c. *Budget.* Please describe what you would like the *Transformation Grant* to fund over the 24-month grant period. In your response, please include the following information about the anticipated costs associated with a transformation effort for your pro bono program:

• The estimated total cost and a clear description of what the grant will fund. Your narrative should provide a breakdown of the major expenses including, but not limited to, personnel, project expenses, contracts or sub-grants, etc., and how each expense supports the transformation effort to improve your pro bono program.

• For expenses related to personnel, please indicate how many and which positions will be fully or partially funded by the proposed grant.

• For contracts, please describe whether you intend to use consultants, implement new technology systems, conduct business process analysis, etc. and how this supports improvements to you pro bono program.

3. Sustainability Grants

The LOI Narrative for *Sustainability Grants* should respond to the following questions.

a. *Justification for Sustaining the Pro Bono Innovation Project.* Please describe why you are seeking a Sustainability Grant. In your response, please discuss the following:

• The impact of the Pro Bono Innovation Fund project to date, supported by data and analysis as to whether the goals of the project were achieved.

• Evidence of ongoing client need and how you intend to make the project part of your core legal services.

• The level of engagement of pro bono volunteers/private bar and the best practices in pro bono delivery that can be replicated by others.

• How ongoing program evaluation and data collection will be incorporated into the project.

b. *Project Staff and Management Support.* Please briefly identify and describe the project team and project partners. In your response, please include the following:

• The project staff that will be responsible for the sustainability phase of the project. Please include any additional staff, descriptions of new responsibilities for existing project staff and/or organizational changes that will be made.

• The role of your organization's executive management in the decision to seek this Sustainability Grant and recent examples of your organization's track record turning ''new'' or special projects into core legal services.

c. *Budget and Match Requirement.* Please describe what you would like the *Sustainability Grant* to fund. In your response, please be sure to provide the following information:

• Estimated total project cost. This includes the estimate for the Pro Bono Innovation Fund requested amount and other in-kind or cash contributions to support the project. Your narrative should provide a breakdown of the major project expenses including, but not limited to, personnel, project expenses, etc., and how each expense supports the project design.

• A narrative proposing an ambitious match requirement that reduces the Pro Bono Innovation Fund contribution to the project for the grant term. LSC is not setting a specific percentage of required match for Sustainability Grant applicants, but will assess the two-year budget from the applicant's previously funded project with the grant amount proposed in the Sustainability LOI. LSC's expectation is that applicants will propose a meaningful shift from Pro Bono Innovation Fund support to other sources of support during the grant term.

• A narrative discussing the potential sources of funding that have been or will be cultivated. If the project has already received new financial support, please provide the source and amount committed and further describe the plans for ensuring continued financial support.

Dated: November 19, 2018.

Mark F. Freedman,

Senior Associate General Counsel.

[FR Doc. 2018–25557 Filed 11–21–18; 8:45 am]

BILLING CODE 7050–01–P

OFFICE OF MANAGEMENT AND BUDGET

Cost Accounting Standards Board Meeting Agenda

AGENCY: Cost Accounting Standards Board, Office of Federal Procurement Policy, Office of Management and Budget.

ACTION: Notice of agenda for closed Cost Accounting Standards Board meetings.

SUMMARY: The Office of Federal Procurement Policy (OFPP), Cost Accounting Standards Board (CAS Board) is publishing this notice to advise the public of planned meetings on November 27, 2018 and January 24, 2019. The notice is published pursuant to section 820(a) of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2017, which requires the CAS Board to publish agendas of its meetings in the **Federal Register**. The meetings are closed to the public.

DATES: November 27, 2018 and January 24, 2019.

ADDRESSES: New Executive Office Building, 725 17th Street NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Raymond Wong, Staff Director, Cost Accounting Standards Board (telephone: 202–395–6805; email: *rwong@omb.eop.gov*).

SUPPLEMENTARY INFORMATION: Section 820 amended section 1501(d) of title 41 of the United States Code to require that the CAS Board meet at least quarterly and publish a notice of its meetings, including the meeting agenda, in the **Federal Register**. The CAS Board has scheduled meetings for Tuesday, November 27, 2018 and Thursday, January 24, 2019. The list of agenda items for both meetings is set forth below. In light of the complexity of the issues to be discussed, and the proximity of the two meetings, the CAS Board expects to use the same agenda for both sessions and is issuing this notice to provide public awareness for both meetings. Additional notices will be published to announce further CAS Board meetings in FY 2019 and beyond. The CAS Board will discuss its accomplishments and activities for FY 2019 in its annual report to Congress, which will be transmitted after the end of the fiscal year, in accordance with section 820(e).

Planned Agenda for CAS Board Meetings on November 27, 2018 and January 24, 2019

1. *Review of Advanced Notice of Proposed Rulemaking (ANPR) for Pension Adjustments for Extraordinary Events.* The CAS Board intends to continue its review of the ANPR addressing Cost Accounting Standard (CAS) 412 Composition and Measurement of Pension Costs and CAS 413, Pension Adjustments for Extraordinary Events. The ANPR is the second step of a four-step process the CAS Board uses when it is considering a rulemaking. As the Board previously announced, this initiative is intended to address revisions to the treatment of extraordinary pension adjustments in a defined benefit pension plan (*i.e.,* plan terminations, plan curtailments, and segment closings). The CAS Board issued a final rule on December 27, 2011 to harmonize CAS with the Pension Protection Act (PPA). The PPA was enacted by Congress to help ensure that promised pension obligations would be adequately funded to pay workers their promised retirement benefits. As part of the PPA, Congress instructed the CAS Board to ''harmonize'' its standards for measuring pension costs with the PPA to avoid undue hardship on contractors that could arise from the faster funding required by the PPA. The final rule did not reconcile the PPA requirements with respect to the CAS pension segment closing adjustment requirements and other extraordinary events. The ANPR, supported by a dedicated interagency working group, examines these extraordinary events. The CAS Board contemplates it will also issue a Staff Discussion Paper (SDP), the first step of the four-step process, addressing fact-finding that was made by the working group and public outreach conducted subsequent to the issuance of the 2011 final rule to help inform the CAS Board in its deliberations.

2. *Conformance of CAS to Generally Accepted Accounting Principles (GAAP).* Section 820 requires the CAS Board to review and conform CAS, where practicable, to GAAP. The Board intends to discuss development of an SDP addressing conformance of CAS 404, Capitalization of Tangible Assets, and CAS 411, Accounting for Acquisition Costs of Material, to GAAP. This is the second SDP addressing CAS–GAAP conformance and will build on the first SDP (under final review for publication and public comment) that (i) lays out a proposed conceptual framework and guiding principles to prioritize the evaluation of whether and to what extent CAS may be conformed to GAAP and (ii) presents an initial comparison of CAS 408, Accounting for Costs of Compensated Personal Absence, and CAS 409, Cost Accounting Standard Depreciation of Tangible Capital Assets, for public comment. The Board intends to receive and review public comment on the first SDP before publishing the second SDP.

3. *CAS Applicability Thresholds.* The Advisory Panel on Streamlining and Codifying Acquisition Regulations, established by section 809 of the FY 2016 NDAA (the Panel), has issued a recommendation addressing potential increases in the CAS applicability thresholds. The recommendation appears in volume 2 of the 809 Panel's report, issued in June 2018. The Board will continue its discussion of the Panel's recommendation.

4. *Review of Section 809 Panel Recommendation on Defense Cost Accounting Standards Board (Defense CAS Board).* The Board will discuss the analysis and recommendation made by the Panel (in volume 2 of its report) to repeal the provisions in section 820 of the FY 2017 NDAA that created the Defense CAS Board. See section 820(b), which amends title 10 by adding a new section 190.

Lesley A. Field,

Deputy Administrator.

[FR Doc. 2018–25437 Filed 11–21–18; 8:45 am]

BILLING CODE 3110–01–P

NATIONAL SCIENCE FOUNDATION

Business and Operations Advisory Committee; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Business and Operations Advisory Committee (9556).

Date and Time: December 12, 2018; 1:00 p.m. to 5:15 p.m. (EST).

December 13, 2018; 8:00 a.m. to 12:00 p.m. (EST).

Place: National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia, 22314; Room E 2030.

Type of Meeting: Open.

Contact Person: Joan Miller, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA, 22314; (703) 292–8200.

Purpose of Meeting: To provide advice concerning issues related to the oversight, integrity, development and enhancement of NSF's business operations.

Agenda

Wednesday, December 12, 2018; 1:00 p.m.–5:15 p.m.

Welcome/Introductions; BFA/OIRM/OLPA/Budget Updates; Results from the 2018 Federal Employee Viewpoint Survey; Facilities Subcommittees Updates; CFO Office of the Future.

Thursday, December 13, 2018; 8:00 a.m.–12:00 p.m.

Renewing NSF; Renewing NSF—Partnerships Pillar; Meeting with Drs. Córdova and Crim; Committee Business/Wrap Up.

Dated: November 16, 2018.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2018–25451 Filed 11–21–18; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board (NSB), pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended, (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the scheduling of meetings for the transaction of NSB business as follows:

TIME AND DATE: Wednesday, November 28, 2018 from 8:00 a.m. to 5:00 p.m. and Thursday, November 29, 2018, from 8:15 a.m. to 1:45 p.m. EST.

PLACE: These meetings will be held at the NSF headquarters, 2415 Eisenhower Avenue, Alexandria, VA 22314. Meetings are held in the boardroom on the 2nd floor. The public may observe public meetings held in the boardroom. All visitors must contact the Board Office (call 703–292–7000 or send an email to *nationalsciencebrd@nsf.gov*) at least 24 hours prior to the meeting and provide your name and organizational affiliation. Visitors must report to the NSF visitor's desk in the building lobby to receive a visitor's badge.

STATUS: Some of these meetings will be open to the public. Others will be closed to the public. See full description below.

MATTERS TO BE CONSIDERED:

Wednesday, November 28, 2018

Plenary Board meeting

Open Session: 8:00–9:15 a.m.

- NSB Chair's Opening Remarks Introduction of new NSB members
- NSF Director's Remarks
- Summary of DC Meetings
- NSB Vision Project Discussion/Decision

Committee on Strategy (CS)

Open Session: 9:15–10:45 a.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- FY 2019 Budget Request Update
- Directorate for Mathematical and Physical Sciences Portfolio Review
- NSB Vision Project

Committee on Oversight (CO)

Open Session: 11:00 a.m.–12:15 p.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- Merit Review Report Update
- Report on Status of OIG Semiannual Report and NSF Management Response
- Inspector General's Update
- Chief Financial Officer's Update
- Responsible Conduct of Research
- Reducing Administrative Burdens on Research

Committee on Strategy (CS)

Closed Session: 1:15–1:30 p.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- FY 2020 Budget Submission Update

Committee on Awards and Facilities (A&F)

Closed Session: 1:30–3:20 p.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- Action Item: Sacramento Peak Observatory
- Update on Astronomy Facility Transitions
- Information Item: International Ocean Discovery Program (IODP)
- Information Item: Antarctic Infrastructure Modernization for Science (AIMS)
- Chief Officer for Research Facilities Report

Committee on Awards and Facilities (A&F)

Open Session: 3:30–4:00 p.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- CY 2018–2019 Schedule of Planned Action and Information Items
- Status of the National Ecological Observatory Network (NEON)
- Discussion and Vote on the A&F Action Approval Process Policy Document

Plenary Board

Open Session: 4:00–5:00 p.m.

- White House Office of Science and Technology Policy Briefing

MATTERS TO BE DISCUSSED:

Thursday, November 29, 2018

Committee on National Science and Engineering Policy (SEP)

Open Session: 8:15–9:20 a.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- Update on Future Indicators Project
- Update on *Science and Engineering Indicators (SEI)* Thematic Reports and Roadmap
- Discussion of Draft *SEI 2018* Policy Companion
- Discussion of Future Policy Topics

Committee on External Engagement (EE)

Open Session: 9:20–10:00 a.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- NSB One-page Resources
- NSB Congressional Home District Office Meetings
- NSB Alumni Network Pilot Project

Task Force on the Skilled Technical Workforce (STW)

Open Session: 10:00–10:45 a.m.

- Chair's Opening Remarks
- Approval of Prior Minutes
- NSB/SBE National Center for Science and Engineering Statistics STW Data Update
- Discussion of Task Force Progress and Next Steps

Plenary Board

Closed Session: 11:00–11:15 a.m.

- Chair's Opening Remarks
- Director's Remarks
- Approval of Prior Minutes
- Closed Committee Reports
- Vote: Sacramento Peak Record of Decision

Plenary Board (Executive)

Closed Session: 11:15 a.m.–12:00 p.m.

- Chair's Opening Remarks
- Approval of Prior Minutes
- Director's Remarks
- Board Member Award Review
- Honorary Award Recommendations

Plenary Board

Open Session: 1:15–1:45 p.m.

- Chair's Opening Remarks
- Director's Remarks
- Approval of Prior Minutes
- Open Committee Reports
- Vote: OIG Semiannual Report and Management Response
- Chair's Closing Remarks

Meeting Adjourns: 1:45 p.m.

MEETINGS THAT ARE OPEN TO THE PUBLIC:

Wednesday, November 28, 2018

8:00–9:15 a.m. Plenary NSB Introduction
9:15–10:45 a.m. Committee on Strategy (CS)
11:00 a.m.–12:15 p.m. Committee on Oversight (CO)
3:30–4:00 p.m. Committee on Awards & Facilities (A&F)
4:00–5:00 p.m. Plenary

Thursday, November 29, 2018

8:15–9:20 a.m. Committee on Science and Engineering Policy (SEP)
9:20–10:00 a.m. Committee on External Engagement (EE)
10:00–10:45 a.m. Task Force on Skilled Technical Workforce (STW)
1:15–1:45 p.m. Plenary

MEETINGS THAT ARE CLOSED TO THE PUBLIC:

Wednesday, November 28, 2018

1:15–1:30 p.m. Committee on Strategy (CS)
1:30–3:20 p.m. (A&F)

Thursday, November 29, 2018

11:00–11:15 a.m. Plenary
11:15 a.m.–12:00 p.m. Plenary Executive

CONTACT PERSONS FOR MORE INFORMATION: The NSB Office contact is Brad Gutierrez, *bgutierr@nsf.gov,* 703–292–7000. The NSB Public Affairs contact is Nadine Lymn, *nlymn@nsf.gov,* 703–292–2490.

SUPPLEMENTARY INFORMATION: Public meetings and public portions of meetings held in the 2nd floor boardroom will be webcast. To view these meetings, go to: *http://www.tvworldwide.com/events/nsf/180717* and follow the instructions. The public may observe public meetings held in the boardroom. The address is 2415 Eisenhower Avenue, Alexandria, VA, 22314.

Please refer to the NSB website for additional information. You will find any updated meeting information and schedule updates (time, place, subject matter, or status of meeting) at *https://www.nsf.gov/nsb/meetings/notices.jsp#sunshine.*

The NSB will continue its program to provide some flexibility around meeting times. After the first meeting of each day, actual meeting start and end times will be allowed to vary by no more than 15 minutes in either direction. As an example, if a 10:00 meeting finishes at 10:45, the meeting scheduled to begin at 11:00 may begin at 10:45 instead. Similarly, the 10:00 meeting may be allowed to run over by as much as 15 minutes if the Chair decides the extra time is warranted. The next meeting would start no later than 11:15. Arrive at the NSB boardroom or check the webcast 15 minutes before the scheduled start time of the meeting you wish to observe.

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2018–25717 Filed 11–20–18; 4:15 pm]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 72–1051–ISFSI; ASLBP No. 19–959–01–ISFSI–BD01]

Establishment of Atomic Safety and Licensing Board: Interim Storage Partners LLC

Pursuant to delegation by the Commission, *see* 37 FR 28,710 (Dec. 29, 1972), and the Commission's regulations, *see, e.g.,* 10 CFR 2.104, 2.105, 2.300, 2.309, 2.313, 2.318, 2.321, notice is hereby given that an Atomic Safety and Licensing Board (Board) is being established to preside over the following proceeding:

Interim Storage Partners LLC

(WCS Consolidated Interim Storage Facility)

This proceeding involves an application from Interim Storage Partners LLC for a license to construct and operate a Consolidated Interim Storage Facility on its approximately 14,900-acre site in western Andrews County, Texas. In response to a notice published in the **Federal Register** announcing the opportunity to request a hearing, *see* 83 FR 44,070 (Aug. 29, 2018), multiple requests for hearing have been filed.

The Board is comprised of the following Administrative Judges:

- Paul S. Ryerson, Chairman, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.
- Nicholas G. Trikouros, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.
- Dr. Gary S. Arnold, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

All correspondence, documents, and other materials shall be filed in accordance with the NRC E-Filing rule. *See* 10 CFR 2.302.

Dated: November 16, 2018, in Rockville, Maryland.

Edward R. Hawkens,

Chief Administrative Judge, Atomic Safety and Licensing Board Panel.

[FR Doc. 2018–25453 Filed 11–21–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of November 26, December 3, 10, 17, 24, 31, 2018.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of November 26, 2018

Thursday, November 29, 2018

9:45 a.m. Affirmation Session (Public Meeting) (Tentative)
Motion to Quash Office of Investigations Subpoena Filed by Reed College (Tentative)
9:45 a.m. Affirmation Session (Public Meeting) (Tentative)
Crow Butte Resources, Inc. (In Situ Leach Uranium Recovery Facility)
Consolidated Intervenor's Petition for Review of LBP–16–13 (Tentative)

Thursday, November 29, 2018

10:00 a.m. Briefing on Security Issues (Closed Ex. 1)

Week of December 3, 2018—Tentative

Monday, December 3, 2018

10:00 a.m. Briefing on Equal Employment Opportunity, Affirmative Employment, and Small Business (Public) (Contact: Larniece McKoy Moore: 301–415–1942)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Thursday, December 6, 2018

10:00 a.m. Meeting with Advisory Committee on Reactor Safeguards (Public) (Contact: Mark Banks: 301–415–3718)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of December 10, 2018—Tentative

There are no meetings scheduled for the week of December 10, 2018.

Week of December 17, 2018—Tentative

There are no meetings scheduled for the week of December 17, 2018.

Week of December 24, 2018—Tentative

There are no meetings scheduled for the week of December 24, 2018.

Week of December 31, 2018—Tentative

There are no meetings scheduled for the week of December 31, 2018.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.* The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Kimberly Meyer-Chambers, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or by email at *Wendy.Moore@nrc.gov.*

Dated at Rockville, Maryland, this 20th day of November, 2018.

For the Nuclear Regulatory Commission.

Denise L. McGovern

Policy Coordinator, Office of the Secretary.

[FR Doc. 2018–25701 Filed 11–20–18; 4:15 pm]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2018–58; MC2019–18 and CP2019–18; MC2019–19 and CP2019–19; MC2019–20 and CP2019–20; and MC2019–21 and CP2019–21]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing recent Postal Service filings for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 26, 2018 (Comment due date applies to CP2018–58; MC2019–18 and CP2019–18; MC2019–19 and CP2019–19; MC2019–20 and CP2019–20); November 27, 2018 (Comment due date applies to MC2019–21 and CP2019–21).

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2018–58; *Filing Title:* USPS Notice of Amendment to Priority Mail Express, Priority Mail & First-Class Package Service Contract 27, Filed Under Seal; *Filing Acceptance Date:* November 16, 2018; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Christopher C. Mohr; *Comments Due:* November 26, 2018.

2. *Docket No(s).:* MC2019–18 and CP2019–18; *Filing Title:* USPS Request to Add Priority Mail Contract 475 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 16, 2018; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Kenneth R. Moeller; *Comments Due:* November 26, 2018.

3. *Docket No(s).:* MC2019–19 and CP2019–19; *Filing Title:* USPS Request to Add Priority Mail Contract 476 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 16, 2018; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Kenneth R. Moeller; *Comments Due:* November 26, 2018.

4. *Docket No(s).:* MC2019–20 and CP2019–20; *Filing Title:* USPS Request to Add Priority Mail Contract 477 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 16, 2018; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Lawrence Fenster; *Comments Due:* November 26, 2018.

5. *Docket No(s).:* MC2019–21 and CP2019–21; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & First-Class Package Service Contract 46 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 16, 2018; *Filing Authority:* 39 U.S.C.

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Christopher C. Mohr; *Comments Due:* November 27, 2018.

This Notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2018–25483 Filed 11–21–18; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Transfer of Inbound Letter Post Small Packets and Bulky Letters, and Inbound Registered Service Associated With Such Items, to Competitive Product List

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service hereby provides notice that it has filed a request with the Postal Regulatory Commission to transfer Inbound Letter Post small packets and bulky letters, and inbound registered service associated with such items, from the market-dominant product list to the competitive product list.

DATES: *Date of notice:* November 23, 2018.

FOR FURTHER INFORMATION CONTACT: Anthony F. Alverno, 202–268–2997.

SUPPLEMENTARY INFORMATION: On November 16, 2018, the United States Postal Service® filed with the Postal Regulatory Commission the United States Postal Service Request to Transfer Inbound Letter Post Small Packets and Bulky Letters, and Inbound Registered Service Associated with Such Items, to the Competitive Product List, pursuant to 39 U.S.C. 3642. Documents pertinent to this request are available at *http://www.prc.gov,* Docket No. MC2019–17.

Christopher C. Meyerson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2018–25429 Filed 11–21–18; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 23, 2018.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 16, 2018, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 475 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–18, CP2019–18.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2018–25447 Filed 11–21–18; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 23, 2018.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 16, 2018, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 476 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–19, CP2019–19.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2018–25448 Filed 11–21–18; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, & First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 23, 2018.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 16, 2018, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, & First-Class Package Service Contract 46 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–21, CP2019–21.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2018–25450 Filed 11–21–18; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 23, 2018.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 16, 2018, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 477 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–20, CP2019–20.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2018–25449 Filed 11–21–18; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84611; File No. SR–NSCC–2018–010]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Enhance the Mutual Fund Profile Service To Provide for the Transmission of Event Notifications Through a New Feature Called MF Info Xchange

November 16, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 13, 2018, National Securities Clearing Corporation (''NSCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. NSCC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act [3] and Rule 19b–4(f)(4) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of modifications to NSCC's Rules & Procedures (''Rules'') in order to reflect proposed enhancements to NSCC's Mutual Fund Services.[5] The proposed rule change would enhance the Mutual Fund Profile Service (''MFPS'') [6] of NSCC to provide for the delivery and receipt of event notifications relating to funds and pooled investment entities through a new feature called MF Info Xchange, as described in greater detail below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The proposed rule change consists of modifications to the Rules in order to reflect proposed enhancements to NSCC's Mutual Fund Services. The proposed rule change would enhance MFPS to provide for the delivery and receipt of event notifications relating to funds and pooled investment entities through a new feature called MF Info Xchange, as described in greater detail below.

(i) Background

In 1996, NSCC launched MFPS, providing participating Members with an automated method of transmitting and receiving daily price and rate information pertaining to funds and other pooled investment entities (collectively referred hereto as ''Funds'') through a centralized and standardized facility.[7] In 1998, NSCC implemented three new databases as part of MFPS, (i) the participant profile database, (ii) the security issue profile database and (iii) the distribution declaration information profile database,[8] through which NSCC offers the Funds industry a centralized repository for prospectus and operational information relating to Fund securities, Fund distributions and Fund processing capabilities.

MF Info Xchange would be a new feature of MFPS that would facilitate communication of event notifications among Funds, their principal underwriters or other entities authorized to process transactions on behalf of Funds, that are Members, Mutual Fund/Insurance Services Members, Investment Manager/Agent Members, TPP Members, TPA Members, Data Services Only Members and Fund Members (''data providers''), on the one hand, and the distribution partners of the Funds, such as broker-dealers and banks that are NSCC Members [9] and other third parties identified by the data providers to receive event notifications (''data receivers''), on the other hand. On a daily basis, data providers and data receivers exchange a number of event notifications via email, fax and phone call outside of NSCC relating to events affecting the Funds. Such event notifications include corporate actions, such as Fund name changes, mergers, acquisitions and closures, and other events, such as expense ratio changes and benchmark changes. These event notifications are not standardized across the industry, and data receivers do not currently have an efficient standardized method to view and manage past and upcoming Fund events.

The mutual fund industry has requested that NSCC deliver a data sharing solution for participants in the Fund industry to exchange such event notifications, and create standardization to the event notification process. The current event notification process is inconsistent among data providers and data receivers, with data providers sending event notifications using various methods without standardized formats across the industry. The existing methods of sending event notifications are often time consuming manual processes that add risk and complexity by increasing the chance of manual errors and leaving event notifications open to interpretation because of the lack of standardized formats. MF Info Xchange has been developed with the active participation of an industry working group to streamline the delivery and receipt of various types of Fund event notifications to provide a standardized method of sending event notifications.

Data providers using MF Info Xchange would be able to submit event notifications for distribution, using data entry, uploads and other input mechanisms, modify previously submitted event notifications, view upcoming and past notifications and manage distribution lists. Upon receipt of the event notification data through MF Info Xchange, NSCC would create a unique ID associated with the event relating to the notification, and track corrections and updates to the same event using the same event ID. NSCC would also store the data in a data repository for retrieval by NSCC Members. In addition, NSCC would distribute the event notifications via email to a defined distribution list provided by the data providers. Data providers could also indicate the NSCC Members on the distribution list that could be given access to the event notifications on the data repository. Such NSCC Members that have subscribed to MF Info Xchange would have access to the data repository to retrieve the event notifications and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(4).

[5] Capitalized terms used herein and not otherwise defined shall have the meaning assigned to such terms in the Rules, *available at http://dtcc.com/~/media/Files/Downloads/legal/rules/nscc_rules.pdf.*

[6] Section D of Rule 52, *supra* note 5.

[7] Securities Exchange Act Release No. 37171 (May 8, 1996), 61 FR 24343 (May 14, 1996) (SR–NSCC–1996–04).

[8] Securities Exchange Act Release No. 40614 (October 28, 1998), 63 FR 59615 (November 4, 1998) (SR–NSCC–1998–09).

[9] For purposes of this filing, ''NSCC Members'' shall mean Members and Limited Members.

updates to those event notifications from a centralized location.

NSCC Members would be able to use MF Info Xchange to transmit event notifications for certain predefined event types. Upon the initial launch, Fund mergers/acquisitions and Fund closures would be the only event types for which event notifications could be sent using MF Info Xchange. NSCC would announce by Important Notice posted on its website any enhancements of MF Info Xchange that result in new event types available for event notifications. Given the limited number of Fund event types available for event notifications upon the launch of MF Info Xchange, NSCC would not charge fees initially for the use of MF Info Xchange. NSCC would file with the Commission an appropriate rule change proposal to implement any fees for MF Info Xchange if NSCC adds a fee for the feature.

(ii) Proposed Rule Changes

The proposed rule change would amend Rule 52 to state that NSCC would provide MF Info Xchange to enable data providers that are Members, Mutual Fund/Insurance Services Members, Investment Manager/Agent Members, TPP Members, TPA Members, Data Services Only Members and Fund Members to transmit event notifications relating to Funds to other NSCC Members and to other third parties identified by the data providers to receive the event notifications, or to otherwise supply and provide access to event notifications directly to or from NSCC through a data repository. The proposed rule change would provide that NSCC may determine from time to time, and would announce by Important Notice, which types of event notifications may be transmitted using MF Info Xchange. The proposed rule change would provide that NSCC would not be responsible for the completeness or accuracy of any event notifications transmitted using MF Info Xchange nor for any errors, omissions or delays that may occur relating to the event notifications.

(iii) Implementation Timeframe

NSCC expects to implement MF Info Xchange on November 29, 2018. As proposed, a legend would be added to Rule 52 stating there are changes that became effective upon filing with the Commission but have not yet been implemented. The proposed legend also would include a date on which such changes would be implemented and the file number of this proposal, and state that, once this proposal is implemented, the legend would automatically be removed from Rule 52.

2. Statutory Basis

Section 17A(b)(3)(F) of the Act [10] requires, in part, that the Rules be designed to foster cooperation and coordination with persons engaged in the clearance and settlement of securities transactions. NSCC believes that the proposed rule change would enhance the ability of data providers to send, and for data receivers to access and retrieve, Fund event notification data in a standardized format and in a centralized location. Currently, there is not an industry-wide structured method of providing such event notification data, and data providers send, and data receivers receive, such event notifications in an inefficient and non-standardized manner across the industry. NSCC believes that the proposed rule change would provide the Fund industry a more efficient and streamlined method for data providers to communicate Fund event notification data to data receivers. As such, NSCC believes that the proposed rule change would foster cooperation and coordination among persons engaged in the clearance and settlement of securities, consistent with the requirements of Section 17A(b)(3)(F) of the Act.[11]

In addition, the proposed rule change is designed to be consistent with Rule 17Ad–22(e)(21) promulgated under the Act.[12] Rule 17Ad–22(e)(21) requires NSCC to, inter alia, establish, implement, maintain and enforce written policies and procedures reasonably designed to be efficient and effective in meeting the requirements of its participants and the markets it serves. The proposed rule change would streamline the Fund event notifications process, which would enhance (i) efficiency in making such event notifications by reducing reliance on emails, faxes and phone calls for event notifications, which are inconsistent and a time consuming manual process, and (ii) effectiveness in making such event notifications by providing a standardized format to send such event notifications, which NSCC believes would reduce errors in the event notification process that occur as a result of the current inconsistent and unstructured event notification process. Therefore, by establishing a more efficient and effective process for data providers to deliver, and data receivers to receive, Fund event notifications, NSCC believes that the proposed change is consistent with the requirements of Rule 17Ad–22(e)(21), promulgated under the Act.[13]

(B) Clearing Agency's Statement on Burden on Competition

NSCC does not believe that the proposed rule change would have any adverse impact, or impose any burden, on competition because the proposed rule change would add an optional feature to NSCC's services that would provide data providers the ability to send event notification data in a standardized format. As an optional feature available for subscription with no additional fees, the proposed rule change would not disproportionally impact any NSCC participants.

Moreover, because the proposed rule change would allow data providers to more effectively communicate Fund event notifications, NSCC believes the proposed rule change would have a positive effect on competition among Fund industry participants. The proposed feature would provide data providers with a more efficient method of distributing event notifications to parties that need to see such information in order to facilitate the trading and processing of Fund securities. NSCC believes this would enhance competition among Funds and Fund participants by allowing parties to distribute such information more quickly and in a more streamlined manner.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

NSCC has not received or solicited any written comments relating to this proposal. NSCC will notify the Commission of any written comments received by NSCC.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [14] and paragraph (f) of Rule 19b–4 thereunder.[15] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of

[10] 15 U.S.C. 78q–1(b)(3)(F).

[11] *Id.*

[12] 17 CFR 240.17Ad–22(e)(21).

[13] *Id.*

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f).

investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NSCC–2018–010 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–NSCC–2018–010. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of NSCC and on DTCC's website (*http://dtcc.com/legal/sec-rule-filings.aspx*). All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NSCC–2018–010 and should be submitted on or before December 14, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–25468 Filed 11–21–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84612; File No. SR–BOX–2018–35]

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Permit Up to Ten Expiration Months for Long-Term Options on the SPDR® S&P® 500 Exchange-Traded Fund Shares (''SPY'')

November 16, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 16, 2018, BOX Exchange LLC (''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend BOX Rule 5070 (Long-term Options Contracts) to permit up to ten (10) expiration months for long-term options on SPY. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's internet website at *http://boxoptions.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend BOX Rule 5070 (Long-term Options Contracts) to permit up to ten (10) long-term options (''LEAPS'') expiration months for options on SPY.[3] BOX Rule 5070 currently provides that the Exchange may list LEAPS that expire from twelve (12) to one hundred eighty (180) months from the time they are listed; and there may be up to six (6) expiration months.[4] The Exchange believes the proposal will add liquidity to the SPY options market by allowing market participants to hedge risks relating to SPY positions over a longer time period with a known and limited cost. This is a filing that is based on a proposal recently submitted by Nasdaq PHLX LLC (''Phlx'').[5]

The SPY options market today is characterized by its tremendous daily and annual liquidity. As a consequence, the Exchange believes that the listing of additional SPY LEAPS expiration months would be well received by investors. This proposal to expand the number of permitted SPY long-term expiration months would not apply to LEAPS on any other class of stock or Exchange-Traded Fund Shares.[6]

Finally, BOX Rule 5070(a) currently states that there may be ''up to six (6) additional expiration months.'' Because the rule does not specify which expiration months the six months are in addition to, and thus is ambiguous, the Exchange proposes to delete the word ''additional.'' As amended, the rule would clearly and simply provide that the Exchange may list six expiration months having from twelve (12) to one

[16] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In contrast to Rule 5070, Exchange Rule 6090(b)(1)(i), which applies to index options, permits the Exchange to list LEAPS on any class of index options, adding up to ten expiration months. The Exchange seeks to list ten expiration months of LEAPS on SPY, just as it now may list ten LEAPS expiration months on index options, in order to provide investors with a wider choice of investments.

[4] Strike price interval, bid/ask differential and continuity rules shall not apply to such options series until the time to expiration is less than nine (9) months. *See* BOX Rule 5070(a).

[5] *See* Securities Exchange Act Release No. 34–84449 (October 18, 2018), 83 FR 53699 (SR–Phlx–2018–64).

[6] Historically, SPY is the largest and most actively traded ETF in the United States as measured by its assets under management and the value of shares traded.

hundred eighty (180) months from the time they are listed until expiration.[7]

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[8] in general, and Section 6(b)(5) of the Act,[9] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest by offering market participants additional LEAPS on SPY options for their investment and risk management purposes. The proposal is intended simply to provide additional trading opportunities, thereby facilitating transactions in options and contributing to the protection of investors and the maintenance of fair and orderly markets.[10] The proposed rule change seeks to fulfill the needs of market participants, particularly portfolio managers and other institutional customers, by providing protection from long-term market moves and by offering an alternative to hedging portfolios with futures positions or off-exchange customized derivatives instruments.

The Exchange believes that additional expiration months for SPY LEAPS does not represent a proliferation of expiration months, but is instead a very modest expansion of LEAPS options. Significantly, the proposal would feature new LEAPS expiration months in only a single class of options that are very liquid and heavily traded, as discussed above. Additionally, the Exchange notes by way of precedent that ten expiration months are already permitted for index LEAPS options. Further, the Exchange has the necessary systems capacity to support the new SPY expiration months.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposal merely provides investors additional investment and risk management opportunities by providing flexibility to the Exchange to list additional long term options expiration series, expanding the number of SPY LEAPS offered on the Exchange from six expiration months to ten expiration months. As indicated above, the Exchange notes that this filing is based on a proposal recently submitted by Phlx.[11]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[12] and Rule 19b–4(f)(6) thereunder.[13]

A proposed rule change filed under Rule 19b–4(f)(6)[14] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[15] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative upon filing, to coincide with the effective date of Phlx's proposed rule change on which the proposal is partially based.[16] The Exchange's proposal would clarify ambiguous rule text and would conform the Exchange's rules relating to the permitted number of SPY LEAPS expiration months to those of Phlx. Accordingly, the Commission believes that the proposal raises no new or novel regulatory issues, and waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. The Commission therefore waives the 30-day operative delay and designates the proposal operative upon filing.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BOX–2018–35 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–BOX–2018–35. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official

[7] The Exchange notes other exchanges have amended their rulebook to also clarify this language. *See* Securities Exchange Act Release No. 34–80769 (May 25, 2017), 82 FR 25472 (SR–Phlx–2017–41).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] As previously mentioned, the Exchange notes that this filing is based on a proposal recently submitted by Phlx, in which Phlx states the reason for filing is, in part, customer demand.

[11] *See supra,* note 5.

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[14] *Id.*

[15] 17 CFR 240.19b–4(f)(6)(iii).

[16] *See supra,* note 5.

[17] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BOX–2018–35 and should be submitted on or before December 14, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–25469 Filed 11–21–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rules 400–404 of Regulation Crowdfunding (Intermediaries); SEC File No. 270–774, OMB Control No. 3235–0727

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information provided for Rule 17Ab2–1 (17 CFR 240.17Ab2–1) and Form CA–1: Registration of Clearing Agencies (17 CFR 249b.200) under the Securities Exchange Act of 1934 (''Exchange Act'') (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

The collections of information required under Rules 400 through 404 is mandatory for all funding portals. Form Funding Portal helps ensure that the Commission can make information about funding portals transparent and easily accessible to the investing public, including issuers and obligated persons who engage funding portals; investors who may purchase securities through offerings on funding portals; and other regulators. Further, the information provided on Form Funding Portal expands the amount of publicly available information about funding portals, including disciplinary history. Consequently, the rules and forms allows issuers and the investing public, as well as others, to become more fully informed about funding portals in a more efficient manner.

Rule 400 requires each person applying for registration with the Commission as a funding portal to file electronically with the Commission Form Funding Portal. Rule 400(a) requires a funding portal to become a member of a national securities association registered under Section 15A of the Exchange Act. Rule 400(b) requires a funding portal to file an amendment to Form Funding Portal if any information previously submitted on Form Funding Portal becomes inaccurate for any reason. Rule 400(c) provides that a funding portal can succeed to the business of a predecessor funding portal upon the successor filing a registration on Form Funding Portal and the predecessor filing a withdrawal on Form Funding Portal.

Rule 400(d) requires a funding portal to promptly file a withdrawal of registration on Form Funding Portal upon ceasing to operate as a funding portal. Rule 400(e) states that duplicate originals of the applications and reports provided for in this section must be filed with surveillance personnel designated by any registered national securities association of which the funding portal is a member. Rule 400(f) requires a nonresident funding portal to: (1) Obtain a written consent and power of attorney appointing an agent for service of process in the United States; (2) furnish the Commission with the name and address of its agent for services of process on Schedule C of Form Funding Portal; (3) certify that it can, as a matter of law, and will provide the Commission and any registered national securities association of which it becomes a member with prompt access to its books and records and can, as a matter of law, and will submit to onsite inspection and examination by the Commission and any registered national securities association of which it becomes a member; and (4) provide the Commission with an opinion of counsel and certify on Schedule C on Form Funding Portal that the firm can, as a matter of law, provide the Commission and registered national securities association of which it becomes a member with prompt access to its books and records and can, as a matter of law, submit to onsite inspection and examination by the Commission and any registered national securities association of which it becomes a member.[1]

Rule 403(a) requires a funding portal to implement written policies and procedures reasonably designed to achieve compliance with the federal securities laws and the rules and regulations thereunder relating to its business as a funding portal. Rule 403(b) provides that a funding portal must comply with privacy rules. Rule 404 requires all registered funding portals to maintain certain books and records relating to their funding portal activities, for not less than five years, the first two in an easily accessible place. Rule 404(e) requires funding portals to furnish promptly to the Commission, its representatives, and the registered national securities association of which the funding portal is a member true, correct, complete and current copies of such records of the funding portal that are requested by the representatives of the Commission and the registered national securities association.

The Commission staff estimates that annualized industry burden would be 17,554.35 hours to comply with Rules 400–404. The Commission staff estimates that the costs associated with complying with Rules 400–404 are estimated to be approximately a total amount of $308,729.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Charles Riddle, Acting Director/Chief Information Officer, Securities and

[18] 17 CFR 200.30–3(a)(12).

[1] Exchange Act Section 3(h)(1)(C) permits us to impose, as part of our authority to exempt funding portals from broker registration, ''such other requirements under [the Exchange Act] as the Commission determines appropriate.''

Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 19, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–25491 Filed 11–21–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Securities Exchange Act of 1934 Release No. 84614/November 16, 2018]

In the Matter of the BOX Exchange LLC Regarding a Suspension of and Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Amend the Fee Schedule on the BOX Market LLC Options Facility To Establish BOX Connectivity Fees for Participants and Non-Participants Who Connect to the BOX Network (File No. SR–BOX–2018–24); Order Granting Petition for Review and Scheduling Filing of Statements

This matter comes before the Securities and Exchange Commission (''Commission'') on petition to review the temporary suspension and institution of proceedings, through delegated authority, of the BOX Exchange LLC (f/k/a BOX Options Exchange LLC) (the ''Exchange'') proposed rule change to amend the fee schedule on the BOX Market LLC (''BOX'') options facility to establish certain connectivity fees and reclassify its high speed vendor feed connection as a port fee.

On July 27, 2018, the Commission issued a notice of filing of the proposed rule change filed with the Commission pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] and Rule 19b–4 [2] thereunder.[3] On September 17, 2018, the Division of Trading and Markets (''Division''), pursuant to delegated authority,[4] issued an order temporarily suspending the proposed rule change pursuant to Section 19(b)(3)(C) of the Exchange Act [5] and simultaneously instituting proceedings under Section 19(b)(2)(B) of the Exchange Act [6] to determine whether to approve or disapprove the proposed rule change (''Order Instituting Proceedings'').[7] On October 17, 2018, the Commission received one comment letter on the proposed rule change, supporting the decision to suspend and institute proceedings on the proposed fee changes.[8]

On September 19, 2018, pursuant to Rule 430 of the Commission Rules of Practice,[9] the Exchange filed a notice of intention to petition for review of the Order Instituting Proceedings. Pursuant to Rule 431(e) of the Commission Rules of Practice,[10] a notice of intention to petition for review results in an automatic stay of the action by delegated authority. On September 26, 2018, the Exchange filed a petition for review of the Order Instituting Proceedings.

Pursuant to Rule 431 of the Commission Rules of Practice,[11] the Exchange's petition for review of the Order Instituting Proceedings is granted. Further, the Commission hereby establishes that any party to the action or other person may file a written statement in support of or in opposition to the Order Instituting Proceedings on or before December 10, 2018.

Further, the Commission finds that it is in the public interest to lift the stay during the pendency of the Commission's review. The Commission believes the continued suspension of the proposed rule change while the Commission conducts proceedings to consider the Exchange's proposal will allow the Commission to further consider the proposed fees' consistency with the Exchange Act without the risk of allowing a fee that is potentially inconsistent with the Exchange Act to remain in effect. The Commission also does not believe that lifting the stay precludes meaningful review of the Order Instituting Proceedings.

For the reasons stated above, it is hereby:

Ordered that the Exchange's petition for review of the Division's action, by delegated authority, to temporarily suspend the proposed rule change and simultaneously institute proceedings to determine whether to approve or disapprove the proposed rule change be granted; and

It is further ordered that any party or other person may file a statement in support of or in opposition to the action made pursuant to delegated authority on or before December 10, 2018; and

It is further ordered that the automatic stay of delegated action pursuant to Commission Rule of Practice 431(e) [12] is hereby discontinued.

The order temporarily suspending such proposed rule change and instituting proceedings to determine whether to approve or disapprove such proposed rule change shall remain in effect.

By the Commission.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–25471 Filed 11–21–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

Extension:

Form N–8A; SEC File No. 270–135, OMB Control No. 3235–0175

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

The Investment Company Act of 1940 (''Investment Company Act'') (15 U.S.C. 80a–1 *et seq.*) requires investment companies to register with the Commission before they conduct any business in interstate commerce. Section 8(a) of the Investment Company Act provides that an investment company shall be deemed to be registered upon receipt by the Commission of a notification of registration in such form as the Commission prescribes. Form N–8A (17 CFR 274.10) is the form for notification of registration that the Commission has adopted under section 8(a). The purpose of such notification of registration provided on Form N–8A is to notify the Commission of the existence of investment companies required to be registered under the Investment

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 83728 (July 27, 2018), 83 FR 37853 (August 2, 2018).

[4] 17 CFR 200.30–3(a)(57) and (58).

[5] 15 U.S.C. 78s(b)(3)(C).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 84168 (September 17, 2018), 83 FR 47947 (September 21, 2018).

[8] *See* letter to Brent J. Fields, Secretary, Commission, from Theodore R. Lazo, Managing Director and Associate General Counsel, and Ellen Greene, Managing Director, Financial Services Operations, Securities Industry and Financial Markets Association, dated October 15, 2018.

[9] 17 CFR 201.430.

[10] 17 CFR 201.431(e).

[11] 17 CFR 201.431.

[12] 17 CFR 201.431(e).

Company Act and to enable the Commission to administer the provisions of the Investment Company Act with respect to those companies. After an investment company has filed its notification of registration under section 8(a), the company is then subject to the provisions of the Investment Company Act which govern certain aspects of its organization and activities, such as the composition of its board of directors and the issuance of senior securities. Form N–8A requires an investment company to provide its name, state of organization, form of organization, classification, the name and address of each investment adviser of the investment company, the current value of its total assets, and certain other information readily available to the investment company. If the investment company is filing a registration statement as required by Section 8(b) of the Investment Company Act concurrently with its notification of registration, Form N–8A requires only that the registrant file the cover page (giving its name, address, and agent for service of process) and sign the form in order to effect registration.

Based on recent filings of notifications of registration on Form N–8A, we estimate that about 96 investment companies file such notifications each year. An investment company must only file a notification of registration on Form N–8A once. The currently approved average hour burden per investment company of preparing and filing a notification of registration on Form N–8A is one hour. Based on the Commission staff's experience with the requirements of Form N–8A and with disclosure documents generally—and considering that investment companies that are filing notifications of registration on Form N–8A simultaneously with the registration statement under the Investment Company Act are only required by Form N–8A to file a signed cover page—we continue to believe that this estimate is appropriate. Therefore, we estimate that the total annual hour burden to prepare and file notifications of registration on Form N–8A is 96 hours. The currently approved cost burden of Form N–8A is $449. We continue to believe that this estimate is appropriate. Therefore, we estimate that the total annual cost burden to associated with preparing and filing notifications of registration on Form N–8A is about $43,104.

Estimates of average burden hours and costs are made solely for the purposes of the Paperwork Reduction Act, and are not derived from a comprehensive or even representative survey or study of the costs of Commission rules and forms. Compliance with the collection of information requirements of Form N–8A is mandatory. Responses to the collection of information will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The public may view the background documentation for this information collection at the following website, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Lindsay.M.Abate@omb.eop.gov* ; and (ii) Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: November 19, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–25490 Filed 11–21–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84610; File No. SR–Phlx–2018–59]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Order Approving a Proposed Rule Change To Amend Rules 1000, 1064, and 1069 To Allow for the Snapshot Functionality of the Floor-Based Management System To Be Used for All Orders

November 16, 2018.

I. Introduction

On September 18, 2018, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to allow the Snapshot functionality of the Floor-Based Management System (''FBMS'') to be used for all orders on the trading floor. The proposed rule change was published for comment in the **Federal Register** on October 2, 2018.[3] The Commission received no comment letters on the proposed rule change. This order approves the proposed rule change.

II. Description of the Proposed Rule Change

The ''Snapshot'' functionality of the FBMS allows a Floor Broker, Registered Options Trader (''ROT''), or Specialist to ''provisionally execute'' [4] a trade in the trading crowd and capture and record the market conditions that exist at the time of the provisional execution.[5] Once the member triggers the Snapshot, the member has up to 30 seconds to use the information recorded on the Snapshot for purposes of entering the terms of the provisionally-executed trade into FBMS and submitting the trade to the Trading System.[6] Once submitted, the Trading System will only execute the trade if it is consistent with the applicable priority and trade-through rules based upon the prevailing market as reflected on the Snapshot at the time of the provisional execution. The Trading System will reject a trade that is subject to a Snapshot if it would violate trade-though or priority rules.[7]

Currently, the ''Snapshot'' feature of the FBMS may only be used to provisionally execute certain types of orders in the trading crowd. Specifically, Floor Brokers, Specialists, and ROTS may only use Snapshot to provisionally execute multi-leg orders and simple orders in options on Exchange Traded Funds (''ETFs'') that are included in the Options Penny Pilot.[8] The Exchange proposes to expand the use of the Snapshot functionality to all orders on the trading floor, subject to the current procedures for and the limitations on the use of Snapshot.[9] The Exchange believes that

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 84290 (September 26, 2018), 83 FR 49596 (''Notice'').

[4] A ''provisional execution'' occurs in the trading crowd when either (1) the participants to a trade reach a verbal agreement in the trading crowd as to the terms of the trade; or (ii) a member announces that he is crossing an order in accordance with Phlx Rule 1064(a). *See* Phlx Rule 1069(a)(i)(A). *See also* Notice, *supra* note 3, at 49596–97 n.5.

[5] *See* Securities Exchange Act Release No. 81980 (October 30, 2017), 82 FR 51313 (November 3, 2017) (SR–Phlx–2017–34) (approving the Snapshot functionality as an exception to Phlx Rule 1000(f)) (''Snapshot Approval''). *See also* Securities Exchange Act Release No. 83656 (July 17, 2018), 82 FR 34899 (July 23, 2018) (SR–Phlx–2018–40) (expanding the availability of the Snapshot feature to ROTS and Specialists).

[6] *See* Notice, *supra* note 3, at 49596–97.

[7] *See id.* at 49597.

[8] *See* Phlx Rule 1069(a)(i)(A).

[9] *See* Notice, *supra* note 3, at 49596–97. The procedures and limitations regarding the current

Continued

its proposed expansion of the use of Snapshot will make the functionality simpler, more consistent, and more useful in a greater number of circumstances than it is currently.[10] To effectuate these changes, the Exchange proposes several modifications to Phlx Rules 1000, 1064, and 1069.[11]

The Exchange represents that it does not anticipate that the use of Snapshot to provisionally execute *all* orders, rather than just multi-leg or simple orders in options on ETFs that are included in the Options Penny Pilot, will materially increase the risk that Snapshot will be overused or abused relative to its current use.[12] Therefore, the Exchange proposes to utilize the same methods it currently uses to surveil its members' use of the Snapshot functionality and represents that if Surveillance detects a significant uptick in improper usage, the Exchange will evaluate whether additional controls are necessary.[13]

Finally, the Exchange notes that it expects to make Snapshot available for all orders before the end of the fourth quarter of 2018 and represents that it will notify its members via an Options Trader Alert, to be posted on the Exchange's website, at least seven calendar days prior to the date when Snapshot will be available for expanded use.[14]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[15] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[16] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities and, in general, to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission notes that use of the Snapshot functionality for certain orders is one of the current exceptions set forth in Phlx Rule 1000(f), and allows Floor Brokers, ROTS, and Specialists to provisionally execute, in the options trading crowd (as opposed to through FBMS), multi-leg orders and simple orders in options on ETFs that are included in the Options Penny Pilot.[17] According to the Exchange, Snapshot promotes just and equitable principles of trade and serves the interests of investors and the public by increasing the likelihood that investors will be able to execute their orders and do so in line with their expectations.[18] The Exchange further represents that Snapshot is designed to mitigate the risk that the Trading System will reject a trade due to a change in market conditions that occurs between the time when the parties to a trade negotiate a valid trade on the trading floor and the time when the Trading System receives the trade. The Exchange believes that expanding the availability of Snapshot to all orders will broaden the scope of these protections to the benefit of investors and will make the exchange's trading floor more competitive with other trading venues because it will make the trading floor operate more efficiently.[19]

Further, the Exchange represents that the proposal is consistent with Rule 611 of Regulation NMS, which requires the Exchange to establish policies and procedures that are reasonably designed to prevent trade-throughs of protected quotations. The Exchange notes that although the proposal will change the time of execution of a trade for purposes of verifying compliance with trade-though and priority rules, the current automated compliance verification process will continue to apply and will systematically prevent any violation of the trade-though and priority rules.[20] Finally, as noted above, the Exchange does not believe that the proposal will increase the risk that Snapshot will be used improperly and believes that its existing design controls are sufficient to continue to closely monitor Snapshot usage by its members.[21]

The Commission notes that, at the time Snapshot was adopted, the Exchange adopted several measures to help ensure that Snapshot operates, and is used by members, in a manner that is consistent with the Act and Phlx's rules.[22] The Commission notes that these measures will continue to apply to the expanded application of Snapshot to all orders and should continue to ensure that the Snapshot functionality will be used in a manner that is consistent with the Act and Phlx's Rules. For example, Phlx Rule 1069(a)(i)(B) will continue to prohibit all members from triggering the Snapshot feature for the purpose of obtaining favorable, or avoiding unfavorable, priority or trade-through conditions. In addition, the Exchange represents that its surveillance staff will monitor the expanded use of Snapshot and will evaluate whether additional controls are needed if the Exchange detects a significant uptick in improper usage.[23]

For the foregoing reasons, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act[24] and the rules and regulations thereunder applicable to national securities exchanges.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[25] that the proposed rule change (SR–Phlx–2018–59) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–25467 Filed 11–21–18; 8:45 am]

BILLING CODE 8011–01–P

use of Snapshot are currently set forth in Phlx Rule 1069 and will continue to apply.

[10] *See* Notice, *supra* note 3, at 49597.

[11] A more detailed description of the proposal appears in the Notice.

[12] *See* Notice, *supra* note 3, at 49597.

[13] *See id.*

[14] *See id.*

[15] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 15 U.S.C. 78f(b)(5).

[17] *See* Phlx Rule 1000(f)(iii)(E).

[18] *See* Notice, *supra* note 3, at 49597.

[19] *See id.* at 49597–98.

[20] *See id.* at 49598.

[21] *See id.* at 49597.

[22] *See* Snapshot Approval, *supra* note 5, at 51316.

[23] *See* Notice, *supra* note 3, at 49597.

[24] 15 U.S.C. 78f(b)(5).

[25] 15 U.S.C. 78s(b)(2).

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–172, OMB Control No. 3235–0169]

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

Extension:
Form N–5.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collection of information summarized below. The Commission

plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Form N–5 (17 CFR 239.24 and 274.5) is the form used by small business investment companies (''SBICs'') to register their securities under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) (''Securities Act'') and the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) (''Investment Company Act''). Form N–5 is the registration statement form adopted by the Commission for use by an SBIC that has been licensed as such under the Small Business Investment Act of 1958 or which has received the preliminary approval of the Small Business Administration (''SBA'') and has been notified by the SBA that the company may submit a license application Form N–5 is an integrated registration form and may be used as the registration statement under both the Securities Act and the Investment Company Act. The purpose of Form N–5 is to meet the filing and disclosure requirements of both the Securities Act and Investment Company Act, and to provide investors with information sufficient to evaluate an investment in an SBIC. The information that is required to be filed with the Commission permits verification of compliance with securities law requirements and assures the public availability and dissemination of the information.

The Commission did not receive any filings on Form N–5 in the last three years (and in the three years before that, received only one Form N–5 filing). Nevertheless, for purposes of this PRA, we conservatively estimate that at least one Form N–5 will be filed in the next three years, which translates to about 0.333 filings on Form N–5 per year. The currently approved internal burden of Form N–5 is 352 hours per response. We continue to believe this estimate for Form N–5's internal hour burden is appropriate. Therefore, the number of currently approved aggregate burden hours, when calculated using the current estimate for number of filings, is about 117 internal hours per year. The currently approved external cost burden of Form N–5 is $30,000 per filing. We continue to believe this estimate for Form N–5's cost burden is appropriate. Therefore, we estimate that the aggregate cost burden, when calculated using the Commission's estimate of 0.333 filings per year, is about $10,000 in external costs per year.

Estimates of average burden hours and costs are made solely for the purposes of the Paperwork Reduction Act, and are not derived from a comprehensive or even representative survey or study of the costs of Commission rules and forms. Compliance with the collection of information requirements of Form N–5 is mandatory. Responses to the collection of information will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Written comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information has practical utility; (b) the accuracy of the Commission's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, C/O Candace Kenner, 100 F Street NE, Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 16, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–25442 Filed 11–21–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84613; File No. SR–MIAX–2018–36]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing of a Proposed Rule Change To Amend Exchange Rule 518, Complex Orders

November 16, 2018.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 9, 2018, Miami International Securities Exchange, LLC (''MIAX Options'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend Exchange Rule 518, Complex Orders [sic]

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/* at MIAX Options' principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rule 518, Complex Orders, to (i) adopt a new Simple Market Auction or Timer (''SMAT'') Event (defined below); (ii) amend the Response Time Interval and Defined Time Period for Complex Auctions (each defined below); (iii) adopt a new Complex Liquidity Exposure Process (''cLEP''); (iv) make minor changes to the Complex MIAX Options Price Collar Protection; and (v) clarify that the Calendar Spread Variance (''CSV'') price protection applies only to strategies in American-style option[3] classes.

Specifically, the Exchange proposes to amend subsection (a)(16), to adopt a new Simple Market Auction or Timer (SMAT) Event. A SMAT Event is

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''American-style option'' means an option contract that, subject to the provisions of Rule 700 (relating to the cutoff time for exercise instructions) and to the Rules of the Clearing Corporation, can be exercised on any business day prior to its expiration date and on its expiration date. *See* Exchange Rule 100.

defined as any one of the following; a PRIME Auction (pursuant to Rule 515A),[4] a Route Timer (pursuant to Rule 529),[5] or a liquidity refresh pause (pursuant to Rule 515(c)(2).[6] The Exchange now proposes to adopt new rule text to add the liquidity exposure process timer (pursuant to proposed Rule 515(c)(2)(i)) as a SMAT Event. The liquidity exposure process timer, which is not to exceed three (3) seconds, is engaged as part of the liquidity exposure process for orders in Proprietary Products[7] that would be posted, managed, or would trade at a price more aggressive than the order's protected price. If a SMAT Event exists during free trading for an option component of a complex strategy, trading in the complex strategy will be suspended.[8] The Exchange also proposes to correct an internal cross reference in subsection (a)(16)(iii) from Rule 515(c)(2) to Rule 515(c)(3) to reflect the new citation under a currently pending proposed rule change. The purpose of adding the liquidity exposure process timer as a SMAT Event is to enhance the continuity, trade-through protection, and orderliness in the simple market and to protect complex order components from being executed at prices that could improve following a SMAT Event.

Additionally, the Exchange proposes to amend subsection (d)(3) which describes the Response Time Interval of a Complex Auction, which is a single-sided auction. The Exchange offers Complex Auction functionality as described in Exchange Rule 518[9] and also a cPRIME process, which is unaffected by this proposal, as described in Exchange Rule 515A.12.

Currently, Rule 518(d)(3) provides that the Response Time Interval means the period of time during which responses to the Request for Responses (''RFR'') message may be entered. The Rule further provides that the Exchange determines the duration of the Response Time Interval, which shall not exceed 500 milliseconds, and communicates it to Members via Regulatory Circular.[10] The Exchange now proposes to adopt new rule text to state that, ''the end of the trading session will also serve as the end of the Response Time Interval for a Complex Auction still in progress.'' In connection with this proposed change the Exchange proposes to amend subsection (d)(2) to remove the reference to the Defined Time Period for a Complex Auction. The Defined Time Period represents the period of time preceding the end of a trading session during which a Complex Auction will not be initiated. Currently, the Defined Time Period is 2,000 milliseconds[11] while the duration of a Complex Auction is just 200 milliseconds. The Exchange believes that removing this restriction will allow for increased price improvement opportunities. The Exchange also proposes to amend subsection (c)(2)(i) to remove the restriction that a cAOA order[12] received during the Defined Time Period will not initiate a new Complex Auction. Under the current rules there is no opportunity at all for price improvement via a Complex Auction when there is less than two seconds left in the trading session. The Exchange believes that removing the Defined Time Period and allowing the end of the trading session to serve as the end of the Response Time Interval in the limited instance that a Complex Auction is initiated with less than 200 milliseconds left in the trading session will allow for more opportunities for price improvement via the auction process. The Exchange warrants that is has the System capability to conduct auctions and execute transactions in a timely fashion at any time during the trading session.

The Exchange also proposes to adopt new subsection (e) to describe a Complex Liquidity Exposure Process (''cLEP'') for complex orders and complex eQuotes that would violate their Complex MIAX Price Collar (''MPC'') price . The MPC price protection feature is an Exchange-wide mechanism under which a complex order or complex eQuote to sell will not be displayed or executed at a price that is lower than the opposite side cNBBO[13] bid at the time the MPC is assigned by the System[14] (*i.e.,* upon receipt or upon opening) by more than a specific dollar amount expressed in $0.01 increments (the ''MPC Setting''), and under which a complex order or eQuote to buy will not be displayed or executed at a price that is higher than the opposite side cNBBO offer at the time the MPC is assigned by the System by more than the MPC Setting (each the ''MPC Price'').[15] The MPC Price is established (i) upon receipt of the complex order or eQuote during free trading, or (ii) if the complex order or eQuote is not received during free trading, at the opening (or reopening following a halt) of trading in the complex strategy; or (iii) upon evaluation of the Strategy Book by the System when a wide market condition, as described in Interpretations and Policies .05(e)(1) of this Rule, no longer exists.[16] Once established the MPC Price will not change during the life of the complex order or eQuote.[17] If the MPC Price is priced less aggressively than the limit price of the complex order or eQuote (*i.e.,* the MPC Price is less than the complex order or eQuote's bid price

[4] The MIAX Price Improvement Mechanism (''PRIME'') is a process by which a Member may electronically submit for execution (''Auction'') an order it represents as agent (''Agency Order'') against principal interest, and/or an Agency Order against solicited interest. *See* Exchange Rule 515A.

[5] The Exchange may automatically route orders to other exchanges under certain circumstances (''Routing Services''). In connection with such services, one of two Route Mechanisms, Immediate Routing or the Route Timer, will be used when a Public Customer order is received and/or reevaluated that is both routable and marketable against the opposite side ABBO upon receipt and the Exchange's disseminated market is not equal to the opposite side ABBO, or is equal to the opposite side ABBO and of insufficient size to satisfy the order. For those initiating Public Customer orders that are routable, but do not meet the additional criteria for Immediate Routing, the System will implement a Route Timer not to exceed one second (the duration of the Timer will be announced to Members through a Regulatory Circular), in order to allow Market Makers and other participants an opportunity to interact with the initiating order. *See* Exchange Rule 529.

[6] The System will pause the market for a time period not to exceed one second to allow additional orders or quotes refreshing the liquidity at the MBBO to be received (''liquidity refresh pause'') when at the time of receipt or reevaluation of the initiating order by the System: (A) Either the initiating order is a limit order whose limit price crosses the NBBO or the initiating order is a market order, and the limit order or market order could only be partially executed; (B) a Market Maker quote was all or part of the MBBO when the MBBO is alone at the NBBO; and (C) and the Market Maker quote was exhausted. *See* Exchange Rule 515(c)(2).

[7] The term ''Proprietary Product'' means a class of options that is listed exclusively on the Exchange and any of its affiliates. *See* proposed Exchange Rule 100.

[8] *See* Exchange Rule 518, Interpretations and Policies .05(e)(2)(i).

[9] Certain option classes, as determined by the Exchange and communicated to Members via Regulatory Circular, will be eligible to participate in a Complex Auction (an ''eligible class''). Upon evaluation as set forth in subparagraph (c)(5) of Rule 518, the Exchange may determine to automatically submit a Complex Auction-eligible order into a Complex Auction. Upon entry into the System or upon evaluation of a complex order resting at the top of the Strategy Book, Complex Auction-eligible orders may be subject to an automated request for responses (''RFR''). *See* Exchange Rule 518(d).

[10] The Exchange notes that the Response Time Interval is currently set to 200 milliseconds. *See* MIAX Regulatory Circular 2016–46.

[11] *See* MIAX Regulatory Circular 2016–63.

[12] A ''Complex Auction-on-Arrival'' or ''cAOA'' order is a complex order designated to be placed into a Complex Auction upon receipt or upon evaluation . *See* Exchange Rule 518(b)(2).

[13] The term cNBBO means the Complex National Best Bid or Offer and is calculated using the National Best Bid or Offer (''NBBO'') for each component of a complex strategy to establish the best net bid and offer for a complex strategy. *See* Exchange Rule 518(a)(2).

[14] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[15] *See* Exchange Rule 518.05(f).

[16] *See* Exchange Rule 518.05(f)(3).

[17] *See* Exchange Rule 518.05(f)(4).

for a buy, or the MPC Price is greater than the complex order or eQuote's offer price for a sell), or if the complex order is a market order, the complex order or eQuote will be displayed and/or executed up to its MPC Price. Any unexecuted portion of such a complex order or eQuote: (A) Will be cancelled if it would otherwise be displayed or executed at a price that is outside the MPC Price; and (B) may be subject to the managed interest process described in Rule 518(c)(4).[18] If the MPC Price is priced more aggressively than the limit price of the complex order or eQuote (*i.e.,* the MPC Price is greater than the complex order or eQuote's bid price for a buy, or the MPC Price is less than the complex order or eQuote's offer price for a sell), the complex order or eQuote will be displayed and/or executed up to its limit price. Any unexecuted portion of such a complex order will be submitted, if eligible, to the managed interest process described in Rule 518(c)(4), or placed on the Strategy Book at its limit price. Any unexecuted portion of such a complex eQuote will be cancelled.[19]

The Exchange now proposes to initiate a Complex Liquidity Exposure Auction (''cLEP Auction'') whenever a complex order or complex eQuote would violate its MPC Price. To begin the cLEP Auction, the System will first broadcast a liquidity exposure message to all subscribers of the Exchange's data feeds. The liquidity exposure message will include the symbol, side of the market, auction start price (MPC Price), quantity of matched contracts, and the imbalance quantity. The inclusion of the quantity of matched contracts at the price included in the RFR message is intended to inform participants considering submitting an RFR Response the number of contracts for which there is matched interest, and the purposes of including the imbalance quantity in the RFR message is to inform such participants of the number of contracts that do not have matched interest.

The System will initiate a Response Time Interval, as determined by the Exchange and communicated via Regulatory Circular which shall be no less than 100 milliseconds and no more than 5,000 milliseconds.[20] The Exchange recently surveyed its Members and established that Members' Systems could submit auction responses in 100 milliseconds or less on average.[21] At the conclusion of the Complex Liquidity Exposure Auction if the resulting trade price is less aggressive than the MPC Price, liquidity will be handled in accordance to Exchange Rule 518(c)(2), Execution of Complex Orders and Quotes. Orders and quotes executed in a cLEP Auction will be allocated in accordance with the Complex Auction allocation procedures described in Exchange Rule 518(d)(7), Allocation at the Conclusion of a Complex Auction.

At the conclusion of a cLEP Auction the System will calculate the next potential MPC Price using the auction start price plus (minus) the next MPC increment for buy (sell) orders. Liquidity with an original price equal to or less aggressive than the new MPC Price is no longer subject to the MPC price protection. Liquidity with an original price more aggressive than the new MPC Price (or market order liquidity) is subject to the MPC price protection feature using the new MPC Price.

The current rule provides that if the MPC Price is priced less aggressively than the limit price of the complex order or eQuote (*i.e.,* the MPC Price is less than the complex order or eQuote's bid price for a buy, or the MPC Price is greater than the complex order or eQuote's offer price for a sell), or if the complex order is a market order, the complex order or eQuote will be displayed and/or executed up to its MPC Price. Any unexecuted portion of such a complex order or eQuote: (A) Will be cancelled if it would otherwise be displayed or executed at a price that is outside the MPC Price, and (B) may be subject to the managed interest process described in 518(c)(4).[22]

The Exchange now proposes to amend subsection(f)(6)(A) to provide that any unexecuted portion of such a complex order or eQuote will be subject to the cLEP as described in proposed subsection (e). The Exchange believes it to be in the best interest of the Member to seek liquidity via the Complex Liquidity Exposure Process as described above, rather than cancel any unexecuted portion of the order.

The examples below demonstrate an order subject to the Complex Liquidity Exposure Process.

Example 1

MPC: $0.25

The Exchange has one order resting on its Strategy Book:[23] +1 component A, −1 component B:

Order 1 is to sell 10 at $1.90
MBBO component A: 4.00(10) × 5.00(10)
MBBO component B: 2.00(10) × 2.50(10)
NBBO component A: 4.05(10) × 4.15(10)
NBBO component B: 2.30(10) × 2.40(10)
cMBBO: 1.50 (10) × 3.00 (10)
cNBBO: 1.65 (10) × 1.85 (10)

The Exchange receives a new order (Order 2) to buy 20 at $2.25.

Order 2 buys 10 from Order 1 at $1.90 and initiates the Complex Liquidity Exposure Process: Order 2 reprices to its protected price of $2.10 (cNBO of 1.85 + 0.25) and is posted at that price on the Complex Order Book and the Complex Liquidity Exposure Process Timer begins.

During the cLEP Auction the Exchange receives a new order (Order 3) to sell 10 at $2.10. This order locks the current same side Book Price of $2.10 and Order 3 sells 10 to Order 2 at $2.10, filling Order 2 and ending the Liquidity Exposure Process.

Example 2

MPC: $0.25

The Exchange has one order resting on its book in Strategy +1 component A, −1 component B:

Order 1 is to sell 10 at $1.90
MBBO component A: 4.00(10) × 5.00(10)
MBBO component B: 2.00(10) × 2.50(10)
NBBO component A: 4.05(10) × 4.15(10)
NBBO component B: 2.30(10) × 2.40(10)
cMBBO: 1.50 (10) × 3.00 (10)
cNBBO: 1.65 (10) × 1.85 (10)

The Exchange receives a new order (Order 2) to buy 20 at $2.25.

Order 2 buys 10 from Order 1 at $1.90 and initiates the Complex Liquidity Exposure Process: Order 2 reprices to its protected price of $2.10 (cNBO of 1.85 + 0.25) and is posted at that price on the Strategy Book and the Complex Liquidity Exposure Process Timer begins.

No new liquidity arrives during the Liquidity Exposure Process. At the end of the timer, Order 2 reprices to its limit of $2.25 and is posted at that price on the Strategy Book, ending the Liquidity Exposure Process.

The Exchange also proposes to make minor technical changes to Interpretations and Policies .05 of Exchange Rule 518 to reflect the proposed changes described above. Specifically, the Exchange proposes to remove subparagraph (f)(4) that provides that once established, the MPC

[18] *See* Exchange Rule 518.05(f)(6).

[19] *See* Exchange Rule 518.05(f)(7).

[20] The Exchange notes that the current duration of a cPRIME Auction is 100 milliseconds and the current duration of a Complex Auction is 200 milliseconds.

[21] *See* Securities Exchange Release No.80940 (June 15, 2017), 82 FR 28369 (June 21, 2017) (SR–MIAX–2017–16).

[22] *See* Exchange Rule 518.05(f)(6).

[23] The term ''Strategy Book'' is the Exchange's electronic book of complex orders and complex quotes. *See* Exchange Rule 518(a)(17).

Price will not change during the life of the complex order or eQuote. As described above the MPC Price for certain liquidities will be subject to a re-evaluation process and may change as a result of such re-evaluation. Also, the Exchange proposes to amend subparagraph (6)(A) to remove the provision that any unexecuted portion of such a complex order or eQuote will be cancelled if it would otherwise be displayed or executed at a price that is outside the MPC Price, and to state instead that it will be subject to the cLEP as described in subsection (e) of this Rule. Additionally, as a result of the removal of paragraph (4) it is necessary to renumber the remaining paragraphs for consistency within the numbering hierarchy of the Exchange's rules. Therefore current paragraph (5) will be renumbered as new paragraph (4); current paragraph (6) will be renumbered as new paragraph (5); and current paragraph (7) will be renumbered as new paragraph (6).

Finally, the Exchange proposes to amend subsection (b) of Interpretations and Policies .05 to adopt new rule text stating that the Calendar Spread Variance (''CSV'') price protection applies only to strategies in American-style option classes. A Calendar Spread is a complex strategy consisting of the purchase of one call (put) option and the sale of another call (put) option overlying the same security that have different expirations but the same strike price. The CSV establishes a minimum trading price limit for Calendar Spreads. The maximum possible value of a Calendar Spread is unlimited, thus there is no maximum price protection for Calendar Spreads. The minimum possible trading price limit of a Calendar Spread is zero minus the pre-set value of $.10. This ensures that the Strategy doesn't trade more than $.10 away from its intrinsic value. (On a basic level the price of an American-style option is comprised of two components; intrinsic value and time value. If the strike price of a call option is $5.00 and the stock is priced at $6.00, there is $1.00 of intrinsic value in the price of the call option, anything above $1.00 represents the time value component.) An American-style option must be worth at least as much as its intrinsic value because the holder of the option can realize the intrinsic value by immediately exercising the option. In a Calendar Spread strategy comprised of American-style options, ceteris paribus, the far month should be worth more than the near month due to its having a greater time to expiration and therefore a higher time value. As European-style options [24] may only be exercised on their expiration date, the relationship between the stock price, option price, and option strike price that exists for American-style options does not exist for European-style options. Therefore the CSV price protection would be ineffective and will not be available for strategies comprised of European-style options.

2. Statutory Basis

The Exchange believes that its proposed rule change is consistent with Section 6(b) of the Act [25] in general, and furthers the objectives of Section 6(b)(5) of the Act [26] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes its proposal to include the liquidity exposure timer as a SMAT Event promotes just and equitable principles of trade, removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest. SMAT Events represent temporary interruptions of free trading in one or more components of a complex strategy. The temporary suspension of trading in complex orders during a SMAT Event is intended to enhance continuity, trade-through protection, and orderliness in the simple market and to protect complex order components from being executed at prices that could improve following a SMAT Event. Once a SMAT Event is concluded or resolved, the System will re-evaluate the Strategy Book.[27]

The Exchange believes that its proposal to eliminate the Defined Time Period to allow Complex Auctions [28] to occur throughout the trading session removes impediments to and perfects the mechanism of a free and open market and a national market system and, in general, protects investors and the public interest by removing an unnecessary barrier which prevented Complex Auctions from occurring with less than two seconds left in the trading session. The current duration of a Complex Auction duration is just 200 milliseconds. The Exchange believes it is in the best interest of the investor to allow for opportunities for price improvement throughout the entire trading session. In the event that a Member initiates a Complex Auction without enough time for Members to respond, the initiating Member is no worse off under the proposed rule than the Member would have been under the current rule which prevents the Member from even attempting to initiate a Complex Auction with less than two seconds left in the trading session.

The Exchange also believes its proposal to adopt a Complex Liquidity Exposure Process promotes just and equitable principles of trade and removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest. The Complex Liquidity Exposure Process provides an additional opportunity for price discovery for those orders that would trade through their MPC Price. The Exchange believes its proposal promotes just and equitable principles of trade as it is in the best interest of the Member to seek liquidity for the unexecuted portion of the order which exceeds the order's MPC Price rather than to simply cancel the unexecuted portion back to the Member.[29]

The Exchange also believes that its proposal to amend Interpretations and Policies .05(f) to reflect the changes resulting from the introduction of the Complex Liquidity Exposure Process promotes just and equitable principles of trade, and removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest by clearly describing the operation of the Exchange's functionality in the Exchange's rules. The Exchange believes it is in the interest of investors and the public to accurately describe the behavior of the Exchange's System in its

[24] The term ''European-style option'' means an option contract that, subject to the provisions of Rule 700 (relating to the cutoff time for exercise instructions) and to the Rules of the Clearing Corporation, can be exercised only on its expiration date. *See* Exchange Rule 100.

[25] 15 U.S.C. 78f(b).

[26] 15 U.S.C. 78f(b)(5).

[27] *See* Exchange Rule 518, Interpretations and Policies .05(f)(2)(i).

[28] Complex Auctions are described in Exchange Rule 518(d) and are separate and distinct from cPRIME Auctions which are described in Interpretations and Policies .12 of Exchange Rule 515A, MIAX Price Improvement Mechanism (''PRIME'') and PRIME Solicitation Mechanism.

[29] The Exchange notes that Members who believe that an execution has occurred at an erroneous price may avail themselves of the protections provided in Exchange Rule 521, Nullification and Adjustment of Options Transactions Including Obvious Errors.

rules as this information may be used by investors to make decisions concerning the submission of their orders. Further, the Exchange's proposal to make non-substantive changes to re-number certain paragraphs for internal consistency within the rule benefits investors and the public interest by providing clarity and accuracy in the Exchange's rules.

Finally, the Exchange believes its proposal to clarify that the Calendar Spread Variance (CSV) price protection is available only for American-style options promotes just and equitable principles of trade, and removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, and protects investors and the public interest by providing clarity and precision in the Exchange's rules. The Exchange believes it is in the interest of investors and the public to accurately describe the behavior of the Exchange's System in its rules as this information may be used by investors to make decisions concerning the submission of their orders. Transparency and clarity are consistent with the Act because it removes impediments to and helps perfect the mechanism of a free and open market and a national market system, and, in general, protects investors and the public interest by accurately describing the behavior of the Exchange's System. In particular, the Exchange believes that the proposed rule change will provide greater clarity to Members and the public regarding the Exchange's Rules, and it is in the public interest for rules to be accurate and concise so as to eliminate the potential for confusion.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange does not believe the proposed rule change will impose any burden on inter-market competition. The Exchange's proposal seeks to enhance complex order trading on the Exchange, and may potentially enhance competition among the various markets for complex order execution, potentially resulting in more active complex order trading on all exchanges.

Additionally, the Exchange does not believe the proposed rule change will impose any burden on intra-market competition as the Rules apply equally to all Members of the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MIAX–2018–36 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2018–36. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2018–36, and should be submitted on or before December 14, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–25470 Filed 11–21–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

Extension:

Form 8–A; SEC File No. 270–054; OMB Control No. 3235–0056.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Form 8–A (17 CFR 249.208a) is a registration statement used to register a class of securities under Section 12(b) or Section 12(g) of the Securities Exchange Act of 1934 (15 U.S.C. 78*l*(b) and 78*l*(g)) (''Exchange Act''). Section 12(a) (15 U.S.C. 78*l*(a)) of the Exchange Act makes it unlawful for any member, broker, or dealer to effect any transaction in any security (other than an exempted security) on a national securities exchange unless such security has been registered under the Exchange Act (15 U.S.C. 78a *et seq.*). Exchange

[30] 17 CFR 200.30–3(a)(12).

Act Section 12(b) establishes the registration procedures. Exchange Act Section 12(g) requires an issuer that is not a bank or bank holding company to register a class of equity securities (other than exempted securities) within 120 days after its fiscal year end if, on the last day of its fiscal year, the issuer has total assets of more than $10 million and the class of equity securities is ''held of record'' by either (i) 2,000 persons, or (ii) 500 persons who are not accredited investors. An issuer that is a bank or a bank holding company, must register a class of equity securities (other than exempted securities) within 120 days after the last day of its first fiscal year ended after the effective date of the JOBS Act if, on the last day of its fiscal year, the issuer has total assets of more than $10 million and the class of equity securities is ''held of record'' by 2,000 or more persons. Form 8–A takes approximately 3 hours to prepare and is filed by approximately 871 respondents for a total annual reporting burden of 2,613 hours (3 hours per response x 871 responses).

Written comments are invited on: (a) Whether this collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

Please direct your written comment to Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 19, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–25492 Filed 11–21–18; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments

ACTION: 60-Day notice and request for comments.

SUMMARY: The Small Business Administration (SBA) intends to request approval, from the Office of Management and Budget (OMB) for the collection of information described below. The Paperwork Reduction Act (PRA) requires federal agencies to publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

DATES: Submit comments on or before January 22, 2019.

ADDRESSES: Send all comments to Dena Moglia, Office of Entrepreneurial Development, Small Business Administration, 409 3rd Street SW, 6th Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Dena Moglia, Senior Management & Program Analyst, 202–205–7034, *dena.moglia@sba.gov,* Curtis B. Rich, Management Analyst, 202–205–7030 *curtis.rich@sba.gov.*

SUPPLEMENTARY INFORMATION: In accordance with regulations and policy, the Small Business Development Centers (SBDC's) must provide SBA semi-annual financial and programmatic reports-outlining expenditures and accomplishments. The information collected will be used to monitor the progress of the program.

Summary of Information Collection

Title: ''Federal Cash Transaction Report; Financial Status Report Program Income Report Narrative Program Report''.

Description of Respondents: SBDC Directors.

Form Number: 2113.

Annual Responses: 126.

Annual Burden: 7,308.

Curtis Rich,

Management Analyst.

[FR Doc. 2018–25519 Filed 11–21–18; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments

ACTION: 60-Day notice and request for comments.

SUMMARY: The Small Business Administration (SBA) intends to request approval, from the Office of Management and Budget (OMB) for the collection of information described below. The Paperwork Reduction Act (PRA) of 1995 requires federal agencies to publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

DATES: Submit comments on or before January 22, 2019.

ADDRESSES: Send all comments to Michael Donadieu, Director, Office of Small Business Investment Companies Examinations, Small Business Administration, 409 3rd Street, 7th Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Michael Donadieu, Director, Office of Small Business Investment Companies Examinations, 202–205–7281, *michael.donadieu@sba.gov,* or Curtis B. Rich, Management Analyst, 202–205–7030, *curtis.rich@sba.gov.*

SUPPLEMENTARY INFORMATION: Form 857 is used by SBA examiners to obtain information about financing provided by small business investment companies (SBICs). This information, which is collected directly from the financed small business, provides independent confirmation of information reported to SBA by SBICs, as well as additional information not reported by SBICs.

Title: ''Request for Information Concerning Portfolio Financing''.

Description of Respondents: Small Business Investment Companies.

Form Number: 857.

Annual Responses: 2,250.

Annual Burden: 2,250.

Curtis Rich,

Management Analyst.

[FR Doc. 2018–25515 Filed 11–21–18; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments

ACTION: 60-Day notice and request for comments.

SUMMARY: The Small Business Administration (SBA) intends to request approval, from the Office of Management and Budget (OMB) for the new collection of information described below. The Paperwork Reduction Act (PRA) requires federal agencies to

publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

DATES: Submit comments on or before January 22, 2019.

ADDRESSES: Send all comments to Sharon Gurley, Director, Office of Business Development, Small Business Administration, 409 3rd Street, 8th Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Sharon Gurley, Director, Office of Business Development, *Sharon.gurley@sba.gov,* 202–205–7084, or Curtis B. Rich, Management Analyst, 202–205–7030, *Curtis.Rich@sba.gov.*

SUPPLEMENTARY INFORMATION: In accordance with 13 CFR 124.604, as part of its annual review submission, each Participant owned by a Tribe, ANC, NHO or CDC must submit to SBA information showing how they have provided benefits to their members and communities. This data includes information relating to funded cultural programs, employment assistance, jobs, scholarships, internships, subsistence activities, and other services provided.

Solicitation of Public Comments

SBA is requesting comments on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Summary of Information Collection

Title: 8(a) Participant Benefits Report.

Description of Respondents: 8(a) Program Participants—Entity Owned (Indian Tribe, Alaskan Native Corporations, Native Hawaiian Organizations, and Community Development Corporations.

Form Number: 2456.

Total Estimated Annual Responses: 329.

Total Estimated Annual Hour Burden: 165.

Curtis Rich,

Management Analyst.

[FR Doc. 2018–25511 Filed 11–21–18; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments

ACTION: 60-Day notice and request for comments.

SUMMARY: The Small Business Administration (SBA) intends to request approval, from the Office of Management and Budget (OMB) for the collection of information described below. The Paperwork Reduction Act (PRA) requires federal agencies to publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

DATES: Submit comments on or before January 22, 2019.

ADDRESSES: Send all comments to Dena Moglia, Office of Entrepreneurial Development, Small Business Administration, 409 3rd Street, 6th Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Dena Moglia, Senior Management & Program Analyst, 202–205–7034, *dena.moglia@sba.gov*, Curtis B. Rich, Management Analyst, 202–205–7030 *curtis.rich@sba.gov*

SUPPLEMENTARY INFORMATION: In October 2014, a new cohort of sites was added to the Regional Innovation Clusters (RIC) initiative, which was originally started in October 1, 2010 by the Small Business Administration (SBA)'s Office of Entrepreneurial Development. Through this initiative, organizations in 11 communities across the U.S. have been selected to provide industry-specific assistance to small businesses, and to develop industry relationships and supply chains within their regions. Clusters—geographically concentrated groups of interconnected businesses, suppliers, service providers, and associated institutions in a particular industry or field—act as a networking hub to convene a number of resources to help navigate the funding, procurement, and supply-chain opportunities in a specific industry.

SBA is conducting an evaluation of the Regional Innovation Clusters initiative to determine how the clusters have developed, the type and volume of services they provided to small businesses, client perceptions of the program, and the various outcomes related to their existence, including collaboration among firms, innovation, and small business growth. Small business growth will be compared to the overall growth of firms in those same regions and industries. This evaluation will also include lessons learned and success stories. SBA proposes the use of three instruments for data collection and analysis of three distinct populations. These instruments are: (1) Small Business Survey, (2) Large Organization Survey and (3) Cluster Administrator Survey. In addition, SBA plans to interview each of the 11 cluster administrators several times a year regarding program impact and successes or challenges, and to obtain clarifications on information provided in quarterly reports. Each of the proposed surveys will be administered electronically and will contain both open- and close-ended questions. The information collected and analyzed from these instruments will contribute to monitoring performance metrics and program goals, as well as recommendations on improving program practices.

Solicitation of Public Comments

Title: Regional Innovation Clusters (RIC) Initiative Evaluation Study.

Description of Respondents: Interconnected businesses, Suppliers, Service providers, and associated institutions.

Form Number: N/A.

Estimated Annual Responses: 1,240.

Estimated Annual Hour Burden: 388.

Curtis Rich,

Management Analyst.

[FR Doc. 2018–25514 Filed 11–21–18; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments

ACTION: 60-Day notice and request for comments.

SUMMARY: The Small Business Administration (SBA) intends to request approval, from the Office of Management and Budget (OMB) for the collection of information described below. The Paperwork Reduction Act (PRA) of 1995 requires federal agencies to publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

DATES: Submit comments on or before January 22, 2019.

ADDRESSES: Send all comments to Mary Frias, Loan Specialist, Office of Financial Assistance, Small Business

Administration, 409 3rd Street SW, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Mary Frias, Loan Specialist, Office of Financial Assistance, *mary.frias@sba.gov* 202–401–8234, or Curtis B. Rich, Management Analyst, 202–205–7030, *curtis.rich@sba.gov.*

SUPPLEMENTARY INFORMATION: The servicing agent agreement is executed by the borrower, and the certified development company as the loan servicing agent. The agreement is primarily used by the certified development company as the loan servicing agent and acknowledges the imposition of various fees allowed in SBA's 504 loan program.

Solicitation of Public Comments

SBA is requesting comments on (a) Whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Summary of Information Collection

Title: Servicing Agent Agreement.

Description of Respondents: SBA Borrowers.

Form Number: SBA Form 1506.

Total Estimated Annual Responses: 6,151.

Total Estimated Annual Hour Burden: 6,151.

Curtis Rich,

Management Analyst.

[FR Doc. 2018–25513 Filed 11–21–18; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 10616]

Certification Pursuant to Section 704 I(F)(3) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2018

By virtue of the authority vested in me under section 7041(f)(3) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2018 (Div. K, Pub. L. 115–141) (SFOAA) and Department of State Delegation of Authority 245–2, I hereby certify that all practicable steps have been taken to ensure that mechanisms are in place for monitoring, oversight, and control of funds made available by section 7041(f) of the SFOAA for assistance for Libya.

This certification shall be published in the **Federal Register** and, along with the accompanying Memorandum of Justification, shall be reported to Congress.

Dated: September 20, 2018.

John J. Sullivan,

Deputy Secretary of State.

[FR Doc. 2018–25563 Filed 11–21–18; 8:45 am]

BILLING CODE 4710–31–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36237]

Tulsa-Sapulpa Union Railway Company, L.L.C.—Lease Renewal Exemption With Interchange Commitment—Union Pacific Railroad Company

Tulsa-Sapulpa Union Railway Company, L.L.C. (TSU), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to renew its lease of approximately 12.86 miles of railroad line owned by Union Pacific Railroad Company (UP), located in Tulsa County, Okla. (the Line). The Line, known as the Jenks Industrial Lead, extends from milepost 136.40 near the Kimberly Clark facility in Jenks, Okla., to the end of UP's ownership at milepost 149.26 and the connection with UP's trackage rights over BNSF Railway Company in Tulsa, Okla.

TSU states that it and UP previously executed a lease agreement regarding the Line in 2001.[1] TSU states that the new lease agreement, dated as of December 21, 2018, has an initial five-year term that may be extended by TSU for an additional 15 years.

TSU certifies that its projected annual revenues from this transaction will not result in its becoming a Class I or Class II rail carrier and will not exceed $5 million. As required under 49 CFR 1150.43(h)(1), TSU has disclosed in its verified notice that the lease renewal agreement contains an interchange commitment that charges TSU an asset use fee for carloads that originate or terminate on the Line that are not interchanged to UP.[2] TSU has provided additional information regarding the interchange commitment as required by 49 CFR 1150.43(h).

TSU states in its verified notice that it intends to consummate the proposed lease renewal on or shortly after December 21, 2018. The earliest this transaction may be consummated is December 7, 2018 (30 days after the verified notice was filed).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than November 30, 2018 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36237, must be filed with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on TSU's representative, Audrey L. Brodrick, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606–3208.

According to TSU, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic reporting under 49 CFR 1105.8(b).

Board decisions and notices are available on our website at *www.stb.gov.*

Decided: November 19, 2018.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Aretha Laws-Byrum,

Clearance Clerk.

[FR Doc. 2018–25529 Filed 11–21–18; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36250]

R.J. Corman Railroad Group, LLC and R.J. Corman Railroad Company, LLC—Acquisition of Control Exemption—Nashville and Western Railroad Corp. and Nashville & Eastern Railroad Corp.

R.J. Corman Railroad Group, LLC (RJCG), a noncarrier holding company, and its wholly owned subsidiary, R.J. Corman Railroad Company, LLC (RJCR), have jointly filed a verified notice of exemption pursuant to 49 CFR 1180.2(d)(2) to acquire control of two Class III railroads, Nashville and Western Railroad Corp. (NWRR) and Nashville & Eastern Railroad Corp. (NERR). NWRR and NERR are currently controlled by William J. Drunsic.[1]

RJCG and RJCR currently control 12 Class III railroads.[2] RJCG and RJCR state

[1] *Tulsa-Sapulpa Union Ry.—Lease & Operation Exemption—Union Pac. R.R.,* FD 33974 (STB served Dec. 26, 2000, corrected Feb. 12, 2001).

[2] TSU submitted under seal a copy of the lease renewal agreement with its verified notice of exemption.

[1] *See William J. Drunsic—Continuance in Control Exemption—Nashville & W. R.R.,* FD 33910 (STB served Aug. 4, 2000).

[2] Two of the 12, R.J. Corman Railroad Property, LLC, and R.J. Corman Railroad Company/Ashland,

that NWRR operates a 28-mile line owned by the Cheatham County Rail Authority extending between Tennessee Central milepost 205.76 at Nashville, Tenn., and Tennessee Central milepost 185 at Ashland City, Tenn. RJCG and RJCR state that NERR operates rail lines owned by the Nashville and Eastern Railroad Authority totaling approximately 130.2 miles, extending between (1) milepost 0.35 at Nashville and milepost 110.5 at Monterey, Tenn., (2) milepost 189.5 at Vine Hill, Tenn., and 194.1 at Southern Junction, Tenn., (3) milepost NX 0.00 at Carthage Junction, Tenn., and milepost NX 7.56 at Carthage, Tenn., and (4) milepost 0.1 at Donelson, Tenn., and milepost 8.0 at Old Hickory, Tenn.

RJCG and RJCR have signed a Plan of Merger and Sale and Purchase of Equity Interests (Agreement) [3] with NWRR and NERR by which RJCG and RJCR will acquire control of NWRR and NERR through the purchase of 100% of their issued and outstanding stock.[4]

The earliest the transaction could be consummated is December 9, 2018, the effective date of the exemption (30 days after the verified notice was filed). RJCG and RJCR state that the transaction is scheduled to be finalized during the first quarter of 2019.

RJCG and RJCR certify that: (i) NWRR and NERR do not connect with each other or any of the RJC Railroads; (ii) the proposed transaction is not part of a series of anticipated transactions that would connect some or all of these railroads; and (iii) the transaction does not involve a Class I carrier. Therefore, the transaction is exempt from the requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(2).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for the labor protection for transactions under sections 11324 and 11325 that involve only Class III rail carriers. Therefore, because this transaction involves only Class III rail carriers, the Board may not impose labor protective conditions for this transaction.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction. Petitions to stay must be filed no later than November 30, 2018 (at least seven days before the exemption becomes effective).

An original and ten copies of all pleadings, referring to Docket No. FD 36250, must be filed with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on David R. Irvin, Esq., Moynahan, Irvin & Mooney P.S.C., 110 N Main Street, Nicholasville, KY 40356.

Board decisions and notices are available on our website at *www.stb.gov.*

Decided: November 19, 2018.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2018–25574 Filed 11–21–18; 8:45 am]

BILLING CODE P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36243]

Watco Holdings, Inc.—Continuance in Control Exemption—Ithaca Central Railroad, LLC

Watco Holdings Inc. (Watco), a noncarrier, has filed a verified notice of exemption under 49 CFR 1180.2(d)(2) to continue in control of Ithaca Central Railroad, LLC (ICR), upon ICR's becoming a Class III rail carrier. Watco owns, indirectly, 100% of the issued and outstanding stock of ICR.

This transaction is related to a verified notice of exemption filed concurrently in *Ithaca Central Railroad, LLC—Lease & Operation Exemption—Norfolk Southern Railway,* Docket No. FD 36238, by which ICR seeks Board approval to lease from Norfolk Southern Railway Company (NSR) and operate approximately 48.8 miles of rail line between milepost 272.2 in Sayre, Pa. and milepost 321.0 in Lansing, N.Y.

The transaction may be consummated on or after December 8, 2018, the effective date of the exemption (30 days after the verified notice of exemption was filed).

According to the verified notice of exemption, Watco currently controls indirectly 38 Class III railroads and one Class II railroad, collectively operating in 25 states. For a complete list of these rail carriers and the states in which they operate, see the November 8, 2018 verified notice of exemption at pages 4–11. The verified notice is available on the Board's website at *www.stb.gov.*

Watco represents that: (1) The rail line to be operated by ICR does not connect with any of the rail lines operated by railroads in the Watco corporate family; (2) this transaction is not part of a series of anticipated transactions that would connect ICR with any railroad in the Watco corporate family; and (3) the transaction does not involve a Class I rail carrier. The proposed transaction is therefore exempt from the prior approval requirements of 49 U.S.C. 11323 pursuant to 49 CFR 1180.2(d)(2). Watco states that the purpose of the transaction is to reduce overhead expenses and coordinate billing, maintenance, mechanical and personnel policies and procedures of its rail carrier subsidiaries, and thereby improve the overall efficiency of rail service provided by the railroads in the Watco corporate family.

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Because the transaction involves the control of one Class II and one or more Class III rail carriers, the transaction is subject to the labor protection requirements of 49 U.S.C. 11326(b) and *Wisconsin Central Ltd.—Acquisition Exemption—Lines of Union Pacific Railroad,* 2 S.T.B. 218 (1997).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than November 30, 2018 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36243, must be filed with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Karl Morell & Associates, 440 1st Street NW, Suite 440, Washington, DC 20001.

LLC, are non-operating carriers. The other 10 operating railroads include R.J. Corman Railroad Company/Western Ohio Line, Inc., R.J. Corman Railroad Company/Pennsylvania Lines, Inc., R.J. Corman Railroad Company/Allentown Lines, Inc., R.J. Corman Railroad Company/Bardstown Line, Inc., R.J. Corman Railroad Company/Cleveland Line, Inc., R.J. Corman Railroad Company/Carolina Lines, LLC, R.J. Corman Railroad Company/Central Kentucky Lines, LLC, R.J. Corman Railroad Company/Texas Lines, LLC, R.J. Corman Railroad Company/Tennessee Terminal, LLC, and R.J. Corman Railroad Company/Memphis Line, Inc., (collectively, RJC Railroads).

[3] An unredacted copy of the Agreement was filed concurrently under seal, along with a motion for protective order, which will be addressed in a separate decision.

[4] RJCG and RJCR indicate that they will purchase the stock of NERR through the creation of a holding company, RJCN, Inc., and its wholly owned entity, RJCMS, Inc., which will be merged into NERR simultaneously, with NERR as the surviving entity. RJCG and RJCR will purchase the stock of NWRR by merging NWRR with newly created entity RJCWMS, Inc., which will be the surviving entity with the name reverting to NWRR.

According to Watco, this action is categorically excluded from environmental review under 49 CFR 1105.6(c).

Board decisions and notices are available on our website at *www.stb.gov.*

Decided: November 19, 2018.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Raina Contee,

Clearance Clerk.

[FR Doc. 2018–25549 Filed 11–21–18; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36238]

Ithaca Central Railroad, LLC—Lease and Operation Exemption—Norfolk Southern Railway Company

Ithaca Central Railroad LLC (ICR), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to lease from Norfolk Southern Railway Company (NSR) and operate approximately 48.8 miles of rail line, extending from milepost 272.2 in Sayre, Pa., to milepost 321.0 in Lansing, N.Y.

This transaction is related to a concurrently filed verified notice of exemption in *Watco Holdings, Inc.—Continuance in Control Exemption—Ithaca Central Railroad,* Docket No. FD 36243, in which Watco Holdings, Inc., seeks to continue in control of ICR upon ICR's becoming a Class III rail carrier.

ICR states that it will shortly enter into an agreement to lease the rail line from NSR and that ICR will be the operator of the leased line. ICR further states that the proposed agreement between ICR and NSR does not contain any provision that prohibits ICR from interchanging traffic with a third party or limits ICR's ability to do so.

ICR certifies that its projected annual revenues as a result of this transaction will not result in ICR's becoming a Class II or Class I rail carrier. ICR further certifies that the projected annual revenue of ICR will not exceed $5 million.

The transaction may be consummated on or after December 8, 2018, the effective date of the exemption (30 days after the verified notice was filed).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than November 30, 2018 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36238, must be filed with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Karl Morell & Associates, 440 1st Street NW, Suite 440, Washington, DC 20001.

According to ICR, this action is excluded from environmental review under 49 CFR 1105.6(c) and from historic reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available on our website at *www.stb.gov.*

Decided: November 19, 2018.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Raina Contee,

Clearance Clerk.

[FR Doc. 2018–25550 Filed 11–21–18; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket Nos. FMCSA–2014–0214; FMCSA–2014–0215]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

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

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for five individuals from the requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) that interstate commercial motor vehicle (CMV) drivers have ''no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.'' The exemptions enable these individuals who have had one or more seizures and are taking anti-seizure medication to continue to operate CMVs in interstate commerce.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates stated in the discussions below. Comments must be received on or before December 24, 2018.

ADDRESSES: You may submit comments identified by the Federal Docket Management System (FDMS) Docket Nos. FMCSA–2014–0214; FMCSA–2014–0215 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, 202–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket numbers for this notice (Docket Nos. FMCSA–2014–0214; FMCSA–2014–0215), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* put the docket number, FMCSA–2014–0214; FMCSA–2014–0215, in the keyword box, and click ''Search.'' When the new screen appears, click on the ''Comment Now!'' button and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an

individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period.

B. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA–2014–0214; FMCSA–2014–0215, in the keyword box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

C. Privacy Act

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

II. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for up to five years if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the five-year period. FMCSA grants exemptions from the FMCSRs for a two-year period to align with the maximum duration of a driver's medical certification.

The physical qualification standard for drivers regarding epilepsy found in 49 CFR 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria to assist Medical Examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce. [49 CFR part 391, APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section H. Epilepsy: § 391.41(b)(8), paragraphs 3, 4, and 5.]

The five individuals listed in this notice have requested renewal of their exemptions from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable two-year period.

III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

IV. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315, each of the five applicants has satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition. The five drivers in this notice remain in good standing with the Agency, have maintained their medical monitoring and have not exhibited any medical issues that would compromise their ability to safely operate a CMV during the previous two-year exemption period. In addition, for Commercial Driver's License (CDL) holders, the Commercial Driver's License Information System (CDLIS) and the Motor Carrier Management Information System (MCMIS) are searched for crash and violation data. For non-CDL holders, the Agency reviews the driving records from the State Driver's Licensing Agency (SDLA). These factors provide an adequate basis for predicting each driver's ability to continue to safely operate a CMV in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

As of October 24, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following individual has satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers: Jeffrey M. Phillips (SC).

This driver was included in docket number FMCSA–2014–0214. The exemption is applicable as of October 24, 2018, and will expire on October 24, 2020.

As of October 15, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following four individuals have satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers:

Thomas Avery, Jr. (NY)
Philip Stewart (CA)
Alan T. VonLintel (KS)
Keith T. White (PA)

The drivers were included in docket number FMCSA–2014–0215. Their exemptions are applicable as of October 15, 2018, and will expire on October 15, 2020.

V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) Each driver must remain seizure-free and maintain a stable treatment during the two-year exemption period; (2) each driver must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free; (3) each driver must undergo an annual medical examination by a certified Medical Examiner, as defined by 49 CFR 390.5; and (4) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy of his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or

regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based on its evaluation of the five exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8). In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for two years unless revoked earlier by FMCSA.

Issued on: November 1, 2018.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2018–25510 Filed 11–21–18; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2018–0102 (Notice No. 2018–19)]

Hazardous Materials: Information Collection Activities

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, PHMSA invites comments on this information collection pertaining to hazardous materials transportation for which PHMSA intends to request renewal from the Office of Management and Budget.

DATES: Interested persons are invited to submit comments on or before January 22, 2019.

ADDRESSES: You may submit comments identified by the Docket No. PHMSA–2018–0102 (Notice No. 2018–19) by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management System; U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, Routing Symbol M–30, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* To the Docket Management System; Room W12–140 on the ground floor of the West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the agency name and Docket Number (PHMSA–2018–0102) for this notice at the beginning of the comment. To avoid duplication, please use only one of these four methods. All comments received will be posted without change to the Federal Docket Management System (FDMS) and will include any personal information you provide.

Requests for a copy of an information collection should be directed to Steven Andrews or Shelby Geller, Standards and Rulemaking Division, (202) 366–8553, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Docket: For access to the dockets to read background documents or comments received, go to *http://www.regulations.gov* or DOT's Docket Operations Office (see **ADDRESSES**).

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

FOR FURTHER INFORMATION CONTACT: Steven Andrews or Shelby Geller, Standards and Rulemaking Division, (202) 366–8553, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION: Section 1320.8 (d), title 5, Code of Federal Regulations (CFR) requires PHMSA to provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests. This notice identifies information collection request that PHMSA will be submitting to the Office of Management and Budget (OMB) for renewal and extension. This information collection is contained in 49 CFR 171.6 of the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180). PHMSA has revised burden estimates, where appropriate, to reflect current reporting levels or adjustments based on changes in proposed or final rules published since this information collection was last approved. The following is provided for this information collection: (1) Title of the information collection, including former title if a change is being made; (2) OMB control number; (3) summary of the information collection activity; (4) description of affected public; (5) estimate of total annual reporting and recordkeeping burden; and (6) frequency of collection. PHMSA will request a 3-year term of approval for this information collection activity and will publish a notice in the **Federal Register** upon OMB's approval.

PHMSA requests comments on the following information collection:

Title: Flammable Hazardous Materials by Rail Transportation.

OMB Control Number: 2137–0628.

Summary: This OMB control number is used for information and recordkeeping requirements pertaining to the sampling and testing certification, routing analysis, and incident reporting for flammable liquids by rail transportation. Rail carriers, shippers, PHMSA's Office of Hazardous Materials Safety (OHMS), the Federal Railroad Administration (FRA), and the Association of American Railroads (AAR) may use this information to ensure that rail tank cars transporting flammable liquids are properly classified, ensure trains are routed appropriately, and collect all relevant incident data. This OMB control number is being offered for renewal includes the following information collections and associated burden hours:

Information collection	Respondents	Responses	Hours per response	Total hours
Sampling and Testing Plan Burden for Subsequent Year Revision	1,804	1,804	10	18,040
Routing—Collection by Segment for Class II Railroads	10	10	40	400
Routing—Collection by Segment for Class III Railroads	160	160	40	6,400
Routing Analysis Burden for Class II Railroads	10	50	16	800
Routing Analysis Burden for Class III Railroads	160	320	8	2,560
Routing Security Analysis Burden for Class II Railroads	10	40	12	480
Routing Security Analysis Burden for Class III Railroads	64	32	4	128

Information collection	Respondents	Responses	Hours per response	Total hours
Tank Car Retrofit Burden	50	50	0.5	25
Crude Oil Incident Reporting	15	15	2	30

Affected Public: Shippers and carriers of petroleum liquids by rail.

Annual Reporting and Recordkeeping Burden:

Number of Respondents: 2,283.

Total Annual Responses: 2,481.

Total Annual Burden Hours: 28,863.

Frequency of Collection: On occasion.

Issued in Washington, DC, on November 19, 2018.

William S. Schoonover,

Associate Administrator for Hazard Materials Safety, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2018–25484 Filed 11–21–18; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2018–0190]

Advisory Committee on Aviation Consumer Protection Matters; Subcommittee on In-Flight Sexual Misconduct

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

ACTION: Notice of reestablishment and first meeting of the Aviation Consumer Protection Advisory Committee.

SUMMARY: The Department of Transportation (''Department'') has reestablished the Aviation Consumer Protection Advisory Committee (''ACPAC'' or ''Committee''), formerly known as the Advisory Committee on Aviation Consumer Protection, as a Federal advisory committee. The Department has also established a National In-Flight Sexual Misconduct Task Force (''Task Force'') as an ACPAC Subcommittee. The Task Force will develop recommendations for the ACPAC's consideration on best practices and protocols for air carriers relating to training, reporting, and data collection of sexual assault onboard commercial aircraft. The Department anticipates the first meeting of the ACPAC will be held on January 16, 2019. The meeting will be held in the Media Center (located on the lobby level of the West Building) at the U.S. Department of Transportation Headquarters,1200 New Jersey Ave, SE, Washington, DC 20590. Three topics will be discussed at that meeting—(1) establishment of the Task Force (including the tasks to be carried out by the Task Force); (2) transparency of airline ancillary service fees; and (3) involuntary changes to travel itineraries.

DATES: The first meeting of the reestablished ACPAC will be held on January 16, 2019, from 9:00 a.m. to 4:00 p.m. Eastern Time.

FOR FURTHER INFORMATION CONTACT: To register to attend the meeting, please contact Stuart Hindman, Senior Attorney, Office of Aviation Enforcement and Proceedings, by email at *stuart.hindman@dot.gov,* or by telephone at 202–366–9342; or Zeenat Iqbal, Senior Attorney, Office of Aviation Enforcement and Proceedings, by email at *zeenat.iqbal@dot.gov,* or by telephone at 202–366–9893. Attendance is open to the public up to the room's capacity of 100 attendees. Since space is limited and access to the DOT headquarters building is controlled for security purposes, any member of the general public who plans to attend this meeting must notify the registration contact identified no later than Wednesday, January 2, 2019.

SUPPLEMENTARY INFORMATION:

Background

On May 24, 2012, the Department established an advisory committee on aviation consumer protection, known as the Advisory Committee on Aviation Consumer Protection, as mandated by section 411 of the FAA Modernization and Reform Act of 2012 (Pub. L. 112–95, 126 Stat. 11 (2012)) (2012 FAA Act) and the Federal Advisory Committee Act (FACA), as amended. The original Committee held nine meetings and examined a broad range of issues affecting consumers. The Committee has contributed significantly to the Department's aviation consumer protection program as it provides a forum for stakeholders, including representatives of airlines, airports and consumers, to discuss important consumer issues.

The statutory termination date for the Committee was originally established by the 2012 FAA Act as September 30, 2015, but has been extended several times, most recently by the FAA Reauthorization Act of 2018 (Pub. L. No: 115–254) (2018 FAA Act) to the current termination date of September 30, 2023.

The Department has updated the Committee's charter to clarify that the Committee's work should concern aviation consumer protection issues that fall within the current statutory authority of the Department and establish a subcommittee to be called the ''National In-Flight Sexual Misconduct Task Force.''

Appointment of New Members

The Secretary has appointed four new members to the Committee. The appointed members are: (1) Patricia Vercelli, General Counsel, Airlines for America, as the airline representative; (2) Mario Rodriguez, Executive Director of the Indianapolis Airport Authority, as the airport operator representative; (3) Pete K. Rahn, Maryland Secretary of Transportation, as the State or local government representative; and (4) Frances Smith, Adjunct Fellow, Competitive Enterprise Institute, as the consumer representative. Mr. Rahn will serve as the Chair of the Committee. The Department chose the Committee members based on two main criteria: (1) Representativeness (does the individual represent one of the four groups mentioned above); and (2) expertise (does the individual bring essential knowledge, expertise, or experience regarding consumer protection).

National In-Flight Sexual Misconduct Task Force Subcommittee

Recent reports of increased incidents of sexual assault and misconduct onboard aircraft have highlighted concerns regarding the response to such incidents. The Joint Explanatory Statement of the 2018 Consolidated Appropriations Act requested that the Department establish a Task Force to provide recommendations in this area. In addition, the Task Force is mandated by the 2018 FAA Act. Accordingly, a Task Force has been established as a subcommittee under the ACPAC to consider best practices and protocols for air carriers relating to training, reporting, and data collection of sexual misconduct by passengers onboard commercial aircraft. The Task Force will include representatives from the Department of Transportation, Department of Justice (including the Federal Bureau of Investigations, Office of Victims of Crime and Office on Violence Against Women), Department of Health and Human Services, national organizations which specialize in providing services to sexual assault

victims, national consumer protection organizations, national travel organizations, labor organizations representing flight attendants and pilots, State and local law enforcement agencies, airports, and air carriers. As a subcommittee, the Task Force will report its recommendations to the ACPAC for deliberation and not provide its recommendations directly to the Department. The Task Force's report of its findings and recommendations to the ACPAC will be released to the public.

ACPAC Administrative Matters; Upcoming Meeting; and Topics

The first meeting of the reestablished ACPAC will take place at the Department's headquarters in Washington, DC on January 16, 2019. During the first meeting, the Department will announce the members of the Task Force and there will be a discussion of the duties of the Task Force members. In addition, two other topics—the transparency of airline ancillary service fees and involuntary changes to itineraries—will be discussed. The Joint Explanatory Statement of the 2018 Consolidated Appropriations Act requests that the Department work in collaboration with industry, consumers and other stakeholders to establish guidelines on transparency of airline ancillary fees. In addition, the 2018 FAA Act mandates that the Department review and make recommendations with regard to air carriers' handling of involuntary changes to passengers' travel itineraries, and that the Department may consult with the Committee for this purpose. Accordingly, the Committee will discuss these issues during the meeting.

The Department's Office of Aviation Enforcement and Proceedings, within the Office of the General Counsel, will provide appropriate funding, logistics, administrative, and technical support for the Committee. The Department's subject matter experts will also provide support to the Committee.

Viewing Documents

You may view any documents mentioned in this preamble as being available in the docket at *http://www.regulations.gov.* After entering the docket number, click the link to ''Open Docket Folder'' and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., E.T., Monday through Friday, except Federal holidays.

Dated: November 8, 2018.

Steven G. Bradbury,

General Counsel.

[FR Doc. 2018–25508 Filed 11–21–18; 8:45 am]

BILLING CODE 4910–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of this person are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: *OFAC:* Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel. 202–622–4855; or the Department of the Treasury's Office of the General Counsel: Office of the Chief Counsel (Foreign Assets Control), tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treasury.gov/ofac*).

Notice of OFAC Action(s)

On November 19, 2018, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following person is blocked under the relevant sanctions authority listed below.

Individual

1. BADI, Salah (a.k.a. BADI, Omal Salem Salah; a.k.a. BADI, Saladin; a.k.a. BADI, Salah Edine Omar; a.k.a. BADI, Salahdin; a.k.a. BADI, Salah-Eddin; a.k.a. BADI, Salahidin), Tripoli, Libya; DOB 23 May 1957; POB Misrata, Libya; nationality Libya; Gender Male (individual) [LIBYA3].

Designated pursuant to Section 1(a)(v) of Executive Order 13726 of April 19, 2016, ''Blocking Property and Suspending Entry Into the United States of Persons Contributing to the Situation in Libya'' (E.O. 13726) for being a leader of an entity that has, or whose members have, engaged in actions or policies that threaten the peace, security, or stability of Libya, including through the supply of arms or related materiel.

Dated: November 19, 2018.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2018–25489 Filed 11–21–18; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Publication of the Tier 2 Tax Rates

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: Publication of the tier 2 tax rates for calendar year 2019 as required by section 3241(d) of the Internal Revenue Code. Tier 2 taxes on railroad employees, employers, and employee representatives are one source of funding for benefits under the Railroad Retirement Act.

DATES: The tier 2 tax rates for calendar year 2019 apply to compensation paid in calendar year 2019.

FOR FURTHER INFORMATION CONTACT: Kathleen Edmondson, CC:TEGE:EOEG:ET1, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224, Telephone Number (202) 317–6798 (not a toll-free number).

Tier 2 Tax Rates: The tier 2 tax rate for 2019 under section 3201(b) on employees is 4.9 percent of compensation. The tier 2 tax rate for 2019 under section 3221(b) on employers is 13.1 percent of compensation. The tier 2 tax rate for 2019 under section 3211(b) on employee representatives is 13.1 percent of compensation.

Dated: November 14, 2018.

Victoria A. Judson,

Associate Chief Counsel (Tax Exempt and Government Entities).

[FR Doc. 2018–25459 Filed 11–21–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Women Veterans, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act that the Advisory Committee on Women Veterans will meet on December 18–20, 2018, at VA Central Office, 810 Vermont Avenue NW, G.V. Sonny Montgomery Veterans Conference Room 230, Washington, DC 20420. The meetings will be held:

Date	Time
Tuesday, December 18, 2018.	8:30 a.m. to 4:00 p.m.
Wednesday, December 19, 2018.	8:30 a.m. to 2:15 p.m.
Thursday, December 20, 2018.	8:30 a.m. to 4:00 p.m.

The meetings are open to the public.

The purpose of the Committee is to advise the Secretary of Veterans Affairs regarding the needs of women Veterans with respect to health care, rehabilitation, compensation, outreach, and other programs and activities administered by VA designed to meet such needs. The Committee makes recommendations to the Secretary regarding such programs and activities.

The agenda will include updates from the Veterans Health Administration, the Veterans Benefits Administration, and Staff Offices, as well as briefings on other issues impacting women Veterans.

No time will be allocated at this meeting for receiving oral presentations from the public. Interested parties should provide written comments for review by the Committee to Ms. Shannon L. Middleton, VA Center for Women Veterans (00W), 810 Vermont Avenue NW, Washington, DC 20420, or email at *00W@mail.va.gov,* or fax to (202) 273–7092. Because the meeting is being held in a government building, a photo I.D. must be presented at the Guard's Desk as a part of the screening process. Due to an increase in security protocols, you should allow an additional 30 minutes before the meeting begins. Any member of the public who wishes to attend the meeting or wants additional information should contact Ms. Middleton at (202) 461–6193.

Dated: November 19, 2018.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2018–25542 Filed 11–21–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on the Readjustment of Veterans; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act that the Advisory Committee on the Readjustment of Veterans will have a closed meeting at the Department of Veterans Affairs Vet Center 721 at 9504 IH 35, North, San Antonio, Texas 78233. The meetings will be held on December 5 and 6, 2018. Sessions are open to the public, except when the Committee is conducting tours of VA facilities, participating in offsite events, participating in workgroup sessions, and conducting official Administrative business. Tours of the VA facilities are closed, to protect Veterans' privacy and personal information.

The purpose of the Committee is to advise the Department of Veterans Affairs (VA) regarding the provision by VA of benefits and services to assist Veterans in the readjustment to civilian life. In carrying out this duty, the Committee shall take into account the needs of Veterans who served in combat theaters of operation. The Committee assembles, reviews, and assesses information relating to the needs of Veterans readjusting to civilian life and the effectiveness of VA services in assisting Veterans in that readjustment.

On Wednesday, December 5, 2018, the Committee will hold a closed session at the San Antonio, TX Vet Center from 8:00 a.m. to 4:30 p.m., while members tour the facility, and meet with key Vet Center staff as well as a panel of individuals who use Vet Center services. The meeting will focus on Veteran experience, and members will solicit information from key staff from various VA entities across San Antonio, and have strategic discussion about what they learned from the interactions. Because the issues discussed will most likely include information learned during the tour and in conversation with service users, to protect their privacy the session will be closed.

On December 6, the Committee will convene an open session from 8:00 a.m. to 10:00 a.m., when they will receive an update from VA Readjustment Counseling Service and Mental Health leadership regarding collective efforts in suicide prevention, and then will engage in strategic discussions formulating conclusions and recommendations for the 20th annual report to Congress. The meeting will adjourn at 10:00 a.m.

This field visit is closed to the public in accordance with 5 U.S.C. 552b (c) (6). Exemption 6 permits the Committee to close a meeting that is likely to disclose information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy, which will most likely be the case throughout this field visit.

The agenda will include time for Executive Sessions, where the committee will focus on the annual operations plan for 2019/2020, and no time will be allotted for receiving oral comments from the public; however, the committee will accept written comments from interested parties on issues outlined in the meeting agenda or other issues regarding the readjustment of Veterans. Parties should contact Ms. Sherry Moravy, via email at *10RCSAction@va.gov,* or by mail at Department of Veterans Affairs, Readjustment Counseling Service (10RCS), 810 Vermont Avenue, Washington, DC 20420. Any member of the public seeking additional information should contact Ms. Moravy to the email address noted above.

Dated: November 19, 2018.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2018–25507 Filed 11–21–18; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 83 Friday,
No. 226 November 23, 2018

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, et al.
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act; Final Rules and Interim Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 415, 425, and 495

[CMS–1693–F, CMS–1693–IFC, CMS–5522–F3, and CMS–1701–F]

RIN 0938–AT31, 0938–AT13, & 0938–AT45

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

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

ACTION: Final rules and interim final rule.

SUMMARY: This major final rule addresses changes to the Medicare physician fee schedule (PFS) and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This final rule also finalizes policies included in the interim final rule with comment period in ''Medicare Program; CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstance Policy for the Transition Year'' that address the extreme and uncontrollable circumstances MIPS eligible clinicians faced as a result of widespread catastrophic events affecting a region or locale in CY 2017, such as Hurricanes Irma, Harvey and Maria. In addition, this final rule addresses a subset of the changes to the Medicare Shared Savings Program for Accountable Care Organizations (ACOs) proposed in the August 2018 proposed rule ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success''. This final rule also addresses certain other revisions designed to update program policies under the Shared Savings Program.

The interim final rule implements amendments made by the SUPPORT for Patients and Communities Act to the Medicare telehealth provisions in the Social Security Act and regarding permissible telehealth originating sites for purposes of treatment of a substance use disorder or a co-occurring mental health disorder for telehealth services furnished on or after July 1, 2019 to an individual with a substance use disorder diagnosis.

DATES: *Effective Dates:* These regulations are effective on January 1, 2019, except for the following:

- Revisions to §§ 414.1415(b)(2) and (3), and 414.1420(b), (c)(2), and (3), which are effective January 1, 2020; and
- Amendments to Part 425, which are effective on December 31, 2018.

Applicability Date: The following provisions related to Section II.I. of this final rule, Evaluation and Management Services, are applicable beginning January 1, 2021: Implementation of a blended payment rate for E/M visits levels 2–4; Payment to adjust the base E/M visit rate(s) upward to account for visit complexity associated with non-procedural specialty care and primary care; Payment to adjust the base visit rate(s) upward to account for the additional resource costs when practitioners need to spend significantly more time with particular patients; and Flexible documentation requirements related to Medical Decision Making, Time or Current E/M visit documentation framework. The amendment to the definition of ''low-volume criteria'' at § 414.1305 is applicable at the start of the first Merit-based Incentive Payment System (MIPS) determination period for CY 2018 MIPS performance period.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 31, 2018.

ADDRESSES: In commenting, please refer to file code CMS–1693–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address *only:* Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1693–IFC, P.O. Box 8010, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address *only:* Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1693–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Jamie Hermansen, (410) 786–2064, for any physician payment issues not identified below.

Lindsey Baldwin, (410) 786–1694, and Emily Yoder, (410) 786–1804, for issues related to evaluation and management (E/M) payment, communication technology-based services and telehealth services.

Lindsey Baldwin, (410) 786–1694, for issues related to sections 2001(a) and 2005 of the SUPPORT for Patients and Communities Act.

Kathy Bryant, (410) 786–3448, for issues related to global surgery data collection.

Isadora Gil, (410) 786–4532, for issues related to payment rates for nonexcepted items and services furnished by nonexcepted off-campus provider-based departments of a hospital, and work relative value units (RVUs).

Ann Marshall, (410) 786–3059, for issues related to E/M documentation guidelines.

Geri Mondowney, (410) 786–1172, for issues related to potentially misvalued services, geographic price cost indices (GPCIs), and malpractice RVUs.

Donta Henson, (410) 786–1947, for issues related to geographic price cost indices (GPCIs).

Tourette Jackson, (410) 786–4735, for issues related to malpractice RVUs.

Patrick Sartini, (410) 786–9252, for issues related to radiologist assistants.

Michael Soracoe, (410) 786–6312, for issues related to practice expense, work RVUs, impacts, and conversion factor.

Pamela West, (410) 786–2302, for issues related to therapy services.

Edmund Kasaitis, (410) 786–0477, for issues related to reduction of wholesale acquisition cost (WAC)-based payment.

Marcie O'Reilly, (410) 786–9764, for issues related to the Potential Model for Radiation Therapy.

Sarah Harding, (410) 786–4001, or Craig Dobyski, (410) 786–4584, for issues related to aggregate reporting of applicable information for clinical laboratory fee schedule.

Amy Gruber, (410) 786–1542, or Glenn McGuirk, (410) 786–5723, for issues related to the ambulance fee schedule.

Corinne Axelrod, (410) 786–5620, for issues related to care management services and communication technology-based services in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).

JoAnna Baldwin, (410) 786–7205, or Sarah Fulton, (410) 786–2749, for issues related to appropriate use criteria for advanced diagnostic imaging services.

Fiona Larbi, (410) 786–7224, for issues related to the Medicare Shared Savings Program (Shared Savings Program) Quality Measures.

Matthew Edgar, (410) 786–0698, for issues related to the physician self-referral law.

Molly MacHarris, (410) 786–4461, for inquiries related to Merit-based Incentive Payment System (MIPS).

Benjamin Chin, (410) 786–0679, for inquiries related to Alternative Payment Models (APMs).

David Koppel, (303) 844–2883, or Elizabeth LeBreton (202) 615–3816 for issues related to the Medicaid Promoting Interoperability Program.

Elizabeth November, (410) 786–8084, for inquiries related to the Medicare Shared Savings Program [Pathways to Success].

SUPPLEMENTARY INFORMATION:

Table of Contents

Addenda Available Only Through the Internet on the CMS Website

The PFS Addenda along with other supporting documents and tables referenced in this final rule are available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2019 PFS final rule, refer to item CMS–1693–F. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this final rule and posted on the CMS website identified above should contact Jamie Hermansen at (410) 786–2064.

CPT (Current Procedural Terminology) Copyright Notice

Throughout this final rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2018 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary

A. Purpose

This major final rule makes payment and policy changes under the Medicare PFS and implements certain provisions of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018) and the SUPPORT for Patients and Communities Act (Pub. L. 115–271, October 24, 2018) related to Medicare Part B payment, and except as specified otherwise, applicable to services furnished in CY 2019. This final rule also revises certain policies under the Medicare Shared Savings Program.

1. Summary of the Major Provisions

The statute requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: Work; practice expense (PE); and malpractice (MP) expense. In addition, the statute requires that we establish by regulation each year's payment amounts for all physicians' services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas. In this major final rule, we establish RVUs for CY 2019 for the PFS, and other Medicare Part B payment policies, to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This final rule includes discussions regarding:

- Potentially Misvalued Codes.
- Communication Technology-Based Services.
- Provisions Expanding Telehealth Services for the Treatment of Opioid Use Disorder and Other Substance Use Disorders under the SUPPORT Act.
- Valuation of New, Revised, and Misvalued Codes.
- Payment Rates under the PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital.
- Evaluation & Management (E/M) Visits.

- Therapy Services.
- Part B Drugs: Application of an Add-on Percentage for Certain Wholesale Acquisition Cost (WAC)-based Payments.
- Potential Model for Radiation Therapy.
- Clinical Laboratory Fee Schedule.
- Ambulance Fee Schedule—Provisions in the Bipartisan Budget Act of 2018.
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).
- Appropriate Use Criteria for Advanced Diagnostic Imaging Services.
- Medicaid Promoting Interoperability Program Requirements for Eligible Professionals.
- Medicare Shared Savings Program Quality Measures.
- Physician Self-Referral Law.
- Physician Self-Referral Law: Annual Update to the List of CPT/HCPCS Codes.
- CY 2019 Updates to the Quality Payment Program (including the extreme and uncontrollable circumstances MIPS eligible clinicians faced as a result of widespread catastrophic events affecting a region or locale in CY 2017).
- Comments in response to the Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers.
- Comments in response to the Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information.

This rule also finalizes certain provisions from the ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success'' proposed rule that appeared in the August 17, 2018 **Federal Register** (83 FR 41786). Under the Medicare Shared Savings Program, providers of services and suppliers that participate in an ACO continue to receive traditional Medicare fee-for-service (FFS) payments under Parts A and B, but the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements. ACOs participating under a two-sided shared savings and shared losses model of the program may also be responsible for repaying shared losses if the Parts A and B FFS expenditures for their assigned beneficiaries exceed the ACO's historical benchmark. The revised policies for ACOs participating in the Medicare Shared Savings Program will ensure continuity of program participation for ACOs whose agreement periods expire on December 31, 2018 by allowing these ACOs the opportunity to elect a voluntary 6-month extension of their current agreement periods; supporting coordination of care across settings and strengthening beneficiary engagement; providing relief for ACOs impacted by extreme and uncontrollable circumstance in performance year 2018 and subsequent years; and promoting interoperable electronic health record technology among ACO providers/suppliers. We plan to address the remaining proposals from the August 2018 proposed rule (83 FR 41786) in a forthcoming second final rule.

2. Summary of Costs and Benefits

We have determined that this major final rule is economically significant. For a detailed discussion of the economic impacts, see section VII. of this final rule.

B. Determination of Practice Expense (PE) Relative Value Units (RVUs)

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding MP expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the RUC and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the Five-Year Review of Work Relative Value Units under the PFS and Proposed Changes to the Practice Expense Methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

Comment: Several commenters requested that CMS include pharmacists as active qualified health care providers for purposes of calculating physician PE direct costs. The commenters stated that pharmacists need to be included in the calculation of direct PE expenses as an element of the clinical labor variable relating to physicians' services. The commenter stated that pharmacists are key members of the healthcare team supporting the advent of digital medicine and telehealth services and suggested that pharmacists should be recognized as staff included in practice expense inputs.

Response: The direct PE input database contains the service-level costs in clinical labor based on the typical service furnished to Medicare beneficiaries. When these resource costs are typically incurred in furnishing services, we do not have any standing policies that would prohibit the inclusion of the costs in the direct PE input database used to develop PE RVUs for individual services, to the extent that inclusion of such costs would not lead to duplicative payments. Therefore, we welcome more detailed information regarding the typical clinical labor costs involving pharmacists for particular PFS services. We note, however, that in the case of many PFS services, especially care management services, certain elements of the services could be provided by clinicians other than the billing professionals, which could include services provided by pharmacists. As such, we encourage interested stakeholders to provide information through the RUC process or directly to us by February 10th prior to annual rulemaking about the inclusion of additional clinical labor costs for specific services described by HCPCS codes for which payment is made under the PFS, as opposed to clinical labor costs that may be typical only under certain circumstances.

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked, in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty that was obtained from the AMA's SMS. The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS-based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file called ''CY 2019 PFS Final Rule PE/HR'' on the CMS website under downloads for the CY 2019 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

Comment: Several commenters recommended that it was time to consider a new nationwide all specialty PE/HR survey, given the amount of time that has passed since the last survey was conducted. The commenters stated that the practice of medicine has significantly and substantially evolved in the past decade and that many specialties have had extensive changes in physician employment models during that time. The commenters stated that continued use of the outdated PPIS survey leads to an inappropriate and inaccurate distortion of the PE RVUs for current practice.

Response: We have previously identified several concerns regarding the underlying data used in determining PE RVUs in the CY 2014 PFS final rule with comment period (78 FR 74246 through 74247). While we continue to believe that the PPIS survey data are the best data currently available, we continue to seek the best broad based, auditable, routinely updated source of information regarding PE costs. To that end, we have engaged a contractor, the RAND Corporation, to explore the feasibility of updating the data used in the development of PE RVUs.

Comment: One commenter requested that CMS consider studying indirect PE associated with emergency departments including Emergency Medical Treatment & Labor Act (EMTALA)-mandated uncompensated care. The commenter stated that emergency physicians are not able to schedule their patients and therefore cannot maximize the use of staff and resources, and that there are costs associated with being open and having to pay shift differentials over nights, weekends, and holidays.

Response: We will take the information under consideration for future rulemaking.

For CY 2019, we have incorporated the available utilization data for two new specialties, each of which became a recognized Medicare specialty during 2017. These specialties are Hospitalists and Advanced Heart Failure and Transplant Cardiology. We proposed to use proxy PE/HR values for these new specialties, as there are no PPIS data for these specialties, by crosswalking the PE/HR as follows from specialties that furnish similar services in the Medicare claims data:

- Hospitalists from Emergency Medicine, and
- Advanced Heart Failure and Transplant Cardiology from Cardiology.

These updates are reflected in the ''CY 2019 PFS Final Rule PE/HR'' file available on the CMS website under the supporting data files for the CY 2019 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

The following is a summary of the public comments we received on our proposal to use proxy PE/HR values for these two new specialties.

Comment: One commenter stated that they supported the CMS proposal to crosswalk the Advanced Heart Failure and Transplant specialty to the cardiology PPIS data.

Response: We appreciate the support from the commenter for our proposal.

Comment: A few commenters wrote to detail their concerns with the current PE/HR assigned to home PT/INR monitoring services. Commenters stated that these services are provided by entities that are enrolled in Medicare as independent testing facilities because there is no other specialty category that currently describes these suppliers; however, home PT/INR monitoring services are fundamentally different in nature. Commenters stated that home PT/INR monitoring services tend to be

more therapeutic than diagnostic in nature, typically utilize different staffing types, and have a different ratio of direct to indirect costs. The commenters encouraged CMS to consider home PT/INR monitoring as a distinct specialty from independent testing facilities and to survey suppliers to determine accurate indirect cost factors for these services, while using either the Pathology or All Physicians specialty as a proxy for PE/HR in the meantime. One commenter suggested that CMS should consider holding payments harmless for home PT/INR monitoring services while additional analysis is completed.

Response: We welcome suggestions from interested parties regarding new indirect PE surveys and the use of PE/HR proxies that could be considered for future rulemaking. Interested parties may wish to submit a physician specialty designation request per the instructions found in Pub. 100–04, Medicare Claims Processing Manual, Chapter 26, Section 10.8 (available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf*). This section of the Medicare Claims Processing Manual includes the criteria that CMS uses to evaluate physician specialty designation requests.

After consideration of the public comments, we are finalizing our proposal to use proxy PE/HR values for Hospitalists and Advanced Heart Failure and Transplant Cardiology as described above.

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

We allocate the indirect costs at the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion (see section II.B.2.b of this final rule). The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Next, we incorporated the specialty-specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: Facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

Comment: One commenter stated that it was not clear why the PE change would differ so greatly between the office and facility settings for CPT code 37227 (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed). The commenter stated that the facility PE RVU for this CPT code was proposed to decrease by 4.8 percent while the non-facility PE RVU was proposed to decrease by 10.6 percent, and the commenter could not understand how these payment rates were determined.

Response: As detailed above, the methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. It is not unusual for facility and nonfacility RVUs for a CPT code to change at different rates from year to year, as the direct costs associated with the facility and nonfacility settings are typically distinct from one another. For a more detailed description of the PE RVU methodology, we refer readers to the CY 2007 PFS final rule with comment period (71 FR 69630 through 69643) and the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746).

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: A professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be

furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file called ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our website under downloads for the CY 2019 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* This file contains a table that illustrates the calculation of PE RVUs as described in this final rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the projected aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to a RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 59283) to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning specialty mix based on the specialties of the practitioners reporting the services in the claims data, we instead use the expected specialty that we identify on a list developed based on medical review and input from expert stakeholders. We display this list of expected specialty assignments as part of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other stakeholders on changes to this list on an annual basis. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 59283) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

For CY 2019, we proposed to add 28 additional codes that we identified as low volume services to the list of codes for which we assign the expected specialty. Based on our own medical review and input from the RUC and from specialty societies, we proposed to assign the expected specialty for each code as indicated in Table 1. For each of these codes, only the professional component (reported with the –26 modifier) is nationally priced. The global and technical components are priced by the Medicare Administrative Contractors (MACs) which establish RVUs and payment amounts for these services. The list of codes that we proposed to add is displayed in Table 1.

TABLE 1—NEW ADDITIONS TO EXPECTED SPECIALTY LIST FOR LOW VOLUME SERVICES

CPT code	Modifier	Short descriptor	Expected specialty	2017 utilization
70557	26	Mri brain w/o dye	Diagnostic Radiology	126
70558	26	Mri brain w/dye	Diagnostic Radiology	32
74235	26	Remove esophagus obstruction	Gastroenterology	10
74301	26	X-rays at surgery add-on	Diagnostic Radiology	73
74355	26	X-ray guide intestinal tube	Diagnostic Radiology	11
74445	26	X-ray exam of penis	Urology	26
74742	26	X-ray fallopian tube	Diagnostic Radiology	5
74775	26	X-ray exam of perineum	Diagnostic Radiology	80
75801	26	Lymph vessel x-ray arm/leg	Diagnostic Radiology	114
75803	26	Lymph vessel x-ray arms/leg	Diagnostic Radiology	41
75805	26	Lymph vessel x-ray trunk	Diagnostic Radiology	50
75810	26	Vein x-ray spleen/liver	Diagnostic Radiology	46

TABLE 1—NEW ADDITIONS TO EXPECTED SPECIALTY LIST FOR LOW VOLUME SERVICES—Continued

CPT code	Modifier	Short descriptor	Expected specialty	2017 utilization
76941	26	Echo guide for transfusion	Obstetrics/Gynecology	15
76945	26	Echo guide villus sampling	Obstetrics/Gynecology	31
76975	26	Gi endoscopic ultrasound	Gastroenterology	49
78282	26	Gi protein loss exam	Diagnostic Radiology	8
79300	26	Nuclr rx interstit colloid	Diagnostic Radiology	2
86327	26	Immunoelectrophoresis assay	Pathology	24
87164	26	Dark field examination	Pathology	30
88371	26	Protein western blot tissue	Pathology	2
93532	26	R & l heart cath congenital	Cardiology	28
93533	26	R & l heart cath congenital	Cardiology	36
93561	26	Cardiac output measurement	Cardiology	28
93562	26	Card output measure subsq	Cardiology	38
93616	26	Esophageal recording	Cardiology	38
93624	26	Electrophysiologic study	Cardiology	51
95966	26	Meg evoked single	Neurology	72
95967	26	Meg evoked each addl	Neurology	61

The complete list of expected specialty assignments for individual low volume services, including the assignments for the codes identified in Table 1, is available on our website under downloads for the CY 2019 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

The following is a summary of the public comments we received on our proposal to update the list of expected specialty assignments for low volume services.

Comment: Several commenters supported the continued use of service-level overrides for low volume codes, and stated that they agreed with the addition of the proposed 28 codes to the list of expected specialties.

Response: We appreciate the support from the commenters.

Comment: Several commenters stated that CPT code 22857 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar) was missing from the proposed list. These commenters requested that CMS include CPT code 22857 in the low utilization category and permanently assign it to the orthopaedic surgery specialty to maintain payment stability and minimize annual fluctuations.

Response: We agree with the commenters that CPT code 22857 qualifies as a low volume code, with an annual Medicare utilization of roughly 20 services. We agree with the commenters that assigning this code to the orthopaedic surgery specialty will help to maintain payment stability, and we are finalizing the addition of CPT code 22857 to the low volume services list.

Comment: One commenter stated that several of the proposed low volume services would be more accurately assigned to different expected specialties based on their practice patterns. The commenter stated that CPT codes 70557 and 70558 are intraoperative exams and are most often performed by neurosurgeons and that CPT code 74235 is a diagnostic radiology code rather than a gastroenterology code. The commenter stated that CPT code 75810 should be assigned to interventional radiology rather than diagnostic radiology, and that CPT codes 78282 and 79300 should be assigned to nuclear medicine rather than diagnostic radiology.

Response: We agree that these codes would be more accurately assigned to the expected specialties described by the commenter based on an examination of the claims data. We are finalizing changes in expected specialty to these six codes as described by the commenter.

Comment: One commenter stated that there are four codes that are still not included in the proposed CY 2019 low volume override list and recommended that the following low volume procedures be added to the override list with the indicated specialty assignment:

- Cardiac Surgery: CPT code 35812, and
- Thoracic Surgery: CPT codes 32654, 33025 and 33251

Response: We agree with the inclusion of CPT codes 32654 and 33251. These are services with very low annual utilization, and we are finalizing their addition to the low volume services list with the expected specialty as described by the commenter. We note that CPT code 33251 is already on the low volume services list with an expected specialty of Cardiac Surgery; we are finalizing a change to the Thoracic Surgery specialty as requested by the commenter. We are not finalizing the addition of CPT code 35812 to the list, as it does not appear to be a current CPT code. We are also not finalizing the addition of CPT code 33025 to the list, as the code had a utilization of more than 5,000 services in the most recent year of claims data, and this would not qualify as a low volume service under the criteria that we have previously finalized through rulemaking.

Comment: One commenter stated that the appropriate low volume overrides were not applied to a series of congenital/pediatric cardiac surgery codes. The commenter stated that each of these operations can only be performed by congenital heart surgeons classified as either cardiac or thoracic surgeons, and that they believe the malpractice RVUs had been improperly decreased as a result of the low volume service overrides not being applied.

Response: Each of the CPT codes identified by the commenter was already present on the low volume services list with an expected specialty assignment of either Cardiac Surgery or Thoracic Surgery. The shifts in malpractice RVUs identified by the commenter were a result of proposed policies associated with E/M visits. We refer readers to section II.I. of this final rule for additional details on these policies.

After consideration of the public comments, we are finalizing the addition of the proposed 28 codes to the low volume services list, with the expected specialty as proposed except where modified in response to comments. We are also finalizing the addition of CPT codes 32654 and 33251 to the list with an expected specialty of Thoracic Surgery as detailed previously.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: The direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: Indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: Indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: Indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(*Note:* For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file called ''Calculation of PE RVUs under Methodology for Selected Codes'', the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

The following is a summary of the public comments we received on the indirect practice cost indices.

Comment: Many commenters stated that they were opposed to the proposed significant shifts in the indirect practice cost indices at the specialty level. Commenters stated that the creation of a separate PE/HR rate for the E/M visits resulted in large unintended effects on specialties given the way that indirect PE is allocated, and that this was inconsistent with CMS' intent to maintain stability in payment. One commenter stated that the proposal to create a separate PE/HR rate for the E/M visits was based on statistically unsound methodology, had opaque analytics, and was not resource-based. Many commenters stated that the effects of the proposed changes to the indirect practice cost indices had not been sufficiently detailed in the proposed rule to allow for proper feedback from commenters. Commenters expressed concern that a reduction in payment due to shifts in the indirect PE allocation could affect patient access to critical services, such as but not limited to CPT codes 96360 (intravenous infusion, hydration; initial, 31 minutes to 1 hour), 96372 (therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular), 96374 (therapeutic, prophylactic or diagnostic injection IV push, single or initial substance/drug), 96375 (therapeutic, prophylactic or diagnostic injection; each additional sequential IV push of a new substance/drug), and HCPCS code G0416 (Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method). A few commenters stated that the proposed indirect practice cost indices ignored statutory requirements that payments under the PFS must be resource based and failed to meet the transparency requirements of the Protecting Access to Medicare Act of 2014 (PAMA). Commenters urged CMS not to finalize the proposed changes to the indirect practice cost indices.

Response: The proposed changes in the indirect practice cost indices identified by the commenters were a result of proposed policies associated with E/M visits, and specifically the proposal to establish a separate specialty for E/M visits. We refer readers to section II.I. of this final rule for additional discussion of these policies.

Comment: One commenter stated that the level of detail in the CY 2019 PFS proposed rule was insufficient to comment on several aspects of the proposed changes in coding and payment related to office/outpatient E/M visits, which was a departure from past rules. The commenter specifically stated that there was insufficient information to model how the proposed changes in the office/outpatient E/M visit codes affected the indirect practice cost indices for all other services. Similarly, the commenter suggested that not enough information was provided to simulate the PFS ratesetting in a way that would isolate the impact of the proposed multiple procedure payment reduction (MPPR), in the proposed rates and associated estimates of specialty-level impact. The commenter requested that CMS provide additional technical information and files going forward to enable the commenter to better model proposed and future policies.

Response: We agree with commenters regarding the importance of transparency and the need for detailed

information about proposed policies so that public commenters can provide a full and informed response. We also understand that there is merit to providing as much information as possible that would allow for complete reproduction of our proposed and final ratesetting methodologies. We also understand that the proposals related to office/outpatient E/M visits are of great importance to the medical community and represent a significant portion of spending under the PFS. We do not agree with the commenter that the level of detail provided in the proposed rule, including the data provided as publicly available download files, was insufficient for public comment due to the extensive documentation associated with the E/M policy proposals, or that it represented a departure from past practice. Over several years, we have invested significant resources in improving the transparency of the data we use in developing proposed and final PFS rates. We intend to maintain a focus on increasing transparency, and believe the commenters' concerns will help us understand the kind of information that can be most helpful to stakeholders interested in the underlying data sets. While we are not finalizing the MPPR element of the E/M proposal, we appreciate the commenter's interest in the use of code-level assumptions regarding proposed payment adjustments that are reflected in the discounts in the setup file, as discussed in section II.B.2.(5)(e) of this final rule.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the proposed aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS budget neutrality. (See ''Specialties excluded from ratesetting calculation'' later in this final rule.)

Step 19: Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year one reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

Comment: We received many comments regarding the ongoing decrease in the technical component of CPT code 76881 (Ultrasound, complete joint (*i.e.,* joint space and peri-articular soft tissue structures) real-time with image documentation). Commenters stated that this procedure is essential for making appropriate diagnosis and managing patients with various rheumatologic conditions and musculoskeletal disorders. Commenters stated that cutting the reimbursement for the code would not only result in poor patient care but also increase total costs through the use of more expensive MRI procedures. Commenters also disagreed with the RUC's recommended direct PE inputs for CPT code 76881 from the CY 2018 rule cycle, citing concerns with the RUC's use of workforce data, and urged CMS not to make further reductions in payment.

Response: The comments regarding CPT code 76881 are out of scope, as we did not make any proposals involving this code for CY 2019. The reductions in payment described by the commenters for CPT code 76881 were finalized as part of the CY 2018 PFS final rule (82 FR 53058–53059), and are continuing to be phased in over time as part of the transition policy described above. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

(e) Setup File Information

• *Specialties excluded from ratesetting calculation:* For the purposes of calculating the PE RVUs, we exclude certain specialties, such as certain NPPs paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 2.

TABLE 2—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION

Specialty code	Specialty description
49	Ambulatory surgical center.
50	Nurse practitioner.
51	Medical supply company with certified orthotist.
52	Medical supply company with certified prosthetist.
53	Medical supply company with certified prosthetist-orthotist.
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist.
56	Individual certified prosthetist.
57	Individual certified prosthetist-orthotist.
58	Medical supply company with registered pharmacist.
59	Ambulance service supplier, *e.g.,* private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies.
61	Voluntary health or charitable agencies.
73	Mass immunization roster biller.
74	Radiation therapy centers.
87	All other suppliers (*e.g.,* drug and department stores).
88	Unknown supplier/provider specialty.

TABLE 2—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION—Continued

Specialty code	Specialty description
89	Certified clinical nurse specialist.
96	Optician.
97	Physician assistant.
A0	Hospital.
A1	SNF.
A2	Intermediate care nursing facility.
A3	Nursing facility, other.
A4	HHA.
A5	Pharmacy.
A6	Medical supply company with respiratory therapist.
A7	Department store.
B2	Pedorthic personnel.
B3	Medical supply company with pedorthic personnel.

• *Crosswalk certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.

• *Physical therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.

• *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).

• *Payment modifiers:* Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 3 details the manner in which the modifiers are applied.

TABLE 3—APPLICATION OF PAYMENT MODIFIERS TO UTILIZATION FILES

Modifier	Description	Volume adjustment	Time adjustment
80, 81, 82	Assistant at Surgery	16%	Intraoperative portion.
AS	Assistant at Surgery—Physician Assistant.	14% (85% * 16%)	Intraoperative portion.
50 or LT and RT	Bilateral Surgery	150%	150% of work time.
51	Multiple Procedure	50%	Intraoperative portion.
52	Reduced Services	50%	50%.
53	Discontinued Procedure	50%	50%.
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims.	Preoperative + Intraoperative portion.
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims.	Postoperative portion.
62	Co-surgeons	62.5%	50%.
66	Team Surgeons	33%	33%.

We also make adjustments to volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

• *Work RVUs:* The setup file contains the work RVUs from this final rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1 − (1/((1 + interest rate) ^ life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage = 1); generally 150,000 minutes.

usage = variable, see discussion in this final rule.

price = price of the particular piece of equipment.

life of equipment = useful life of the particular piece of equipment.

maintenance = factor for maintenance; 0.05.

interest rate = variable, see discussion in this final rule.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Stakeholders have often suggested that particular equipment items are used less frequently than 50 percent of the time in the typical setting and that CMS should reduce the equipment utilization rate based on these recommendations. We appreciate and share stakeholders' interest in using the most accurate assumption regarding the equipment utilization rate for particular equipment items. However, we believe that absent robust, objective, auditable data regarding the use of particular items, the 50 percent assumption is the most appropriate within the relative value system. We welcome the submission of data that would support an alternative rate.

Comment: A few commenters stated that equipment time associated with payment for diagnostic imaging services is not aligned with practice. The commenters disagreed with the CMS statement that certain highly technical equipment is less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff, and stated that the CMS analysis of equipment time is not accurate based on their experience with imaging centers. Commenters stated that there are non-imaging functions that are required by CMS for payment, such as documentation requirements and the need for enrollment in Medicare by professionals, which add to their administrative burden and increase costs yet are underrepresented in the PE methodology. Commenters stated that they disagreed with how CMS defined room time as inconsistent with how imaging centers actually function, and indicated a preference for assigning equipment time based on the total technologist time.

Response: We disagree with the commenters regarding the equipment time assigned to highly technical equipment. We continue to believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure and are typically available for other patients even when one member of clinical staff may be occupied with a preservice or postservice task related to the procedure. For a more detailed description of this topic, we refer readers to the CY 2015 PFS final rule with comment period (79 FR 67639 through 67640).

Maintenance: This factor for maintenance was finalized in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding sources of data containing equipment maintenance rates, commenters were unable to identify an auditable, robust data source that could be used by CMS on a wide scale. We do not believe that voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, we do not believe that we have sufficient information at present to propose a variable maintenance factor for equipment cost per minute pricing. We continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.

Comment: A commenter stated that they continue to believe that maintenance costs for imaging equipment are much higher than the current 5 percent assumption. The commenter stated that they were hopeful that the market-based research into equipment and supply pricing would result in a broad range, systematic data collection methodology that could be applied to collecting information on equipment maintenance costs.

Response: As detailed above, we continue to believe that the current 5 percent maintenance factor likely understates the true cost of maintaining some equipment and overstates the maintenance costs for other equipment. We continue at this time to lack publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining maintenance factor. With regards to the market-based study, the StrategyGen contractors were tasked with updating the commercial pricing of supplies and equipment, and did not include an investigation of equipment maintenance rates as part of their research.

Interest Rate: In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (see 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). We did not propose any changes to these interest rates for CY 2019. The interest rates are listed in Table 4.

TABLE 4—SBA MAXIMUM INTEREST RATES

Price	Useful life (years)	Interest rate (%)
<$25K	<7	7.50
$25K to $50K	<7	6.50
>$50K	<7	5.50
<$25K	7+	8.00
$25K to $50K	7+	7.00
>$50K	7+	6.00

3. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2019 direct PE input database, which is available on the CMS website under downloads for the CY 2019 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640–67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database

instead of only including the number of clinical labor minutes for the preservice, service, and postservice periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to the use of physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. For example, as medical practice and technologies change over time, changes in the standards could be updated simultaneously for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for ''Availability of prior images confirmed'', 2 minutes for ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'', 2 minutes for ''Review examination with interpreting MD'', and 1 minute for ''Exam documents scanned into PACS.'' Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.'' In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a policy to establish a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a policy to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, 4 minutes as the standard for the complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values.

We also finalized standard times for clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902) at 4 minutes for ''Accession specimen/prepare for examination'', 0.5 minutes for ''Assemble and deliver slides with paperwork to pathologists'', 0.5 minutes for ''Assemble other light microscopy slides, open nerve biopsy slides, and clinical history, and present to pathologist to prepare clinical pathologic interpretation'', 1 minute for ''Clean room/equipment following procedure'', 1 minute for ''Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste'', and 1 minute for ''Prepare, pack and transport specimens and records for in-house storage and external storage (where applicable).'' We do not believe these activities would be dependent on number of blocks or batch size, and we believe that these values accurately reflect the typical time it takes to perform these clinical labor tasks.

Historically, the RUC has submitted a ''PE worksheet'' that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time and among the medical specialties developing the recommendations. These variations have made it difficult for both the RUC's development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC has mandated the use of a new PE worksheet for purposes of their recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in developing and submitting recommendations will help us to simplify and standardize the hundreds of different clinical labor tasks currently listed in our direct PE database. As we did for CY 2018, to facilitate rulemaking for CY 2019, we are continuing to display two versions of the Labor Task Detail public use file: one version with the old listing of clinical labor tasks, and one with the same tasks cross-walked to the new listing of clinical labor activity codes. These lists are available on the CMS website under downloads for the CY 2019 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the ''Prepare room, equipment and supplies'' (CA013) clinical labor activity were split into 2 minutes for the ''Prepare room, equipment and supplies'' activity and 1 minute for the ''Confirm order, protocol exam'' (CA014) activity. These RUC-reviewed codes do not currently have clinical labor time assigned for the ''Confirm order, protocol exam'' clinical labor task, and we do not have any reason to believe that the services being furnished by the clinical staff have changed, only the way in which this clinical labor time has been presented on the PE worksheets.

As a result, we proposed to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity wherever we observed this pattern in the RUC-recommended direct PE inputs. If we had received RUC recommendations for codes that currently include clinical labor time for the ''Confirm order, protocol exam'' clinical labor task, we would have left the RUC-recommended clinical labor times unchanged, but there were no such codes reviewed for CY 2019. We note that there is no effect on the total clinical labor direct costs in these situations, since the same 3 minutes of clinical labor time is still being used in the calculation of PE RVUs.

The following is a summary of the public comments we received on our proposal to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity wherever we observed the aforementioned pattern in the RUC-recommended direct PE inputs.

Comment: Several commenters supported CMS' proposal and requested that these clinical labor refinements should be finalized wherever the refinement had been proposed. These commenters noted that there was no change in the total clinical labor direct costs in these situations and urged CMS to finalize the proposal.

Response: We appreciate the support for the proposal from the commenters.

Comment: Other commenters disagreed with the proposal. Commenters stated that the standard clinical labor time for the CA013 ''Prepare room, equipment and supplies'' activity has always been 2 minutes, and that the occasional assignment of additional clinical labor time in individual procedures has not changed this standard.

Response: We agree with the commenters that the standard clinical labor time for the CA013 activity code is 2 minutes. We noted in the proposed rule that 3 minutes has often traditionally been assigned for this clinical labor activity, and our proposal was intended to reflect this common practice pattern. In our table of direct PE refinements, we listed many of these clinical labor refinements using the refinement code ''L1: Refined time to standard for this clinical labor task.'' This was the incorrect refinement code to use in these situations, and we acknowledge that this was a technical error. The direct PE refinements would have more accurately employed the general refinement code ''G1: See preamble text'' instead. We wish to clarify that although we agree that the standard clinical labor time for the CA013 activity is 2 minutes, we continue to believe that 2 minutes would not be typical for many of the codes currently under discussion.

Comment: Commenters explained that when the new version of the PE worksheet introduced the activity codes for clinical labor, there was a need to translate old clinical labor tasks into the new activity codes. In the old version of the PE worksheet, there was a clinical labor task named ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist.'' Commenters stated that this clinical labor task was split into two of the new clinical labor activity codes: CA007 (''Review patient clinical extant information and questionnaire'') in the preservice period, and CA014 (''Confirm order, protocol exam'') in the service period. Commenters stated that the same clinical labor from the old PE worksheet is now divided into the CA007 and CA014 activity codes, with a standard of 1 minute for each activity. The commenters stated that they recognized that the proposal had no effect on the total clinical labor direct costs, but urged CMS not to finalize anyway due to concerns over inaccuracy and long term effects on the direct practice expense inputs across the PFS.

Response: We agree with the commenters that in situations where a CPT code under review had the old clinical labor task ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'' on a prior version of the PE worksheet, and where that old clinical labor task was divided into the new CA007 and CA014 activity codes as described by the commenters, we will not finalize our proposed refinements to maintain 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity, as we agree that the old clinical labor task is adequately accounted for by being divided into the new activity codes. In these cases, we will finalize the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code.

However, when reviewing the clinical labor for the reviewed codes affected by this issue, we found that several of the codes did not include the old clinical labor task ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'' on a prior version of the PE worksheet. We also noted that several of the reviewed codes that contained the CA014 clinical labor activity code for ''Confirm order, protocol exam'' did not contain any clinical labor for the CA007 activity (''Review patient clinical extant information and questionnaire''). In these situations, we believe that it is more accurate to finalize our direct PE refinements to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity as proposed, since the rationale provided by the commenters does not appear to be the case. These codes do not appear to be an instance where the old clinical labor task was split into two new clinical labor activities. We do not understand how time assigned to an old clinical labor task could be divided between the CA007 and CA014 activity codes, as the commenters suggested, in situations where the code under review does not contain any clinical labor for the CA007 activity. We continue to believe that in these cases the 3 total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code, as these codes do not currently have clinical labor time assigned for the CA014 ''Confirm order, protocol exam'' clinical labor activity.

After consideration of the public comments, we are finalizing our proposal for the reviewed codes that did not include the old clinical labor task described above and do not contain any clinical labor for the CA007 clinical labor activity. We are therefore finalizing our proposal for CPT codes 27369, 38792, 76870, 77012, 77021, 92273, and 92274. We are not finalizing our proposal for the reviewed codes where we were able to determine that the old clinical labor task had been divided into the CA007 and CA014 activity codes as described by the commenters. We are therefore finalizing the RUC-recommended CA013 and CA014 clinical labor for CPT codes 76978, 76981, and 76982.

b. Equipment Recommendations for Scope Systems

During our routine reviews of direct PE input recommendations, we have regularly found unexplained inconsistencies involving the use of scopes and the video systems associated with them. Some of the scopes include video systems bundled into the equipment item, some of them include scope accessories as part of their price, and some of them are standalone scopes with no other equipment included. It is not always clear which equipment items related to scopes fall into which of these categories. We have also frequently found anomalies in the equipment recommendations, with equipment items that consist of a scope and video system bundle recommended, along with a separate scope video system. Based on our review, the variations do not appear to be consistent with the different code descriptions.

To promote appropriate relativity among the services and facilitate the transparency of our review process, during the review of the recommended direct PE inputs for the CY 2017 PFS proposed rule, we developed a structure that separates the scope, the associated video system, and any scope accessories that might be typical as distinct equipment items for each code. Under this approach, we proposed standalone prices for each scope, and separate prices for the video systems and accessories that are used with scopes.

(1) Scope Equipment

Beginning in the CY 2017 proposed rule (81 FR 46176 through 46177), we proposed standardizing refinements to the way scopes have been defined in the direct PE input database. We believe that there are four general types of scopes: Non-video scopes; flexible

scopes; semi-rigid scopes, and rigid scopes. Flexible scopes, semi-rigid scopes, and rigid scopes would typically be paired with one of the scope video systems, while the non-video scopes would not. The flexible scopes can be further divided into diagnostic (or non-channeled) and therapeutic (or channeled) scopes. We proposed to identify for each anatomical application: (1) A rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. We proposed to classify the existing scopes in our direct PE database under this classification system, to improve the transparency of our review process and improve appropriate relativity among the services. We planned to propose input prices for these equipment items through future rulemaking.

We proposed these changes only for the reviewed codes for CY 2017 that made use of scopes, along with updated prices for the equipment items related to scopes utilized by these services. We did not propose to apply these policies to codes with inputs reviewed prior to CY 2017. We also solicited comment on this separate pricing structure for scopes, scope video systems, and scope accessories, which we could consider proposing to apply to other codes in future rulemaking. We did not finalize price increases for a series of other scopes and scope accessories, as the invoices submitted for these components indicated that they are different forms of equipment with different product IDs and different prices. We did not receive any data to indicate that the equipment on the newly submitted invoices was more typical in its use than the equipment that we were currently using for pricing.

We did not make further changes to existing scope equipment in CY 2017 to allow the RUC's PE Subcommittee the opportunity to provide feedback. However, we believed there was some miscommunication on this point, as the RUC's PE Subcommittee workgroup that was created to address scope systems stated that no further action was required following the finalization of our proposal. Therefore, we made further proposals in CY 2018 (82 FR 33961 through 33962) to continue clarifying scope equipment inputs, and sought comments regarding the new set of scope proposals. We considered creating a single scope equipment code for each of the five categories detailed in this rule: (1) A rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. Under the current classification system, there are many different scopes in each category depending on the medical specialty furnishing the service and the part of the body affected. We stated our belief that the variation between these scopes was not significant enough to warrant maintaining these distinctions, and we believed that creating and pricing a single scope equipment code for each category would help provide additional clarity. We sought public comment on the merits of this potential scope organization, as well as any pricing information regarding these five new scope categories.

After considering the comments on the CY 2018 PFS proposed rule, we did not finalize our proposal to create and price a single scope equipment code for each of the five categories previously identified. Instead, we supported the recommendation from the commenters to create scope equipment codes on a per-specialty basis for six categories of scopes as applicable, including the addition of a new sixth category of multi-channeled flexible video scopes. Our goal is to create an administratively simple scheme that will be easier to maintain and help to reduce administrative burden. We look forward to receiving detailed recommendations from expert stakeholders regarding the scope equipment items that would be typically required for each scope category, as well as the proper pricing for each scope.

(2) Scope Video System

We proposed in the CY 2017 PFS proposed rule (81 FR 46176 through 46177) to define the scope video system as including: (1) A monitor; (2) a processor; (3) a form of digital capture; (4) a cart; and (5) a printer. We believe that these equipment components represent the typical case for a scope video system. Our model for this system was the ''video system, endoscopy (processor, digital capture, monitor, printer, cart)'' equipment item (ES031), which we proposed to re-price as part of this separate pricing approach. We obtained current pricing invoices for the endoscopy video system as part of our investigation of these issues involving scopes, which we proposed to use for this re-pricing. In response to comments, we finalized the addition of a digital capture device to the endoscopy video system (ES031) in the CY 2017 PFS final rule (81 FR 80188). We finalized our proposal to price the system at $33,391, based on component prices of $9,000 for the processor, $18,346 for the digital capture device, $2,000 for the monitor, $2,295 for the printer, and $1,750 for the cart. In the CY 2018 PFS final rule (82 FR 52991 through 52993), we outlined, but did not finalize, a proposal to add an LED light source into the cost of the scope video system (ES031), which would remove the need for a separate light source in these procedures. We also described a proposal to increase the price of the scope video system by $1,000 to cover the expense of miscellaneous small equipment associated with the system that falls below the threshold of individual equipment pricing as scope accessories (such as cables, microphones, foot pedals, etc.). With the addition of the LED light (equipment code EQ382 at a price of $1,915), the updated total price of the scope video system would be set at $36,306. We did not finalize this updated pricing to the scope video system in CY 2018, and indicated our intention to address these changes in CY 2019 to incorporate feedback from expert stakeholders.

(3) Scope Accessories

We understand that there may be other accessories associated with the use of scopes. We finalized a proposal in the CY 2017 PFS final rule (81 FR 80188) to separately price any scope accessories outside the use of the scope video system, and individually evaluate their inclusion or exclusion as direct PE inputs for particular codes as usual under our current policy based on whether they are typically used in furnishing the services described by the particular codes.

(4) Scope Proposals for CY 2019

We understand that the RUC has convened a Scope Equipment Reorganization Workgroup that will be incorporating feedback from expert stakeholders with the intention of making recommendations to us on scope organization and scope pricing. Since the workgroup was not convened in time to submit recommendations for the CY 2019 PFS rulemaking cycle, we proposed to delay proposals for any further changes to scope equipment until CY 2020 so that we can incorporate the feedback from the aforementioned workgroup. However, we proposed to update the price of the scope video system (ES031) from its current price of $33,391 to a price of $36,306 to reflect the addition of the LED light and miscellaneous small equipment associated with the system that falls below the threshold of individual equipment pricing as scope accessories, as we explained in detail in the CY 2018 PFS final rule (82 FR 52992 through 52993). We also proposed to update the name of the ES031

equipment item from ''video system, endoscopy (processor, digital capture, monitor, printer, cart)'' to ''scope video system (monitor, processor, digital capture, cart, printer, LED light)'' to reflect the fact that the use of the ES031 scope video system is not limited to endoscopy procedures.

The following is a summary of the public comments we received on our proposals involving scopes and scope systems.

Comment: Several commenters supported the decision to delay proposals for any further changes to scope equipment until CY 2020 in order to incorporate the feedback from the RUC's Scope Equipment Reorganization Workgroup. One commenter thanked CMS for adding a scope category for multi-channeled flexible video scopes. A different commenter supported the proposal to increase the price of the scope video system (ES03l) from its current price of $33,391 to a price of $36,306 and also supported the proposed update to the name of the ES03l equipment item since the use of the scope video system is not limited to endoscopy procedures.

Response: We appreciate the support for our proposals from the commenters.

Comment: One commenter stated that they were concerned that the proposed pricing for both the scope video system (ES03l) and the stroboscopy system (ES065) are less than the true cost of the equipment items, and therefore do not accurately reimburse physicians for their direct overhead costs. The commenter stated that they had supplied more recent invoices for these equipment items, which should be taken into consideration for pricing, and reiterated their disagreement with the CMS proposal from the previous calendar year to create single scope equipment categories for all specialties, as scope equipment is not always comparable across specialties. A different commenter supplied invoices for several other scope equipment items and requested that CMS update the prices for these equipment codes and that the new pricing take effect for CY 2019.

Response: We continue to believe that any further changes to scope equipment, including invoice submissions to update scope pricing, should be delayed until CY 2020 so that we can incorporate the feedback from the RUC's Scope Equipment Reorganization Workgroup.

After consideration of the public comments, we are finalizing our scope proposals for CY 2019 without refinement.

c. Balloon Sinus Surgery Kit (SA106) Comment Solicitation

Several stakeholders contacted CMS with regard to the use of the kit, sinus surgery, balloon (maxillary, frontal, or sphenoid) (SA106) supply in CPT codes 31295 (Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (*e.g.,* balloon dilation), transnasal or via canine fossa), 31296 (Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (*e.g.,* balloon dilation)), and 31297 (Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (*e.g.,* balloon dilation)). The stakeholders stated that the price of the SA106 supply (currently $2,599.86) had decreased significantly since it was priced through rulemaking for CY 2011 (75 FR 73351 through 75532), and that the Medicare payment for these three CPT codes using the supply no longer seemed to be in proportion to what the kits cost. They also indicated that the same catheter could be used to treat multiple sinuses rather than being a disposable one-time use supply. The stakeholders stated that marketing firms and sales representatives are advertising these CPT codes as a method for generating additional profits due to the payment for the procedures exceeding the resources typically needed to furnish the services, and requested that CMS investigate the use of the SA106 supply in these codes.

When CPT codes 31295 through 31297 were initially reviewed during the CY 2011 and CY 2012 PFS rulemaking cycles (75 FR 73251, and 76 FR 73184 through 73186, respectively), we expressed our reservations about the pricing and the typical quantity of this supply item used in furnishing these services. The RUC recommended for the CY 2012 rulemaking cycle that CMS remove the balloon sinus surgery kit from each of these codes and implement separately billable alpha-numeric HCPCS codes to allow practitioners to be paid the cost of the disposable kits per patient encounter instead of per CPT code. We stated at the time, and we continue to believe, that this option presents a series of potential problems that we have addressed previously in the context of the broader challenges regarding our ability to price high cost disposable supply items. (For a discussion of this issue, we direct the reader to our discussion in the CY 2011 PFS final rule with comment period (75 FR 73251)). We stated at the time that since the balloon sinus surgery kits can be used when furnishing more than one service to the same beneficiary on the same day, we believed that it would be appropriate to include 0.5 balloon sinus surgery kits for each of the three codes, and we have maintained this 0.5 supply quantity when CPT codes 31295–31297 were recently reviewed again in CY 2018.

In light of the additional information supplied by the stakeholders, we solicited comments on two aspects of the use of the balloon sinus surgery kit (SA106) supply. First, we solicited comments on whether the 0.5 supply quantity of the balloon sinus surgery kit in CPT codes 31295–31297 would be typical for these procedures. We are concerned that the same kit can be used when furnishing more than one service to the same beneficiary on the same day, and that even the 0.5 supply quantity may be overstating the resources typically needed to furnish each service. Second, we solicited comments on the pricing of the balloon sinus surgery kit, given that we have received letters stating that the price has decreased since the initial pricing in the CY 2011 final rule. See Table 5 for the current component pricing of the balloon sinus surgery kit.

TABLE 5—BALLOON SINUS SURGERY KIT (SA106) PRICE

Supply components	Quantity	Unit	Price
kit, sinus surgery, balloon (maxillary, frontal, or sphenoid)		kit	$2,599.86
Sinus Guide Catheter	1	item	444.00
Sinus Balloon Catheter	1	item	820.80
Sinus Illumination System (100 cm lighted guidewire)	1	item	454.80
Light Guide Cable (8 ft)	1	item	514.80
ACMI/Stryker Adaptor	1	item	42.00
Sinus Guide Catheter Handle	1	item	66.00
Sinus Irrigation Catheter (22 cm)	1	item	150.00
Sinus Balloon Catheter Inflation Device	1	item	89.46
Extension Tubing (High Pressure) (20 in)	1	item	18.00

We are interested in any information regarding possible changes in the pricing for this kit or its individual components since the initial pricing we adopted in CY 2011. The following is a summary of the public comments we received on our comment solicitation regarding the balloon sinus surgery kit supply.

Comment: Several commenters stated that the variability inherent in the underlying patient anatomy makes it extremely difficult to reliably assign a fixed number of sinuses that can be dilated per balloon or establish a supply quantity that would constitute the typical case. These commenters urged CMS to create a separate HCPCS code for the balloon sinus surgery kit that would be billable based on the number of balloons used per patient.

Response: As we stated in the proposed rule, we continue to believe that this option presents a series of potential problems that we have addressed previously in the context of the broader challenges regarding our ability to maintain appropriate relativity while pricing high cost disposable supply items. For a discussion of this issue, we direct the reader to our discussion in the CY 2011 PFS final rule with comment period (75 FR 73251).

Comment: One commenter provided extensive information regarding the pricing and composition of the balloon sinus surgery kit. This commenter stated that the components of the supply kit have changed from those listed in Table 5, and that there are multiple different types of this kit available for purchase. The commenter stated that the total cost of the balloon sinus surgery kit varies by sinus dilated, whether navigation is used, and by manufacturer, with the average price of a basic kit costing $2,204 and the average price of the kit used for navigation costing $2,850, not including the navigation device itself. The commenter stated that the kit components should not be individually priced and that invoices could be made available upon request.

With regards to the number of sinus dilation procedures that typically can be performed per balloon, the commenter repeated that the variability inherent in the underlying patient anatomy makes it extremely difficult to assign a fixed number of sinuses that can be dilated per balloon. The commenter also urged CMS to consider a shift away from the current supply methodology and instead create a separate HCPCS code for the balloon sinus surgery kit which would be billable based on the number of balloons used per patient. The commenter stated that should CMS elect to preserve the current policy of assigning a fixed number of sinus dilations per kit, they recommended maintaining the current supply quantity that allows one kit for every two sinuses, as they were unable to find compelling evidence to support a more appropriate supply amount.

Response: We are particularly interested in the feedback suggesting that there may be multiple types of balloon sinus surgery kits that have different prices, and we would be interested in further information, including invoice submissions, on this subject for future rulemaking.

After consideration of the public comments, we are not finalizing any changes to the balloon sinus surgery kit (SA106) supply for CY 2019, outside of the market-based supply and equipment pricing update to the supply cost. We do not believe that we have sufficient information to finalize any other changes to the supply cost or supply quantity in the associated CPT codes at this point in time.

d. Technical Corrections to Direct PE Input Database and Supporting Files

Subsequent to the publication of the CY 2018 PFS final rule, stakeholders alerted us to several clerical inconsistencies in the direct PE database. We proposed to correct these inconsistencies as described below and reflected in the CY 2019 final direct PE input database displayed on the CMS website under downloads for the CY 2019 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

For CY 2019, we proposed to address the following inconsistencies:

- The RUC alerted us that there are 165 CPT codes billed with an office E/M code more than 50 percent of the time in the nonfacility setting that have more minimum multi-specialty visit supply packs (SA048) than post-operative visits included in the code's global period. This indicates that either the inclusion of office E/M services was not accounted for in the code's global period when these codes were initially reviewed by the PE Subcommittee, or that the PE Subcommittee initially approved a minimum multi-specialty visit supply pack for these codes without considering the resulting overlap of supplies between SA048 and the E/M supply pack (SA047). The RUC regarded these overlapping supply packs as a duplication, due to the fact that the quantity of the SA048 supply exceeded the number of postoperative visits, and requested that CMS remove the appropriate number of supply item SA048 from 165 codes. After reviewing the quantity of the SA048 supply pack included for the codes in question, we proposed to refine the quantity of minimum multi-specialty visit packs as displayed in Table 6.

TABLE 6—PROPOSED REFINEMENTS—MINIMUM MULTISPECIALTY VISIT PACK (SA048)

CPT code	Number of post-op office visits	CY 2018 nonfacility quantity of minimum visit pack (SA048)	Proposed CY 2019 nonfacility quantity of minimum visit pack (SA048)
10040	1	2	1
10060	1	2	1
10061	2	3	2
10080	1	2	1
10120	1	2	1
10121	1	2	1
10180	1	2	1
11200	1	2	1
11300	0	1	0
11301	0	1	0
11302	0	1	0

TABLE 6—PROPOSED REFINEMENTS—MINIMUM MULTISPECIALTY VISIT PACK (SA048)—Continued

CPT code	Number of post-op office visits	CY 2018 nonfacility quantity of minimum visit pack (SA048)	Proposed CY 2019 nonfacility quantity of minimum visit pack (SA048)
11303	0	1	0
11306	0	1	0
11307	0	1	0
11310	0	1	0
11311	0	1	0
11312	0	1	0
11400	1	2	1
11750	1	2	1
11900	0	1	0
11901	0	1	0
12001	0	1	0
12002	0	1	0
12004	0	1	0
12011	0	1	0
12013	0	1	0
16020	0	1	0
17000	1	2	1
17004	1	2	1
17110	1	2	1
17111	1	2	1
17260	1	2	1
17270	1	2	1
17280	1	2	1
19100	0	1	0
20005	1	2	1
20520	1	2	1
21215	6	7	6
21550	1	2	1
21920	1	2	1
22310	1.5	2.5	1.5
23500	2.5	3.5	2.5
23570	2.5	3.5	2.5
23620	3	4	3
24500	4	5	4
24530	4	5	4
24650	3	4	3
24670	3	4	3
25530	3	4	3
25600	5	6	5
25605	5	6	5
25622	3.5	4.5	3.5
25630	3	4	3
26600	4	5	4
26720	2	3	2
26740	2.5	3.5	2.5
26750	2	3	2
27508	4	5	4
27520	3.5	4.5	3.5
27530	4	5	4
27613	1	2	1
27750	3.5	4.5	3.5
27760	4	5	4
27780	3.5	4.5	3.5
27786	3.5	4.5	3.5
27808	4	5	4
28190	1	2	1
28400	3	4	3
28450	2.5	3.5	2.5
28490	1.5	2.5	1.5
28510	1.5	2.5	1.5
30901	0	1	0
30903	0	1	0
30905	0	1	0
31000	1	2	1
31231	0	1	0
31233	0	1	0
31235	0	1	0

TABLE 6—PROPOSED REFINEMENTS—MINIMUM MULTISPECIALTY VISIT PACK (SA048)—Continued

CPT code	Number of post-op office visits	CY 2018 nonfacility quantity of minimum visit pack (SA048)	Proposed CY 2019 nonfacility quantity of minimum visit pack (SA048)
31238	0	1	0
31525	0	1	0
31622	0	1	0
32554	0	1	0
36600	0	1	0
38220	0	1	0
40490	0	1	0
42800	1	2	1
43200	0	1	0
45330	0	1	0
46040	3	4	3
46050	1	2	1
46083	1	2	1
46320	0.5	1.5	0.5
46600	0	1	0
46604	0	1	0
46900	1	2	1
51102	0	2	0
51701	0	1	0
51702	0	1	0
51703	0	1	0
51710	0	1	0
51725	0	1	0
51736	0	1	0
51741	0	1	0
51792	0	1	0
51798	0	1	0
52000	0	1	0
52001	0	1	0
52214	0	1	0
52265	0	1	0
52281	0	1	0
52285	0	1	0
53601	0	1	0
53621	0	1	0
53660	0	1	0
53661	0	1	0
54050	1	2	1
54056	1	2	1
54100	0	1	0
54235	0	1	0
54450	0	1	0
55000	0	1	0
56405	1	2	1
56605	0	1	0
56820	0	1	0
57061	1	2	1
57100	0	1	0
57420	0	1	0
57500	0	1	0
57505	1	2	1
62252	0	1	0
62367	0	1	0
62368	0	1	0
62370	0	1	0
64413	0	1	0
64420	0	1	0
64450	0	1	0
64611	1	2	1
69000	1	2	1
69100	0	1	0
69145	1.5	2.5	1.5
69210	0	1	0
69420	1	2	1
69433	1	2	1
69610	1	2	1
93292	0	1	0

TABLE 6—PROPOSED REFINEMENTS—MINIMUM MULTISPECIALTY VISIT PACK (SA048)—Continued

CPT code	Number of post-op office visits	CY 2018 nonfacility quantity of minimum visit pack (SA048)	Proposed CY 2019 nonfacility quantity of minimum visit pack (SA048)
93303	0	1	0
94667	0	1	0
95044	0	0.028	0
95870	0	1	0
95921	0	1	0
95922	0	1	0
95924	0	1	0
95972	0	1	1
96904	0	1	1

In general, we proposed to align the number of minimum multi-specialty visit packs with the number of post-operative office visits included in these codes. We did not propose any supply pack quantity refinements for CPT codes 11100, 95974, or 95978 since they are being deleted for CY 2019. We also did not propose any supply pack quantity refinements for CPT codes 45300, 46500, 57150, 57160, 58100, 64405, 95970, or HCPCS code G0268 since these codes were reviewed by the RUC this year and their previous direct PE inputs will be superseded by the new direct PE inputs we establish through this rulemaking process for CY 2019.

Comment: One commenter stated that they supported this effort as it serves to remedy any discrepancies/errors that may be in the PFS related to postoperative visits and the required multi-specialty packs needed to render those visits.

Response: We appreciate the support for our proposal from the commenter.

Comment: One commenter stated that removal of the SA048 supply pack was inappropriate for CPT code 43200 (Esophagoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)) as it is required for the esophagoscopy procedure and the supply is included in the other codes in the family (CPT codes 43201–43233) as well as for the other GI endoscopy code families. The commenter requested that CMS not remove the SA048 supply from CPT code 43200.

Response: After reviewing the supply inputs for the group of codes identified by the commenter, we agree that it would not be consistent to remove the SA048 multi-specialty pack from CPT code 43200 while retaining the supply pack in CPT codes 43201–43233. As a result, we are not finalizing the removal of the SA048 multi-specialty pack from CPT code 43200. However, we note that many of the CPT codes in this range also contain SA048 supply packs without having any postoperative office visits included in their global periods. We believe that it may be more accurate to achieve consistency within this range of CPT codes by removing the SA048 supply pack from all of these codes, as opposed to adding the SA048 supply pack to CPT code 43200. In regard to this topic, stakeholders can always provide data to us if they believe the code is not bundled/valued/etc. correctly.

After consideration of the public comments, we are finalizing our proposal to align the number of minimum multi-specialty visit packs with the number of post-operative office visits included in these CPT codes listed in Table 6, with the exception of CPT code 43200 as detailed above.

A stakeholder notified us regarding a potential rank order anomaly in the direct PE inputs established for the Shaving of Epidermal or Dermal Lesions code family through PFS rulemaking for CY 2013. Three of these CPT codes describe benign shave removal of increasing lesion sizes: CPT code 11310 (Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.5 cm or less), CPT code 11311 (Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.6 to 1.0 cm), and CPT code 11312 (Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 1.1 to 2.0 cm). Each of these codes has a progressively higher work RVU corresponding to the increasing lesion diameter, and the recommended direct PE inputs also increase progressively from CPT codes 11310 to 11311 to 11312. However, the nonfacility PE RVU we established for CPT code 11311 is lower than the nonfacility PE RVU for CPT code 11310, which the stakeholder suggested may represent a rank order anomaly.

We reviewed the direct PE inputs for CPT code 11311 and found that there were clerical inconsistencies in the data entry that resulted in the assignment of the lower nonfacility PE RVU for CPT code 11311. We proposed to revise the direct PE inputs to reflect the ones previously finalized through rulemaking for CPT code 11311.

Comment: One commenter agreed that a significant clerical error occurred after the RUC recommended its valuation of CPT code 11311 and its final acceptance by CMS. The commenter recommended that the direct PE inputs of CPT code 11310 be replicated for CPT code 11311 and submitted a table with recommended values.

Response: After reviewing this information, we found that the direct PE inputs requested by the commenter mostly, but do not entirely, match the direct PE inputs that CMS finalized through rulemaking for CY 2013. The commenter requested the inclusion of an additional SB007 (drape, sterile barrier 16in x 29in) supply and a SB011 (drape, sterile, fenestrated 16in x 29in) supply while leaving out a SK075 (skin marking pen, sterile (Skin Skribe)) supply, 3 SM022 (sanitizing cloth-wipe (surface, instruments, equipment)) supplies, and 4 SL463 (Aluminum Chloride 70%) supplies. Since we proposed to revise the direct PE inputs to match the ones previously finalized through rulemaking for CPT code 11311, we are not finalizing these five changes to the direct PE inputs requested by the commenter. In all other respects, the direct PE inputs recommended by the commenter matched the direct PE inputs previously finalized through

rulemaking. We are therefore finalizing our proposal to revise the direct PE inputs to reflect the ones previously finalized in CY 2013 for CPT code 11311.

• In CY 2018, we inadvertently assigned too many minutes of clinical labor time for the ''Obtain vital signs'' task to three therapy codes, given that these codes are typically billed in multiple units and in conjunction with other therapy codes for the same patient on the same day, and we do not believe that it would be typical for clinical staff to obtain vital signs for each time a code is reported. The codes are: CPT code 97124 (Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)); CPT code 97750 (Physical performance test or measurement (*e.g.,* musculoskeletal, functional capacity), with written report, each 15 minutes); and CPT code 97755 (Assistive technology assessment (*e.g.,* to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes).

Therefore, we proposed to refine the ''Obtain vital signs'' clinical labor task for these three codes back to their previous times of 1 minute for CPT codes 97124 and 97750 and to 3 minutes for CPT code 97755. We also proposed to refine the equipment time for the table, mat, hi-lo, 6 x 8 platform (EF028) for CPT code 97124 to reflect the change in the clinical labor time.

Comment: Several commenters agreed with the CMS rationale for refining the clinical labor task times for each of these codes.

Response: We appreciate the support for our proposal from the commenters.

Comment: One commenter opposed the CMS proposal to refine the equipment time for the table, mat, hi-lo, 6 x 8 platform (EF028) for CPT code 97124 to reflect the change in the clinical labor time.

Response: We continue to believe that changes in clinical labor time should be matched with corresponding changes in equipment time. Since the commenter did not supply a rationale as to why the EF028 equipment time should not match the change in clinical labor time, we are finalizing our proposal to refine the ''Obtain vital signs'' clinical labor task for these three codes back to their previous times of 1 minute for CPT codes 97124 and 97750 and to 3 minutes for CPT code 97755.

We received a letter from a commenter alerting us to an anomaly in the direct PE inputs for CPT code 52000 (Cystourethroscopy (separate procedure)). The commenter stated that the inclusion of an endoscope disinfector, rigid or fiberoptic, w-cart equipment item (ES005) was inadvertently overlooked in the recommendations for CPT code 52000 when it was reviewed during PFS rulemaking for CY 2017, and that the equipment would be necessary for endoscope sterilization. The commenter requested that this piece of equipment should be added to the direct PE inputs for CPT code 52000.

After reviewing the direct PE inputs for this code, we agreed with the commenter and we proposed to add the endoscope disinfector (ES005) to CPT code 52000, and to add 22 minutes of equipment time for that item to match the equipment time of the other non-scope items included in this code.

Comment: One commenter supported the CMS proposal to add an endoscope disinfector to CPT code 52000 and to add 22 minutes of equipment time to match the equipment time of the other non-scope items included in the code. This commenter requested that this addition apply to all endoscopic urologic procedures that do not already include the endoscope disinfector.

Response: We do not agree that the endoscope disinfector should be added to all endoscopic urologic procedures that lacked the equipment, as the addition of this equipment to CPT code 52000 is a technical correction to address a specific anomaly with the recommendations for CPT code 52000 and not the implementation of a new policy. After consideration of the public comments, we are finalizing the addition of 22 minutes of equipment time for the endoscope disinfector (ES005) to CPT code 52000 as proposed.

The following is a summary of the public comments we received on additional technical corrections to the direct PE input database and supporting files.

Comment: A commenter stated that they had reviewed the CY 2019 Proposed Rule physician work time file and discovered an issue with 13 CPT codes that had incorrect work times. The commenter stated that these were technical errors in which the current work time values did not match what CMS had finalized through rulemaking, and the commenter requested that these services be corrected in the CY 2019 CMS work time file for the CY 2019 Final Rule.

Response: We agree with the commenter that some of these CPT codes are subject to technical corrections, while disagreeing with the commenter with regards to other CPT codes, as described in more detail below.

Listed in order, the commenter identified these issues:

Comment: For CPT code 15220 (Full thickness graft, free, including direct closure of donor site, scalp, arms, and/or legs; 20 sq cm or less), the commenter stated that their records showed CMS missing 15 min of positioning time from the Harvard study.

Response: We are not finalizing a change in the work time of this code at this time, as we were unable to verify the positioning time of CPT code 15220 as originally measured by the Harvard study.

Comment: For CPT code 22558 (Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar), the commenter stated that the CMS work time file accidentally double counted postoperative visit time in the immediate postoperative time field.

Response: We agree with the commenter that this is subject to a technical correction, and we are finalizing an immediate postservice work time of 25 minutes for CPT code 22558.

Comment: For CPT code 43760 (Change of gastrostomy tube, percutaneous, without imaging or endoscopic guidance), the commenter stated that the code is being deleted for CY 2019 and should not appear in the work time file.

Response: We agree with the commenter, and we are finalizing the removal of this code from the work time file.

Comment: For CPT codes 61645 (Percutaneous arterial transluminal mechanical thrombectomy and/or infusion for thrombolysis, intracranial, any method, including diagnostic angiography, fluoroscopic guidance, catheter placement, and intraprocedural pharmacological thrombolytic injection(s)) and 61650 (Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; initial vascular territory), the commenter stated that CMS incorrectly applied 23 hour stay rule for these codes even though the RUC recommended these services as typically inpatient. The commenter stated that there are now available data to see that these CPT codes are done on an inpatient basis 98 percent and 86 percent of the time respectively.

Response: We do not believe that the work times of these codes are subject to

a technical correction, as the work times finalized for these codes in the CY 2017 PFS final rule (81 FR 80307–08) were based on a disagreement in policy with the commenter and not a technical error.

Comment: For CPT code 91200 (Liver elastography, mechanically induced shear wave (*e.g.,* vibration), without imaging, with interpretation and report), the commenter stated that the RUC recommended 5 minutes of immediate postservice work time, not 3 minutes, and that CMS had finalized the code without a time refinement. The commenter stated that the immediate postservice work time for CPT code 91200 should be 5 minutes in accordance with the RUC recommendations.

Response: We investigated the RUC recommendations from the April 2015 RUC meeting when CPT code 91200 was reviewed, and we found that the RUC recommended an immediate postservice work time of 3 minutes on the code family's cover sheet and the accompanying summary spreadsheet. Although the RUC may have intended to recommend an immediate postservice work time of 5 minutes for this code, we proposed and finalized an immediate postservice work time of 3 minutes for CPT code 91200 without receiving any comments on the issue. Therefore we are not finalizing any changes to the work time of CPT code 91200 at this time, which will remain 3 minutes.

Comment: For CPT codes 93281 (Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead pacemaker system), 93284 (Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system), and 93286 (Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead pacemaker system), the commenter stated that CMS has the wrong intraservice work times, despite the CY 2018 final rule indicating no time refinement for these codes.

Response: After reviewing the work times for these codes, we agree with the commenter and we are finalizing a technical correction to the intraservice work times as recommended.

Comment: For CPT code 97166 (Occupational therapy evaluation, moderate complexity), the commenter stated that the HCPAC recommended 15 min of immediate postservice work time, not 10 minutes, and that CMS had finalized the code without a time refinement.

Response: We investigated the RUC recommendations from the October 2015 RUC meeting when CPT code 97166 was reviewed, and we found that the HCPAC recommendations contained two different values for the immediately postservice work time. The written recommendations stated that the immediate postservice work time was recommended at 15 minutes, while the data on the summary spreadsheet stated that the immediate postservice work time was recommended at 10 minutes. Although there were two conflicting HCPAC recommendations for this code, we finalized in the CY 2017 PFS final rule (81 FR 80331) an immediate postservice work time of 10 minutes for CPT code 97166 without receiving any comments on the issue. Therefore we are not finalizing any changes to the work time of CPT code 97166 at this time.

Comment: For CPT code 33866 (Aortic hemiarch graft including isolation and control of the arch vessels, beveled open distal aortic anastomosis extending under one or more of the arch vessels, and total circulatory arrest or isolated cerebral perfusion (List separately in addition to code for primary procedure)), the commenter stated that the RUC recommendation was rescinded and that the code should be removed from the work time file.

Response: We disagree with the commenter, and we are not finalizing the removal of CPT code 33866 from the work time file; we refer readers to the code valuation section of this final rule for additional details regarding CPT code 33866.

Comment: For CPT code 96X11 (Psychological or neuropsychological test administration using single instrument, with interpretation and report by physician or other qualified health care professional and interactive feedback to the patient, family member(s), or caregivers(s), when performed), the commenter stated that the code is not being created for CY 2019 by the CPT Editorial Panel and should be removed from the work time file.

Response: We agree with the commenter and we are finalizing the removal of this code from the work time file.

Comment: For HCPCS code G0281 (Electrical stimulation, (unattended), to one or more areas, for chronic stage iii and stage iv pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a therapy plan of care), the commenter stated that their records show an intraservice time for this code of 11 minutes and not 7 minutes as currently listed in the work time file.

Response: We disagree with the commenter. As we stated in the CY 2003 PFS final rule with comment period (67 FR 80014), the work, practice expense, and malpractice values G0281 are based on a crosswalk to CPT code 97014 (Application of a modality to 1 or more areas; electrical stimulation (unattended)), and the intraservice work time of CPT code 97014 remains 7 minutes.

Comment: Many commenters raised concerns about the use of the portable X-ray machine (EF041) equipment in CPT code 71045 (Radiologic examination, chest; single view). Commenters stated that the use of the portable X-ray machine in CPT code 71045 understated the price of the equipment typically used in the service, and that the default equipment utilization rate of 50 percent did not reflect the experience of portable X-ray suppliers. Commenters supplied an invoice for a Digital Radiography portable X-ray machine, which they stated would be typical for use in this procedure, along with data on the equipment utilization rate that suggested a utilization rate significantly lower than 50 percent would be typical. Commenters requested modifying the direct PE inputs for CPT code 71045 to include the use of the Digital Radiography portable X-ray machine at a distinctive utilization rate of approximately 22 percent, or alternatively, to use the same equipment as the other three codes in the Chest X-Ray code family (CPT codes 71046–71048) as direct PE inputs for CPT code 71045.

Response: We agree with the commenters and we are finalizing the replacement of the 9 minutes of equipment time for the portable X-ray machine (EF041) with 9 minutes of equipment time for a basic radiology room (EL012) for CPT code 71045. The equipment cost per minute of the basic radiology room (48.4 cents) is nearly identical to the equipment cost per

minute of the proposed Digital Radiography portable X-ray machine (46.0 cents), and we believe that it would better serve the interests of relativity for CPT code 71045 to match the same equipment inputs as the rest of the Chest X-Ray code family. We previously updated the PE RVU of this code in the July 2018 Quarterly Update (CMS Change Request 10644) based on the same information previously supplied by the commenters, and due to a technical error, this update to the direct PE inputs of CPT code 71045 was not included in the CY 2019 PFS proposed rule. We are finalizing this technical correction to the direct PE inputs of CPT code 71045 for CY 2019.

Comment: One commenter stated that there was a typographical error in Attachment B of the proposed rule, which resulted in the misstatement of the total RVUs for CPT code 48554 (Transplantation of pancreatic allograft). The commenter recommended that we include 74.81 total RVUs for CPT code 48554 to correct the error of 73.70 total RVUs.

Response: We do not agree with the commenter that there was a typographical error in Addendum B for CPT code 48554, which appears to sum its component parts of the work RVU (37.80), PE RVU (27.72), and malpractice RVU (9.29) to the correct total RVU of 74.81.

We also received comments regarding a variety of subjects about which we did not make proposals for CY 2019. These included comments regarding: The level of physician supervision for CPT code 99091, the 7 percent reduction to the technical component of computed radiography services not performed using digital radiography, a request to migrate the RUC recommended RVU assignment of CPT code 77387 to HCPCS code G6017, a request that CMS not finalize the proposed changes in payment for the revascularization codes (CPT codes 37225–37231) that were a byproduct of the E/M proposals and the supply/equipment pricing update, a request that CMS should assign direct cost inputs and PE RVUs to several disposable negative pressure wound therapy codes (CPT codes 97607–97608), a disagreement with previous reductions in the payment rate for HCPCS code G0416 from past calendar years, a request for clarification regarding the facility PE RVUs for CPT code 99153, a request for CMS to provide additional reimbursement stability for vascular access services by increasing the work RVUs and direct PE inputs for these codes (CPT codes 36901–36909), and a request for CMS to study the possible effect of tariffs on the cost of imaging equipment manufactured overseas. These comments are considered out of scope for the CY 2019 PFS final rule, as we did not make any proposals on these issues in the CY 2019 PFS Proposed Rule. We will take the feedback from the commenters under consideration for future rulemaking.

After consideration of the public comments, we are finalizing technical corrections to the direct PE input database and supporting files as described above.

e. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. For CY 2019, we proposed the following price updates for existing direct PE inputs.

We proposed to update the price of four supplies and one equipment item in response to the public submission of invoices. As these pricing updates were each part of the formal review for a code family, we proposed that the new pricing take effect for CY 2019 for these items instead of being phased in over 4 years. For the details of these proposed price updates, please refer to section II.H. of this final rule, Table 15: Invoices Received for Existing Direct PE Inputs.

(1) Market-Based Supply and Equipment Pricing Update

Section 220(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types and prices of PE inputs; overhead and accounting information for practices of physicians and other suppliers, and any other elements that would improve the valuation of services under the PFS.

As part of our authority under section 1848(c)(2)(M) of the Act, as added by PAMA, we initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the PFS direct PE inputs (DPEI) for supply and equipment pricing for CY 2019. These supply and equipment prices were last systematically developed in 2004–2005. StrategyGen has submitted a report with updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs. This report is available as a public use file displayed on the CMS website under downloads for the CY 2019 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

The StrategyGen team of researchers, attorneys, physicians, and health policy experts conducted a market research study of the supply and equipment items currently used in the PFS direct PE input database. Resources and methodologies included field surveys, aggregate databases, vendor resources, market scans, market analysis, physician substantiation, and statistical analysis to estimate and validate current prices for medical equipment and medical supplies. StrategyGen conducted secondary market research on each of the 2,072 DPEI medical equipment and supply items that CMS identified from the current DPEI. The primary and secondary resources StrategyGen used to gather price data and other information were:

- Telephone surveys with vendors for top priority items (Vendor Survey).
- Physician panel validation of market research results, prioritized by total spending (Physician Panel).
- The General Services Administration system (GSA).
- An aggregate health system buyers database with discounted prices (Buyers).
- Publicly available vendor resources, that is, Amazon Business, Cardinal Health (Vendors).
- **Federal Register**, current DPEI data, historical proposed and final rules prior to FY 2018, and other resources; that is, AMA RUC reports (References).

StrategyGen prioritized the equipment and supply research based on current share of PE RVUs attributable by item provided by CMS. StrategyGen developed the preliminary Recommended Price (RP) methodology based on the following rules in hierarchical order considering both data representativeness and reliability.

1. If the market share, as well as the sample size, for the top three commercial products were available, the weighted average price (weighted by percent market share) was the reported RP. Commercial price, as a weighted average of market share, represents a more robust estimate for each piece of

equipment and a more precise reference for the RP.

2. If StrategyGen did not have market share for commercial products, then they used a weighted average (weighted by sample size) of the commercial price and GSA price for the RP. The impact of the GSA price may be nominal in some of these cases since it is proportionate to the commercial samples sizes.

3. Otherwise, if single price points existed from alternate supplier sites, the RP was the weighted average of the commercial price and the GSA price.

4. Finally, if no data were available for commercial products, the GSA average price was used as the RP; and when StrategyGen could find no market research for a particular piece of equipment or supply item, the current CMS prices were used as the RP.

After reviewing the StrategyGen report, we proposed to adopt the updated direct PE input prices for supplies and equipment as recommended by StrategyGen. For the reasons subsequently discussed, the GSA price was not incorporated into the calculation for the StrategyGen recommended prices printed in the proposed rule. The proposed recommended price was developed as follows:

Recommended CMS Price: The StrategyGen proposed recommended price was the researched-commercial price, when available. If not, the StrategyGen proposed recommended price was the current CMS price.

StrategyGen found that despite technological advancements, the average commercial price for medical equipment and supplies has remained relatively consistent with the current CMS price. Specifically, preliminary data indicate that there was no statistically significant difference between the estimated commercial prices and the current CMS prices for both equipment and supplies. This cumulative stable pricing for medical equipment and supplies appears similar to the pricing impacts of non-medical technology advancements where some historically high-priced equipment (that is, desktop PCs) has been increasingly substituted with current technology (that is, laptops and tablets) at similar or lower price points. However, while there were no statistically significant differences in pricing at the aggregate level, medical specialties will experience increases or decreases in their Medicare payments if CMS were to adopt the pricing updates recommended by StrategyGen. At the service level, there may be large shifts in PE RVUs for individual codes that happened to contain supplies and/or equipment with major changes in pricing, although we note that codes with a sizable PE RVU decrease would be limited by the requirement to phase in significant reductions in RVUs, as required by section 1848(c)(7) of the Act. The phase-in requirement limits the maximum RVU reduction for codes that are not new or revised to 19 percent in any individual calendar year.

We believe that it is important to make use of the most current information available for supply and equipment pricing instead of continuing to rely on pricing information that is more than a decade old. Given the potentially significant changes in payment that would occur, both for specific services and more broadly at the specialty level, we proposed to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY 2019), 50/50 percent (CY 2020), 75/25 percent (CY 2021), and 100/0 percent (CY 2022) split between new and old pricing. This approach is consistent with how we have previously incorporated significant new data into the calculation of PE RVUs, such as the 4-year transition period finalized in CY 2007 PFS final rule with comment period when changing to the ''bottom-up'' PE methodology (71 FR 69641). This transition period will not only ease the shift to the updated supply and equipment pricing, but will also allow interested parties an opportunity to review and respond to the new pricing information associated with their services.

We proposed to implement this phase-in over 4 years so that supply and equipment values transition smoothly from the prices we currently include to the final updated prices in CY 2022. We proposed to implement this pricing transition such that one quarter of the difference between the current price and the fully phased in price is implemented for CY 2019, one third of the difference between the CY 2019 price and the final price is implemented for CY 2020, and one half of the difference between the CY 2020 price and the final price is implemented for CY 2021, with the new direct PE prices fully implemented for CY 2022. An example of the proposed transition from the current to the fully-implemented new pricing is provided in Table 7.

TABLE 7—EXAMPLE OF DIRECT PE PRICING TRANSITION

Current Price	$100	
Final Price	200	
Year 1 (CY 2019) Price	125	¼ difference between $100 and $200.
Year 2 (CY 2020) Price	150	⅓ difference between $125 and $200.
Year 3 (CY 2021) Price	175	½ difference between $150 and $200.
Final (CY 2022) Price	200	

For new supply and equipment codes for which we establish prices during the transition years (CYs 2019, 2020 and 2021) based on the public submission of invoices, we proposed to fully implement those prices with no transition since there are no current prices for these supply and equipment items. These new supply and equipment codes would immediately be priced at their newly established values. We also proposed that, for existing supply and equipment codes, when we establish prices based on invoices that are submitted as part of a revaluation or comprehensive review of a code or code family, they will be fully implemented for the year they are adopted without being phased in over the 4-year pricing transition. The formal review process for a HCPCS code includes a review of pricing of the supplies and equipment included in the code. When we find that the price on the submitted invoice is typical for the item in question, we believe it would be appropriate to finalize the new pricing immediately along with any other revisions we adopt for the code valuation.

For existing supply and equipment codes that are not part of a comprehensive review and valuation of a code family and for which we establish prices based on invoices submitted by the public, we proposed to implement the established invoice price as the updated price and to phase in the new price over the remaining years of the proposed 4-year pricing transition. During the proposed transition period, where price changes for supplies and

equipment are adopted without a formal review of the HCPCS codes that include them (as is the case for the many updated prices we proposed to phase in over the 4-year transition period), we believe it is important to include them in the remaining transition toward the updated price. We also proposed to phase in any updated pricing we establish during the 4-year transition period for very commonly used supplies and equipment that are included in 100 or more codes, such as sterile gloves (SB024) or exam tables (EF023), even if invoices are provided as part of the formal review of a code family. We would implement the new prices for any such supplies and equipment over the remaining years of the proposed 4-year transition period. Our proposal was intended to minimize any potential disruptive effects during the proposed transition period that could be caused by other sudden shifts in RVUs due to the high number of services that make use of these very common supply and equipment items (meaning that these items are included in 100 or more codes).

We believed that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy, while maintaining stability and allowing stakeholders the opportunity to address potential concerns about changes in payment for particular items. Updating the pricing of direct PE inputs for supplies and equipment over a longer time frame will allow more opportunities for public comment and submission of additional, applicable data. We welcomed feedback from stakeholders on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration. We were particularly interested in comments regarding the supply and equipment pricing for CPT codes 95165 and 95004 that are frequently used by the Allergy/Immunology specialty. The Allergy/Immunology specialty was disproportionately affected by the updated pricing, even with a 4-year phase-in. The direct PE costs for CPT code 95165 would go down from $8.43 to $8.17 as a result of the updated supply and equipment pricing information. This would result in the PE RVU for CPT code 96165 to decrease from 0.30 to 0.26. We are seeking feedback on the supply and equipment pricing for the affected codes typically performed by this specialty and whether the direct PE inputs should be reviewed along with the pricing. The full report from the contractor, including the updated supply and equipment pricing that we proposed to be implemented over the proposed 4-year transition period, will be made available as a public use file displayed on the CMS website under downloads for the CY 2019 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

The following is a summary of the public comments we received on our proposals associated with the market research study to update the PFS direct PE inputs for supply and equipment pricing.

Comment: Many commenters were concerned with the transparency of the data used to calculate medical equipment and supply prices. The commenters were particularly concerned about the use of a subscription-based benchmark database as a source for pricing data. The commenters stated that without identification of the database and access to the precise data used in determining the pricing update, they would have no systematic way to evaluate pricing accuracy. In addition, these commenters were concerned that small physician practices are not well represented in benchmark databases, with the consequence that the proposed repricing did not reflect the typical price paid by smaller stakeholders. Commenters stated a general concern that any methodology that more heavily weighs larger physician groups, group purchasing organizations (GPOs), or even hospital contract pricing would result in pricing that is significantly depressed compared to the pricing that can be obtained by an individual practitioner. The commenters asserted that this has the potential to pressure the financial viability of smaller physician practices and to force lower cost non-facility procedures into hospital outpatient or inpatient sites of service.

Response: As to whether there is sufficient transparency to enable others to replicate and validate the proposed pricing, the StrategyGen contractors carried out a market research plan designed to estimate the typical discounted prices that physicians and other providers normally pay. The proprietary database of buyer reported pricing is one of the few sources of typical discounted price data available. Other potential sources of typical discounted pricing were other proprietary databases and the publicly available GSA pricing. For each item priced, the analysis from the contractors included research on as many as five current sources of prices: (1) A proprietary database of buyer reported pricing, (2) Prices reported by GSA, (3) Amazon Business, (4) Cardinal Healthcare, and (5) Vendors' and manufacturers' catalogs.

The proprietary database of buyer reported pricing offers three advantages: (1) It represents discounted prices as opposed to retail pricing, (2) It has the largest sample sizes to represent a wider range of pricing as opposed to single invoices, and (3) The database provides variety with respect to the purchaser's geographic location, purchasing method, procedure volume and other purchasing arrangements. We initially assumed that GSA also represents typical discounted pricing across regions with smaller sample sizes, but subsequently rejected GSA data because we did not believe that its prices were typically representative of commercially available pricing. As a result, GSA data were *not* used to calculate the StrategyGen recommended prices included in the proposed rule. Amazon Business and Cardinal Healthcare represent typical retail pricing, with smaller sample sizes. In addition, the StrategyGen contractors utilized vendors' and manufacturers' catalogs to identify publicly available pricing. Table 8 summarizes sources of online pricing and characteristics of each source:

TABLE 8—MARKET-BASED SUPPLY AND EQUIPMENT PRICING UPDATE DATA SOURCES

Source of pricing data	Discounted pricing	Sample size	Variety (that is, geography, purchasing arrangement, etc.)
Buyers database	Actual discounts	Largest	National footprint.
GSA	Wholesale price	3–5	Government purchasers only.
Amazon Business (on-line)	Retail price	3–5	National footprint.
Cardinal Healthcare (on-line)	Retail price	3–5	National footprint.
Catalogs (on-line)	Retail price	3–5	National footprint.

The Buyers database provides the most accurate market pricing estimates that include market discounts for a range of buyer organizations. Its larger sample sizes provide more confidence that the proposed pricing is not skewed toward higher or lower pricing but toward the actual market price paid by purchasers.

The StrategyGen contractors chose not to include invoice research in the market research plan as there is already an existing process to modify Direct Practice Expense Input (DPEI) prices based on invoices. Additionally, the contractors determined that providing specific models and other identifying data with the researched prices would offer a broader and more consistent source of pricing data. We do not agree with the commenters that the updated supply and equipment prices will pressure the financial viability of smaller physician practices, as we believe that the larger sample sizes obtained by StrategyGen's research provide more accurate and more consistent pricing of actual market conditions than the single invoices that we have traditionally been reliant upon for pricing.

As to whether the proposed pricing is representative of prices available to small physician practices and non-facility practitioners generally, one of the objectives of the primary market research was to understand what kind of discounts are available to small physician practices similar to discounted pricing available to large health systems under GPOs. The market research plan included a series of questions to vendors designed to illuminate typical discounts they offer to large and small providers other than GPOs. This market research indicates that there are a variety of discount purchasing options available. Vendors indicated that both volume and timing can influence pricing discounts. Approximately 80 percent of respondents indicated that timing has some impact on the price of equipment, and about half of respondents indicated that timing had some impact on the price of supplies. Discussions with other subject matter experts also indicated that timing of purchase is an important factor in pricing. For example, the end of the sales cycle can drive discounts. Less than 10 percent of vendors indicated that these timing discounts may not be available to smaller practices outside of a GPO. The vendor research also indicated that other factors beyond ''size and timing'' influence discounted pricing, such as service agreements and bundled purchases.

Research indicates that service agreements often include discounts for equipment and supplies. For example, longer term service agreements generally result in larger discounts. However, some vendors indicated that the effect of service agreements was to reduce the size of the discounts, negatively impacting providers. This may be a difference in service agreement strategies across different vendors. Regardless, only 3 percent of respondents indicated that the availability of service agreement discounts was dependent on a GPO.

The vendors identified other factors that impact pricing decisions including:

- Market demand and competitive pricing;
- Contract renewal;
- Customer history and contract history; and
- Vendor considerations independent of the purchaser such as manufacturer and sales incentives, revenue goals, and new product releases.

In conclusion, while volume purchasing and GPOs can drive down prices for many large providers, these are not the only drivers of discounts for providers. A number of additional factors applicable to large, small, and non-facility practices may result in discounts for the buying organizations. We believe that the pricing update required looking at a broad range of data that was collected from different sources, which included pricing data from both large and small organizations. We note that not all private practices are small in nature, and we do not agree that it would be more accurate to obtain prices only from small practices as opposed to the broader data collection undertaken by the StrategyGen contractor.

Comment: Some commenters were concerned that the researched GSA price was incorporated into the recommended commercial price. These commenters expressed concern as to how the GSA price fit into the calculation of new recommended prices.

Response: We want to clarify how the GSA price was used in developing the new recommended DPEI prices for equipment and supplies. We regret the confusion on this issue, which was due to a technical error in the drafting of the language in the proposed rule. We wish to clarify that the GSA price was *not* used to calculate the StrategyGen recommended prices printed in the proposed rule. Our use of the GSA website to research supply and equipment pricing was found to have a number of limitations. Only suppliers that meet stringent qualifications and that complete a lengthy and detailed application process are eligible to participate in GSA Advantage, GSA's online shopping and ordering system. These requirements sharply curtail the number and type of suppliers whose products may be accessed on the GSA Advantage website. In addition, only products that are purchased by federal agencies or other qualified government entities are listed on the GSA Advantage website, which has the effect of eliminating a number of medical supplies and equipment that are reflected in the CMS DPEI codes. This limitation was especially acute when researching bundled codes for equipment rooms and lanes, and supply packs, kits, and trays. The GSA website does not record comparable bundled purchasing of medical equipment or supplies, so no GSA pricing could be recovered for products included in the bundled codes organized as rooms, lanes, packs, kits or trays. Finally, the prices listed on the GSA Advantage website are required to be the supplier's best offer, which may often be lower than prices that are available to non-governmental purchasers.

For these reasons, the GSA price was not incorporated into the calculation for the StrategyGen recommended prices printed in the proposed rule. The final recommended price for CY 2019 was the commercially researched price, if available. Otherwise the current CY 2018 CMS price remained in place as the CY 2019 CMS price.

Comment: Several commenters were concerned with the methodology used by StrategyGen to conduct market research to determine an updated price for medical equipment and supplies. There were significant concerns with the use of market research to supplement the current AMA/Specialty Society RVS Update Committee (RUC) process. A number of commenters stated that CMS should only use invoices supplied by the specialty society via the RUC process, and should not finalize the updated prices researched by the StrategyGen contractor.

Response: We determined that the most effective way to update the DPEI for CY 2019 was through comprehensive market research. The current RUC process has resulted in updates to many of the equipment and supply codes, but many of the prices in the CY 2018 DPEI are over a decade old, and a significant number date back to research conducted 15 years ago. Therefore, we requested a market research plan from the StrategyGen contractor designed to research current pricing to estimate the typical discounted prices that physicians and other providers normally pay.

The comprehensive market research plan to update DPEI equipment and supplies was designed to supplement the AMA RUC process, not replace it. The current RUC process, while indispensable, does not provide for comprehensive pricing updates. Under the current process, physicians and other providers voluntarily submit invoices for items to RUC for consideration, and after review, the RUC submits these invoices to us. This process results in inherent biases due to the limited number of items represented by submitted invoices and due to the voluntary selection of reported invoices.

The StrategyGen market research plan examined up to five online sources of current prices for each item of equipment or supply researched, including: (1) A proprietary database of buyer reported pricing, (2) Prices offered on GSA (*Note:* This data was subsequently excluded from the recommended 2019 CMS prices), (3) Amazon Business, (4) Cardinal Healthcare, and (5) Vendors' and manufacturers' catalogs. Each of these sources contains nationally reported vendor and buyer pricing data. The research plan also included vendor interviews to clarify the variety of discount programs available to physicians and other providers.

The comprehensive research plan for the 2019 DPEI required researching approximately 2,000 supply and equipment codes. Qualitative and potentially quantitative research to include all the specialty societies impacted by the DPEI updates was beyond the resources and time allocated to this update. The market research plan did include a physician panel with specialists and a general practitioner to review the reasonableness of the researched data. In addition, the regulatory process remains available to all specialty societies to comment on the recommended prices. We encouraged interested stakeholders to continue to provide feedback on supply and equipment pricing, including the submission of invoices, throughout the 4-year pricing transition.

Comment: Several commenters stated that there is an inherent bias to prioritizing the medical equipment and supplies based on spending and code utilization. These commenters stated that any attempt to accurately price items in the supply and equipment list should devote equal effort to each item of equipment or supply and should not devote additional attention to the most utilized codes. These commenters stated that using utilization data as the primary driver for identifying supply and equipment items to review suggests that there may have been specific intent to lower the cost of high utilization items, perhaps to the detriment of pricing accuracy. In addition, there was concern that some underutilized codes were not researched.

Response: To control for potential research bias, the StrategyGen market research team used an identical online methodology to research commercial pricing data for each of the supply and equipment codes, regardless of the code's prioritization. The prioritization of high-utilization supply and equipment codes was not designed to reduce prices for these codes.

The prioritization of supply and equipment codes was designed to facilitate understanding and validation of the researched commercial prices for these items. Surveying other market entities, including vendors, as opposed to buyers, was used to more precisely identify the range of commercial pricing and factors impacting those prices. For example, additional priority research included a physician panel that reviewed the researched commercial prices for reasonableness. The prioritization of research for certain codes did not change the recommended commercial prices.

In addition, limited time and resources required prioritizing the codes based on use. We recognize that a few medical supply and equipment codes do not have updated recommended prices, and we continue to welcome the submission of updated pricing information from stakeholders for these and other codes.

Comment: Many commenters were supportive of the proposal to use a 4-year pricing transition. Commenters agreed with using the transition period as an opportunity for specialty societies and other stakeholders to continue to evaluate the new pricing and submit invoices and other pricing data as needed. Commenters who disagreed with the use of the 4-year pricing transition also requested that CMS not finalize the proposal. One commenter stated that CMS should phase in the new prices for equipment and supplies during a shorter transition period than the proposed 4-year transition, and suggested a 2-year transition instead.

Response: Our proposal was intended to minimize any potential disruptive effects during the proposed transition period, and we continue to believe that implementing the proposed updated prices with a 4-year phase-in will improve payment accuracy, while maintaining stability and allowing stakeholders the opportunity to address potential concerns about changes in payment for particular items. Updating the pricing of direct PE inputs for supplies and equipment over a longer time frame will allow more opportunities for public comment and submission of additional, applicable data.

Comment: Several commenters stated that CMS should consider delaying implementation of this proposal until there could be a more thorough and adequate review of the inputs and give medical societies and/or practices more time to gather invoices in order to determine if the proposed pricing is accurate. Some commenters similarly requested that the 4-year pricing transition should begin in CY 2020 to provide stakeholders with additional time to evaluate the approach used by StrategyGen. A few commenters stated that they would prefer a delay of more than 1 year before implementation began.

Response: We disagree with the commenters that delaying the implementation of the pricing updates for a year or longer would lead to more accurate pricing. We believe that our proposal to update the pricing of direct PE inputs for supplies and equipment over a 4 year-transition already allows many opportunities for public comment and the submission of additional, applicable data. We welcomed feedback from commenters on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration, and many commenters provided detailed feedback regarding the pricing of individual supply and equipment items. We note that we received feedback from commenters on approximately 65 individual supply and equipment codes, which is roughly 3 percent of the total number of items we proposed to update. We also note that commenters did not identify an alternative source for pricing information outside of the sources employed by the StrategyGen contractors, with commenters largely suggesting that we should continue to rely on invoice submissions included along with the review of individual codes via the RUC process.

We continue to believe that a delay in implementation would be unlikely to result in more accurate pricing information. Therefore, we are finalizing the 4-year pricing transition, beginning in CY 2019. We look forward to working with commenters over the 4-year transition for assistance in identifying individual supply and equipment codes that may require additional research into their pricing. As a reminder, to be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th

deadline used for consideration of RUC recommendations. However, we would consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule, and would consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices for the following year.

Comment: Many commenters addressed the proper pricing of some multi-component items, including supply kits, packs, and trays as well as some items of equipment. Several commenters noted some of the proposed prices for supply and equipment items that contain multiple components may not accurately reflect all the components, while other commenters noted that some of the components could be improperly priced. Commenters expressed concerns that some equipment may not possess precise components that are necessary for a specific procedure.

Response: Using the information provided by these commenters, the StrategyGen contractors re-examined the pricing of the multi-component supply and equipment items that had been identified. In some instances, the additional research confirmed some commenters' concerns, as the contractors found that a limited set of these multi-item supply and equipment kits required further clarification of components. For example, an item within a kit, pack, or tray may have had an updated component, resulting in a mispriced item within that kit. To further clarify the prices of these kits, the kits were broken into their most basic components and priced individually. The total price of the kit was determined by adding the specific item prices together. If one of the items within a kit was misidentified, it resulted in an incorrect price of the entire kit.

For example, a review of the recommended price for the ''Antigens, multi'' (SH007) supply code identified the need to add pricing data for additional antigens and to refine the unit of measurement used in calculating the price. For SH007, additional antigens were added and data analyzed for 1 milliliter vials of two allergy antigens. The first antigen is an allergy antigen for pollen and mites and contains antigens for Timothy, Birch, Ragweed, Cocklebur, MarshElde, and the mites Dermatophagoides pteronyssinus and Dermatophagoides farina. The second antigen is an allergy antigen for mold and cats and contains antigens for Alternaria, Helminth, Hormoden, Penicillium, and Fel d1. To determine the price of the allergy antigen, the StrategyGen contractor researched each component of the antigen separately and averaged the price of the separate vials as the recommended price to arrive at an updated recommended price of $8.96.

In instances related to equipment, an item may have been improperly priced because a specific component was omitted but the items priced could perform the requisite task. An example of this occurred in the pricing of the ''SRS System, SBRT'' (ER083) equipment item where the equipment priced would retrofit a system to perform SBRT procedures, but pricing did not include the linear accelerator. When re-examining this specific medical equipment, we ensured it was a linear accelerator with SBRT capabilities and arrived at an updated recommended price of $2,973,721.83.

We reexamined the recommended price of each multi-component item cited by a commenter. Table 9 at the conclusion of this section lists the supply and equipment codes with price changes based on feedback from the commenters and the resulting additional research into pricing.

Comment: Several commenters questioned the prices of certain supply codes based on their conclusion that the quantity of the items priced was inaccurate. Depending on the type of supply, a number of different units of measurement are used to set prices for DPEI supply codes. Commenters stated that StrategyGen had used the incorrect unit of measurement in their recommended prices, and identified specific supply codes where they believed these errors had taken place.

Response: In each instance in which a commenter questioned the accuracy of a DPEI code's recommended price based on a concern about the unit quantity of the item priced, the StrategyGen contractor conducted further research of the item and its price with special attention to ensuring that the recommended price was based on the clarified unit of measure. The price assigned to a given code may be for a single item, a kit, a tray, or it may be based on a per test or per ml basis. For example, the price for the SG055 supply is for a single sterile 4in x 4in gauze sponge; whereas the price for SG056 is for a tray/pack of 10 sterile 4in x 4in gauze sponges. In other situations, such as the ''Embedding Mold'' (SL060) supply, the price for a package of multiple molds was reported instead of the price of a single embedding mold. After consideration of comments received and additional price research, we have updated the recommended prices for a number of relevant supply codes identified by the commenters. Table 9 at the conclusion of this section lists the supply and equipment codes with price changes based on feedback from the commenters and the resulting additional research into pricing.

Comment: Several commenters addressed the subject of the proper pricing for certain items of medical supply and equipment. These commenters requested these specific CMS codes be reviewed again to ensure the correct items were being researched and priced accordingly.

Response: Based on the commenters' requests, the StrategyGen contractor conducted an extensive examination of the pricing of any supply or equipment items that any commenter identified as requiring additional review. Invoices submitted by multiple commenters were greatly appreciated and ensured that medical equipment and supplies were re-examined and clarified. Multiple researchers reviewed these specified supply and equipment codes for accuracy and proper pricing. In most cases, the contractor also reached out to a team of nurses and their physician panel to further validate the accuracy of the data and pricing information. In some cases, the pricing for individual items needed further clarification due to a lack of information or due to significant variation in packaged items. An example of such clarification occurred with the ''Covered Stent (Viabahn, Gore)'' (SD254) supply, which encompasses a wide range of stents, with varying sizes and other qualities. In other cases, such as the ''Patient Worn Telemetry System'' (EQ340) equipment, an inpatient unit was originally priced as opposed to an outpatient unit. After an extensive review and validation process, we updated our recommended prices for a number of supply and equipment codes. Table 9 at the conclusion of this section lists the supply and equipment codes with price changes based on feedback from the commenters and the resulting additional research into pricing.

Comment: Several commenters expressed concerns with the proposed prices for individual supply and equipment codes, and recommended that the price of these codes remain unchanged until additional research can be conducted.

Response: The StrategyGen contractor investigated the accuracy of components or features included in an item by researching the identity of the item based on the description contained in the item's supply or equipment code, as well as the identity of any item's prices

in submitted invoices. Additional research into approximately half a dozen supply/equipment codes failed to produce reliable product data sufficient to calculate a recommended price. To price these equipment and supply items accurately, we believe additional information is required. Therefore, we will continue to use the current CMS price for these supply and equipment items pending additional research and analysis. We welcome the submission of updated pricing information regarding these supply and equipment items through submission of valid invoices from commenters and other stakeholders. These supply and equipment codes are also listed in Table 9 at the conclusion of this section.

Comment: A few commenters stated that CMS should ensure that the direct practice expenses for HCPCS codes G6001–G6015 are applied consistent with the directives of the Patient Access and Medicare Protection Act (PAMPA) (Pub. L. 114–115) and the Bipartisan Budget Act (BBA) of 2018 (Pub. L. 115–123). Commenters stated that Congress established via statute that the direct PE inputs for these radiation treatment delivery services furnished in CY 2017, CY 2018, and CY 2019 shall be the same as such inputs as established for these services in CY 2016. These commenters stated that the proposed changes to the PE RVUs for HCPCS codes G6001–G6015 were directly opposed to current law, and that CMS should revisit its analysis to ensure that the direct PE inputs are consistent with those used in 2016 as required by Congress.

Response: We disagree with the commenters that the proposed direct PE inputs for HCPCS codes G6001–G6015 were not applied consistent with the directives established in the PAMPA and the BBA. The statute at section 1848(b)(11) of the Act (as added by the PAMPA and amended) specifies that the code definitions, work RVUs, and direct inputs for the practice expense RVUs for these services shall be the same as such definitions, units, and inputs for such services for the fee schedule established for services furnished in CY 2016. We did not propose to change the code definitions, work relative value units, or direct practice expense inputs from those established for CY 2016. We proposed to update the pricing of those same supply and equipment inputs as part of the market-based study of commercial pricing undertaken by the contractor, which was not a subject addressed by the statutory provisions concerning HCPCS codes G6001–G6015. We did not propose changes to the direct practice expense inputs for these services. We simply proposed to update pricing for these inputs; and to adopt the same prices for these supplies and equipment across the PFS for all codes that include them. We note that we estimate that the overall effect of incorporating the new prices in calculating the payment rates for these services results in higher overall RVUs for these services, on the whole, than the potential alternative of relying exclusively on pricing from prior years.

After consideration of the public comments, we are finalizing our proposals associated with the market research study to update the PFS direct PE inputs for supply and equipment pricing. We continue to believe that implementing the proposed updated prices with a 4-year phase-in will improve payment accuracy, while maintaining stability and allowing stakeholders the opportunity to address potential concerns about changes in payment for particular items. We continue to welcome feedback from stakeholders on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration. However, while we are adopting most of the prices for supplies and equipment as recommended by StrategyGen and included in the proposed rule, in response to the initial feedback provided by the commenters, we are finalizing changes to the proposed pricing of approximately 60 supply and equipment codes as detailed in Table 9:

TABLE 9—SUPPLY AND EQUIPMENT PRICES UPDATED IN RESPONSE TO COMMENTS

Supply/ equipment code	Description	CY 2018 price	Proposed CY 2019 price	Final CY 2019 price
ED033	treatment planning system, IMRT (Corvus w-Peregrine 3D Monte Carlo)	$350,545.000	$157,392.835	$197,247.000
EF031	table, power	6,153.630	5,438.120	5,906.760
EL015	room, ultrasound, general	369,945.000	130,252.571	369,945.000
EL016	Room—Ultrasound, vascular/Original submission	466,492.000	199,449.308	466,492.000
EP014	flow cytometer	119,850.000	147,210.980	192,000.000
EP088	ThermoBrite	6,120.000	3,467.000	4,795.000
EP116	VP–2000 Processor	30,800.000	81,775.462	37,993.000
EQ031	INR monitor, home	2,000.000	6,014.819	635.000
EQ125	glucose continuous monitoring system	1,170.540	835.527	850.000
EQ288	ultrasonic cleaning unit	895.000	76,725.556	895.000
EQ312	INR analysis and reporting system w-software	21,085.000	6,014.819	19,325.000
EQ340	Patient Worn Telemetry System	23,537.000	18,565.719	23,494.000
EQ343	Radioaerosol Administration System	2,560.250	30.000	623.000
ER003	HDR Afterload System, Nucletron—Oldelft	375,000.000	111,425.876	132,574.780
ER083	SRS system, SBRT, six systems, average	4,000,000.000	931,965.479	2,973,721.836
ES052	brachytherapy treatment vault	175,000.000	134,998.000	193,114.250
SA026	kit, radiofrequency introducer	50.000	658.700	24.160
SA074	kit, endovascular laser treatment	519.000	313.460	323.330
SA081	pack, drapes, ortho, small	1.128	1.000	2.250
SA099	Kit, probe, cryoablation, prostate (Galil-Endocare)	4,700.000	1,539.560	1,539.560
SA100	kit, probe, radiofrequency, Xli-enhanced RF probe	2,695.000	753.420	1,966.670
SA105	UroVysion test kit	176.800	132.130	129.280
SA106	Balloon Sinus Surgery Kit	2,599.860	2,876.220	2,374.330
SA117	Universal Detection Kit	4.000	6.510	4.000
SA122	Claravein Kit	890.000	575.000	883.330
SB019	drape-towel, sterile 18in x 26in	0.282	0.920	0.470
SB026	gown, patient	0.533	3.540	0.590
SD109	probe, radiofrequency, 3 array (StarBurstSDE)	2,233.000	871.660	2,289.000
SD114	sensor, glucose monitoring (interstitial)	53.080	43.950	59.310

TABLE 9—SUPPLY AND EQUIPMENT PRICES UPDATED IN RESPONSE TO COMMENTS—Continued

Supply/ equipment code	Description	CY 2018 price	Proposed CY 2019 price	Final CY 2019 price
SD134	tubing, suction, non-latex (6ft) with Yankauer tip (1)	2.961	0.290	2.670
SD155	catheter, RF endovenous occlusion	725.000	1,010.550	550.000
SD250	introducer sheath, Ansel [45 cm 6 Fr Ansel]	90.000	64.450	72.640
SD251	Sheath Shuttle (Cook)	0.000	0.000	109.690
SD253	atherectomy device (Spectronetics laser or Fox Hollow)	4,979.670	2,293.100	3,048.330
SD254	covered stent (VIABAHN, Gore)	3,768.000	2,573.000	3,129.000
SD255	Reentry device (Frontier, Outback, Pioneer)	0.000	0.000	2,343.120
SD304	IVUS catheter	1,025.000	727.750	858.330
SF040	suture, vicryl, 3–0 to 6–0, p, ps	7.852	4.310	8.520
SG055	gauze, sterile 4in x 4in	0.159	0.030	0.190
SG056	gauze, sterile 4in x 4in (10 pack uou)	0.798	0.030	1.200
SH007	antigen, multi (pollen, mite, mold, cat)	6.700	4.780	8.960
SH009	antigen, venom	20.140	27.360	30.930
SH010	antigen, venom, tri-vespid	44.050	51.320	60.240
SH033	fluorescein inj (5ml uou)	5.442	10.310	24.390
SJ055	test strip, INR	5.660	3.750	4.710
SL012	antibody IgA FITC	41.180	274.090	30.025
SL060	embedding mold	0.149	5.140	0.123
SL182	mounting media (DAPI II counterstain)	67.000	14.420	54.000
SL184	slide, negative control, Her-2	29.400	21.240	29.400
SL185	slide, positive control, Her-2	29.400	25.000	26.200
SL191	ethanol, 85%	0.003	0.170	0.021
SL195	kit, FISH paraffin pretreatment	20.850	23.290	20.850
SL196	kit, HER-2/neu DNA Probe	105.000	80.450	79.050
SL258	Control slides	228.000	279.000	203.730
SL261	FISH pre-treatment kit	549.000	454.480	579.210
SL474	Confirm anti-CD15 Mouse Monoclonal Antibody (Ventana 760–2504)	3.610	3.880	3.820
SL483	Hematoxylin II (Ventana 790–2208)	0.023	0.023	0.780
SL484	Bluing reagent (Ventana 760–2037)	4.522	0.290	0.450
SL488	UltraView Universal DAB Detection Kit	10.485	15.390	9.700
SL493	Antibody Estrogen Receptor monoclonal	14.470	322.400	16.117
SL497	(EBER) DNA Probe Cocktail	8.570	420.060	8.189
SL498	Kappa Probe Cocktail	0.095	0.070	0.910

The updated supply and equipment pricing as it will be implemented over the 4-year transition period will be made available as a public use file displayed on the CMS website under downloads for the CY 2019 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

To maintain relativity between the clinical labor, supplies, and equipment portions of the PE methodology, we believe that the rates for the clinical labor staff should also be updated along with the updated pricing for supplies and equipment. We solicited public comment regarding whether to update the clinical labor wages used in developing PE RVUs in future calendar years during the 4-year pricing transition for supplies and equipment, or whether it would be more appropriate to update the clinical labor wages at a later date following the conclusion of the transition for supplies and equipment, for example, to avoid other potentially large shifts in PE RVUs during the 4-year pricing transition period.

The following is a summary of the public comments we received on our comment solicitation regarding whether to update of the rates for the clinical labor staff types during the 4-year pricing transition for supplies and equipment.

Comment: Most commenters were supportive of the idea of updating the clinical labor wages during the 4-year pricing transition for supplies and equipment. Several commenters requested that the updated pricing for clinical labor should continue to be based on Bureau of Labor Statistics wage data and remain open for public comment from interested commenters through the rulemaking process. One commenter supported updating the prices for the clinical labor staff types and stated that they had convened an expert physician panel that suggested that the clinical labor costs for radiation therapists and nurses are up to 33 percent higher than what is currently included in the CMS database. A few commenters did not support updating clinical labor wages during the 4-year pricing transition for supplies and equipment, in one case stating that the clinical labor pricing should be updated after the pricing transition for supplies and equipment was complete, and in another case stating that CMS should not make any changes to clinical labor costs for the foreseeable future.

Response: We will take this information into account for future rulemaking on the subject of whether or not to update the clinical labor wages used in future calendar years alongside the 4-year pricing transition for supplies and equipment.

(2) Breast Biopsy Software (EQ370)

Following the publication of the CY 2018 PFS final rule, a stakeholder contacted us and requested that we update the price for the Breast Biopsy software (EQ370) equipment. This equipment item currently lacks a price in the direct PE database, and when an invoice for the Breast Biopsy software was first submitted during CY 2014 PFS rulemaking, we stated that this item served clinical functions similar to other items already included in the Magnetic Resonance (MR) room equipment package (EL008) included in the same CPT codes under review. Therefore, we did not create new direct PE inputs for this equipment item (78 FR 74344

through 74345). The stakeholder suggested that this software is used to subtract the imaging raw data series from the MRI Scanner, reformat the images in multiple planes to allow accurate targeting of the lesion to be biopsied, identify the location of a fiducial marker on the patient's skin, and then target the location of the enhancing lesion to be biopsied. The stakeholder requested that EQ370 be renamed as ''Breast MRI computer aided detection and biopsy guidance software'' and added to existing CPT codes 19085 (Biopsy, breast, with placement of breast localization device(s) (*e.g.,* clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including magnetic resonance guidance), 19086 (Biopsy, breast, with placement of breast localization device(s) (*e.g.,* clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including magnetic resonance guidance), 19287 (Placement of breast localization device(s) (*e.g.,* clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including magnetic resonance guidance), and 19288 (Placement of breast localization device(s) (*e.g.,* clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including magnetic resonance guidance), as well as adding the equipment to two newly created MR breast codes with CAD, CPT codes 77048 (Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD-real time lesion detection, characterization and pharmacokinetic analysis) when performed; unilateral) and 77049 (Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD-real time lesion detection, characterization and pharmacokinetic analysis) when performed; bilateral). The stakeholder supplied an invoice with a purchase price of $52,275 for the equipment.

After reviewing the use of the Breast Biopsy software (EQ370) equipment in these six codes, we did not propose to update the price or add the software to these procedures. As we stated in the CY 2014 PFS final rule with comment period (78 FR 74345), we continue to believe that equipment item EQ370 serves clinical functions similar to other items already included in the MR room equipment package (EL008), and that it would be duplicative to include this Breast Biopsy software as a separate direct PE input. We also note that the RUC recommendations for the new CPT codes 77048 and 77049 do not include EQ370 in the recommended equipment for these procedures, and we do not have any reason to believe that the inclusion of additional Breast Biopsy software beyond what is already contained in the MR room equipment package would be typical. However, we will update the name of the EQ370 equipment item from ''Breast Biopsy software'' to the requested ''Breast MRI computer aided detection and biopsy guidance software'' to help better describe the equipment in question.

The following is a summary of the public comments we received on our proposal not to update the price of the Breast Biopsy software or add the software to the listed procedures.

Comment: Several commenters stated that CAD or biopsy software is not part of any standard MRI room package available for purchase, and that these are different equipment items sold by different vendors. One commenter requested that CMS clarify the equipment items that make up the MR room (EL008) in order to verify whether or not legitimate duplication exists with the Breast Biopsy software. Another commenter stated that the new CAD Software equipment (ED058) in CPT codes 77048 and 77049 is actually synonymous with the ''breast biopsy software'' (EQ370). This commenter stated that there had been a lack of consistency in identifying the equipment item between the breast biopsy codes and the MR breast codes, and requested updating the price of the equipment item consistent with the submitted invoices.

Response: In response to the comment requesting that CMS clarify the equipment items that make up the MR room (EL008), we can state that the MR room contains a 1.5T MR Scanner as well as coils, NV array, torso array, shoulder, wrist, extremity, dual array, power injector, and a computer workstation.

After consideration of the public comments, we are finalizing our proposal not to update the price of the Breast Biopsy software (EQ370). However, we note that in light of the information supplied by the commenter that the new CAD Software equipment (ED058) is actually synonymous with the Breast Biopsy software (EQ370), we had already proposed to include this equipment in CPT codes 77048 and 77049. We are finalizing the inclusion of the new CAD Software equipment (ED058) in these procedures, and we are finalizing an update in the price of the CAD Software to $43,308.12. This is based on a submitted invoice from the commenters which contained a price of $52,725 as averaged together with additional invoices for the same CAD Software equipment researched by the StrategyGen contractor. We are also finalizing the replacement of the time assigned to the EQ370 Breast Biopsy software in CPT codes 19085, 19086, 19287, and 19288 with an equal amount of time assigned to the new ED058 CAD Software equipment. Finally, due to the continued confusion and lack of price for the EQ370 equipment item, and due to its redundancy with the new ED058 equipment code, we are deleting EQ370.

(3) Invoice Submission

We routinely accept public submission of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often these invoices are submitted in conjunction with the RUC-recommended values for the codes. For CY 2019, we noted that some stakeholders have submitted invoices for new, revised, or potentially misvalued codes after the February 10th deadline established for code valuation recommendations. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we would consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule, and would consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices.

(4) Adjustment to Allocation of Indirect PE for Some Office-Based Services

In the CY 2018 PFS final rule (82 FR 52999 through 53000), we established criteria for identifying the services most affected by the indirect PE allocation anomaly that does not allow for a site of service differential that accurately reflects the relative indirect costs involved in furnishing services in nonfacility settings. We also finalized a modification in the PE methodology for allocating indirect PE RVUs to better reflect the relative indirect PE resources involved in furnishing these services. The methodology, as described, is based on the difference between the ratio of indirect PE to work RVUs for each of the codes meeting eligibility criteria and the ratio of indirect PE to work RVU for the most commonly reported visit code. We refer readers to the CY 2018 PFS final

rule (82 FR 52999 through 53000) for a discussion of our process for selecting services subject to the revised methodology, as well as a description of the methodology, which we began implementing for CY 2018 as the first year of a 4-year transition. For CY 2019, we proposed to continue with the second year of the transition of this adjustment to the standard process for allocating indirect PE.

We received no comments specific to our proposal to continue with the 2nd year of the transition to the standard process for allocating indirect PE. Therefore, we are finalizing our proposal to proceed with the second year of implementing an alternative methodology for the allocation of indirect PE for some office-based services.

C. Determination of Malpractice Relative Value Units (RVUs)

1. Overview

Section 1848(c) of the Act requires that the payment amount for each service paid under the PFS be composed of three components: Work; PE; and malpractice (MP) expense. As required by section 1848(c)(2)(C)(iii) of the Act, beginning in CY 2000, MP RVUs are resource-based. Section 1848(c)(2)(B)(i) of the Act also requires that we review, and if necessary adjust, RVUs no less often than every 5 years. In the CY 2015 PFS final rule with comment period, we implemented the third review and update of MP RVUs. For a comprehensive discussion of the third review and update of MP RVUs see the CY 2015 PFS proposed rule (79 FR 40349 through 40355) and final rule with comment period (79 FR 67591 through 67596).

To determine MP RVUs for individual PFS services, our MP methodology is composed of three factors: (1) Specialty-level risk factors derived from data on specialty-specific MP premiums paid by practitioners; (2) service level risk factors derived from Medicare claims data of the weighted average risk factors of the specialties that furnish each service; and (3) an intensity/complexity of service adjustment to the service level risk factor based on either the higher of the work RVU or clinical labor RVU. Prior to CY 2016, MP RVUs were only updated once every 5 years, except in the case of new and revised codes.

In the CY 2016 PFS final rule with comment period (80 FR 70906 through 70910), we finalized a policy to begin conducting annual MP RVU updates to reflect changes in the mix of practitioners providing services (using Medicare claims data), and to adjust MP RVUs for risk, intensity and complexity (using the work RVU or clinical labor RVU). We also finalized a policy to modify the specialty mix assignment methodology (for both MP and PE RVU calculations) to use an average of the 3 most recent years of data instead of a single year of data. Under this approach, for new and revised codes, we generally assign a specialty risk factor to individual codes based on the same utilization assumptions we make regarding the specialty mix we use for calculating PE RVUs and for PFS budget neutrality. We continue to use the work RVU or clinical labor RVU to adjust the MP RVU for each code for intensity and complexity. In finalizing this policy, we stated that the specialty-specific risk factors would continue to be updated through notice and comment rulemaking every 5 years using updated premium data, but would remain unchanged between the 5-year reviews.

In CY 2017, we finalized the 8th GPCI update, which reflected updated MP premium data. We did not propose to use the updated MP premium data to propose updates for CY 2017 to the specialty risk factors used in the calculation of MP RVUs because it was inconsistent with the policy we previously finalized in the CY 2016 PFS final rule with comment period. That is, we indicated that the specialty-specific risk factors would continue to be updated through notice and comment rulemaking every 5 years using updated premium data, but would remain unchanged between the 5-year reviews. However, we solicited comment on whether we should consider doing so, perhaps as early as for CY 2018, prior to the fourth review and update of MP RVUs that must occur no later than CY 2020. After consideration of the comments received, we stated in the CY 2017 PFS final rule that we would consider the possibility of using the updated MP data to update the specialty risk factors used in the calculation of the MP RVUs prior to the next 5-year update in future rulemaking (81 FR 80191 through 80192).

In the CY 2018 PFS proposed rule, we proposed to use the updated MP data to update the specialty risk factors used in calculation of the MP RVUs prior to the next 5-year update (CY 2020). However, in the CY 2018 PFS final rule (82 FR 53000 through 53006), after consideration of the comments received and some differences we observed in the descriptions on the raw rate filings as compared to how those data were categorized to conform with the CMS specialties, we did not finalize our proposal to use the updated MP data. We are required to review, and if necessary, adjust the MP RVUs by CY 2020. We appreciate the feedback provided by commenters in response to the CY 2018 PFS proposed rule.

In the CY 2019 PFS proposed rule, we solicited additional comment regarding the next MP RVU update which must occur by CY 2020. Specifically, we solicited comment on how we might improve the way that specialties in the state-level raw rate filings data are crosswalked for categorization into CMS specialty codes, which are used to develop the specialty-level risk factors and the MP RVUs.

We received a few comments in response to the comment solicitation, and we appreciate the commenters' feedback and input. We will consider the suggestions and information received for future rulemaking, and in particular for the CY 2020 statutorily required update to MP RVUs.

D. Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services

The health care community uses the term ''telehealth'' broadly to refer to medical services furnished via communication technology. Under current PFS payment rules, Medicare routinely pays for many of these kinds of services. This includes some kinds of remote patient monitoring (either as separate services or as parts of bundled services), interpretations of diagnostic tests when furnished remotely and, under conditions specified in section 1834(m) of the Act, services that would otherwise be furnished in person but are instead furnished via real-time, interactive communication technology. Over the past several years, we have also established several PFS policies to explicitly pay for non-face-to-face services included as part of ongoing care management.

Although all of the kinds of services stated above might be called ''telehealth'' by patients, other payers and health care providers, we have generally used the term ''Medicare telehealth services'' to refer to the subset of services defined in section 1834(m) of the Act. Section 1834(m) of the Act defines Medicare telehealth services and specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunication technology. Section 1834(m)(4)(F)(i) of the Act enumerates certain Medicare telehealth services and section 1834(m)(4)(F)(ii) of the Act allows the Secretary to specify

additional Medicare telehealth services using an annual process to add or delete services from the Medicare telehealth list. Section 1834(m)(4)(C) of the Act limits the scope of Medicare telehealth services for which payment may be made to those furnished to a beneficiary who is located in certain types of originating sites in certain, mostly rural, areas. Section 1834(m)(1) of the Act permits only physicians and certain other types of practitioners to furnish and be paid for Medicare telehealth services. Although section 1834(m)(4)(F)(ii) of the Act grants the Secretary the authority to add services to, and delete services from, the list of telehealth services based on the established annual process, it does not provide any authority to change the limitations relating to geography, patient setting, or type of furnishing practitioner because these requirements are specified in statute. However, we note that sections 50302, 50324, and 50325 of the Bipartisan Budget Act of 2018 (BBA 18) (Pub. L. 115–123) have modified or removed the limitations relating to geography and patient setting for certain telehealth services, including for certain home dialysis end-stage renal disease-related services, services furnished by practitioners in certain Accountable Care Organizations, and acute stroke-related services, respectively.

In the CY 2018 PFS proposed rule (82 FR 53012), we solicited information from the public regarding ways that we might further expand access to telehealth services within the current statutory authority and pay appropriately for services that take full advantage of communication technologies. Commenters were very supportive of CMS expanding access to these kinds of services. Many commenters noted that Medicare payment for telehealth services is restricted by statute, but encouraged CMS to recognize and support technological developments in healthcare.

We believe that the provisions in section 1834(m) of the Act apply particularly to the kinds of professional services explicitly enumerated in the statutory provisions, like professional consultations, office visits, and office psychiatry services. Generally, the services we have added to the telehealth list are similar to these kinds of services. As has long been the case, certain other kinds of services that are furnished remotely using communications technology are not considered ''Medicare telehealth services'' and are not subject to the restrictions articulated in section 1834(m) of the Act. This is true for services that were routinely paid separately prior to the enactment of the provisions in section 1834(m) of the Act and do not usually include patient interaction (such as remote interpretation of diagnostic imaging tests), and for services that were not discretely defined or separately paid for at the time of enactment and that do include patient interaction (such as chronic care management services).

As we considered the concerns expressed by commenters about the statutory restrictions on Medicare telehealth services, we recognized that the concerns were not limited to the barriers to payment for remotely furnished services like those described by the office visit codes. The commenters also expressed concerns pertaining to the limitations on appropriate payment for evolving physicians' services that are inherently furnished via communication technology, especially as technology and its uses have evolved in the decades since the Medicare telehealth services statutory provision was enacted.

In recent years, we have sought to recognize significant changes in health care practice, especially innovations in the active management and ongoing care of chronically ill patients, and have relied on the medical community to identify and define discrete physicians' services through the CPT Editorial Panel (82 FR 53163). In response to our comment solicitation on Medicare telehealth services in the CY 2018 PFS proposed rule (82 FR 53012), commenters provided many suggestions for how CMS could expand access to telehealth services within the current statutory authority and pay appropriately for services that take full advantage of communication technologies, such as waiving portions of the statutory restrictions using demonstration authority. After considering those comments we recognized that concerns regarding the provisions in section 1834(m) of the Act may have been limiting the degree to which the medical community developed coding for new kinds of services that inherently utilize communication technology. We have come to believe that section 1834(m) of the Act does not apply to all kinds of physicians' services whereby a medical professional interacts with a patient via remote communication technology. Instead, we believe that section 1834(m) of the Act applies to a discrete set of physicians' services that ordinarily involve, and are defined, coded, and paid for as if they were furnished during an in-person encounter between a patient and a health care professional.

For CY 2019, we aimed to increase access for Medicare beneficiaries to physicians' services that are routinely furnished via communication technology by clearly recognizing a discrete set of services that are defined by and inherently involve the use of communication technology. Accordingly, we made several proposals for modernizing Medicare physician payment for communication technology-based services, described below. These services will not be subject to the limitations on Medicare telehealth services in section 1834(m) of the Act because, as we have explained, we do not consider them to be Medicare telehealth services; instead, they will be paid under the PFS like other physicians' services. Additionally, we note that in furnishing these services, practitioners need to comply with any applicable privacy and security laws, including the HIPAA Privacy Rule.

1. Brief Communication Technology-Based Service, *e.g.* Virtual Check-In (HCPCS Code G2012)

The traditional office visit codes describe a broad range of physicians' services. Historically, we have considered any routine non-face-to-face communication that takes place before or after an in-person visit to be bundled into the payment for the visit itself. In recent years, we have recognized payment disparities that arise when the amount of non-face-to-face work for certain kinds of patients is disproportionately higher than for others, and created coding and separate payment to recognize care management services such as chronic care management and behavioral health integration services (81 FR 80226). We now recognize that advances in communication technology have changed patients' and practitioners' expectations regarding the quantity and quality of information that can be conveyed via communication technology. From the ubiquity of synchronous, audio/video applications to the increased use of patient-facing health portals, a broader range of services can be furnished by health care professionals via communication technology as compared to 20 years ago.

Among these services are the kinds of brief check-in services furnished using communication technology that are used to evaluate whether or not an office visit or other service is warranted. When these kinds of check-in services are furnished prior to an office visit, then we would currently consider them to be bundled into the payment for the resulting visit, such as through an evaluation and management (E/M) visit

code. However, in cases where the check-in service does not lead to an office visit, then there is no office visit with which the check-in service can be bundled. To the extent that these kinds of check-ins become more effective at addressing patient concerns and needs using evolving technology, we believe that the overall payment implications of considering the services to be broadly bundled becomes more problematic. This is especially true in a resource-based relative value payment system. Effectively, the better practitioners are in leveraging technology to furnish effective check-ins that mitigate the need for potentially unnecessary office visits, the fewer billable services they furnish. Given the evolving technological landscape, we believe this creates incentives that are inconsistent with current trends in medical practice and potentially undermines payment accuracy.

Therefore, we proposed to pay separately, beginning January 1, 2019, for a newly defined type of physicians' service furnished using communication technology. We stated this service would be billable when a physician or other qualified health care professional has a brief non-face-to-face check-in with a patient via communication technology, to assess whether the patient's condition necessitates an office visit. We understand that the kind of communication technology used to furnish these kinds of services has broadened over time and has enhanced the capacity for medical professionals to care for patients. We solicited comment on what types of communication technology are utilized by physicians or other qualified health care professionals in furnishing these services, including whether audio-only telephone interactions are sufficient compared to interactions that are enhanced with video or other kinds of data transmission.

The following discussion summarizes particular definitions and billing rules for these services, as proposed, and more detailed comments we received regarding these aspects of the proposal. Our responses below include information regarding the service definitions and billing requirements applicable for CY 2019.

Comment: Many commenters supported the proposal to pay for these kinds of services. Many commenters offered specific suggestions regarding the service definitions and associated billing rules, which we describe in detail below. Several commenters urged CMS to take a cautious approach in paying for these services, given concerns these commenters stated regarding potential overutilization, while some noted that potential overutilization would be mitigated by Medicare's requirements for the visit to be reasonable and medically necessary/appropriate. Specific aspects of these comments are detailed below.

Response: Based on the broad support for the proposal, we are creating coding and finalizing our proposal to make separate payment for this service. We note that in the proposed rule we referred to this service as HCPCS code GVCI1, which was a placeholder code. The code will be described as HCPCS code G2012 (Brief communication technology-based service, *e.g.* virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion).

We appreciate commenters' concerns regarding the potential for overutilization of these services. We plan to monitor utilization with the intention of determining whether changes, such as a frequency limitation on the use of this code, are warranted. We would consider proposing such changes in future rulemaking. We note that, like all other physicians' services billed under the PFS, each of these services must be medically reasonable and necessary to be paid by Medicare.

Comment: Many commenters suggested that we not be overly prescriptive regarding the types of communication technology that are utilized by physicians or other qualified health care professionals in furnishing these services. The commenters noted that technology is evolving at a rapid pace and would require us to have to update our policies frequently. Several commenters suggested that we permit the use of email and Electronic Health Record (EHR) patient portals to qualify. A few commenters stated that audio-visual communication is ideal. Others acknowledged that not all patients have the same level of connectivity and therefore recommended allowing audio-only communication.

Response: We are persuaded by the comments advising us not to be overly prescriptive about the technology that is used, and are finalizing allowing audio-only real-time telephone interactions in addition to synchronous, two-way audio interactions that are enhanced with video or other kinds of data transmission. We note that telephone calls that involve only clinical staff could not be billed using HCPCS code G2012 since the code explicitly describes (and requires) direct interaction between the patient and the billing practitioner.

We further proposed that in instances when the brief communication technology-based service originates from a related E/M service provided within the previous 7 days by the same physician or other qualified health care professional, that this service would be considered bundled into that previous E/M service and would not be separately billable, which is consistent with code descriptor language for CPT code 99441 (Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion), on which this service is partially modeled. We proposed that in instances when the brief communication technology-based service leads to an E/M service with the same physician or other qualified health care professional, this service would be considered bundled into the pre- or post-visit time of the associated E/M service, and therefore, would not be separately billable. We also noted that this service could be used as part of a treatment regimen for opioid use disorders and other substance use disorders to assess whether the patient's condition requires an office visit.

We proposed pricing this distinct service at a rate lower than current E/M in-person visits to reflect the low work time and intensity and to account for the resource costs and efficiencies associated with the use of communication technology. We expect that these services will be initiated by the patient, especially since many beneficiaries would be financially liable for sharing in the cost of these services. For the same reason, we believe it is important for patients to consent to receiving these services. Therefore, we specifically solicited comment on whether we should require, for example, verbal consent that will be noted in the medical record for each service.

Comment: Many commenters stated that it would be burdensome to obtain consent from the patient prior to each occurrence of this service. Some commenters suggested that the patient be informed through the use of a service agreement which could be signed once and kept on file. Several commenters

expressed concern about the cost to beneficiaries, especially since they may have previously received this service without financial liability, and therefore recommended requiring verbal consent that is documented in the medical record.

Response: We understand the potential burden regarding obtaining consent for each occurrence of this service. However, we are persuaded by those commenters who suggest that unexpected cost to beneficiaries would be particularly problematic. We note that under our current policy for several types of care management services, verbal consent is required to be obtained and documented in the medical record. The consent policy was implemented, in part, based on feedback we received from practitioners reporting the care management services, to alleviate burdens of alternative approaches, such as requirements for written consent or completion of particular forms. Consequently, we believe the same requirement could be applied here, without imposition of significant burden. We are finalizing requiring verbal consent that is noted in the medical record for each billed service.

We also proposed that this service can only be furnished for established patients because we believe that the practitioner needs to have an existing relationship with the patient, and therefore, basic knowledge of the patient's medical condition and needs, in order to perform this service.

Comment: Many commenters were supportive of our proposal to limit this service to established patients, while several commenters noted that there would be instances when it would be appropriate to bill this service for new patients. MedPAC noted particular concern regarding potential increases in volume that are not related to ongoing, informed patient care. A few commenters requested that CMS clarify that established patients include those patients who have been seen by a practitioner within the same group practice.

Response: After considering the comments, we are finalizing our proposal to limit this service to established patients, given the concern expressed by commenters regarding the degree to which these services can be furnished without familiarity and experience with individual patients, and in light of MedPAC's concerns regarding increases in utilization that are not related to ongoing, informed patient care. In response to the request for clarification about what constitutes an established patient, we defer to CPT's definition of this term. CPT defines an established patient as one who has received professional services from the physician or qualified health care professional or another physician or qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice, within the past 3 years. We also emphasize that payment for this service would not preclude a physician or other qualified health care professional from having communication via phone or other modalities with any patient, new or existing, for a variety of reasons. We believe that much of the pre- and post-work associated with, and included in the valuation of existing in-person services that are paid under the PFS can include some types of interactions with patients that are not in-person.

We did not propose to apply a frequency limit on the use of this code by the same practitioner with the same patient, but we want to ensure that this code is appropriately utilized for circumstances when a patient needs a brief non-face-to-face check-in to assess whether an office visit is necessary. We solicited comment on whether it would be clinically appropriate to apply a frequency limitation on the use of this code by the same practitioner with the same patient, and on what would be a reasonable frequency limitation.

Comment: Many commenters were opposed to creating a frequency limitation, suggesting we wait and monitor utilization. Others noted that it could be clinically appropriate to utilize this service multiple times in a week. A few commenters stated that this service could be utilized in behavioral health treatment, and cited an example of assessing suicidal risk, in which case they suggested the frequency should not be limited since routine virtual check-ins would be clinically warranted in some cases. Some commenters suggested a frequency limit of three times per week whereas others suggested a limit of once per week.

Response: After considering these comments, we are not implementing a frequency limitation for CY 2019. However, we plan to monitor utilization with the intention of determining whether such a limitation is warranted. In that case, we would consider proposing a limitation in future rulemaking. We note that, like all other physicians' services billed under the PFS, each of these services must be medically reasonable and necessary to be paid by Medicare.

We also solicited comment on the timeframes under which this service would be separately billable compared to when it would be bundled. We believe the general construct of bundling the services that lead directly to a billable visit is important, but we are concerned that establishing strict timeframes may create unintended consequences regarding scheduling of care. For example, we do not want to bundle only the services that occur within 24 hours of a visit only to see a significant number of visits occurring at 25 hours after the initial service. In order to mitigate these incentives, we solicited comment on whether we should consider broadening the window of time and/or circumstances in which this service should be bundled into the subsequent related visit. We noted that these services, like any other physicians' service, must be medically reasonable and necessary in order to be paid by Medicare.

Comment: Several commenters suggested that we remove the language in the code descriptor that states ''or soonest available appointment.'' A few commenters suggested we extend the timeframe to 48 hours following the virtual check-in, while others suggested it would be reasonable to expand the limit to 14 days before and 72 hours after the service. Several commenters stated concerns that it might be difficult to document that a subsequent visit was not the ''soonest available appointment.'' Several commenters expressed concern about the potential for overutilization of this code.

Response: We agree with commenters that urged caution regarding overutilization of this service and believe that the language stating, 'or soonest available appointment' in the code description may serve to reduce potential perverse payment incentives to delay seeing patients to ensure payment for this code. We appreciate the concerns regarding potential difficulty in proving that a particular visit was not the ''soonest available.'' We agree that in each individual case, it might be challenging to prove whether or not other appointments were available prior to the visit, especially since beneficiary convenience is also presumably a factor for when appointments are scheduled. However, we believe that, as written, the code description could help to guard against the potential for abuse that would be present if we instead adopted a purely time-based window for bundling of this service. We also believe that ''soonest available appointment'' might allow for clinically appropriate flexibility. Therefore, after consideration of the public comments, we are finalizing the code descriptor for HCPCS code G2012 as proposed. However, we plan to monitor this service with the intention of determining whether changes are

necessary to the timeframes under which this service would be separately billable compared to when it would be bundled. We would consider any such changes in future rulemaking.

We solicited comment on how clinicians could best document the medical necessity of this service, consistent with documentation requirements necessary to demonstrate the medical necessity of any service under the PFS.

Comment: A few commenters stated that documentation for this service should be consistent with the requirements for an in-person encounter and requested appropriate documentation requirements to ensure that the check-in is fully incorporated into the individual's medical history. Other commenters urged us not to be overly prescriptive.

Response: We appreciate the commenters' input. We do not want to impose undue administrative burden likely to discourage appropriate provision of these services, and are therefore not requiring any service-specific documentation requirements for this service. We note again that these services, like any other physicians' service, must be medically reasonable and necessary in order to be paid by Medicare.

Comment: Several commenters stated that the proposed payment rate would be inadequate for modalities that are both audio- and visual-capable, whereas others stated that the proposed valuation was appropriate. One commenter suggested we create a second code for a virtual check-in that only utilizes synchronous audio/video technology, with a higher reimbursement rate associated with the increased complexity of technology.

Response: As discussed in section II.H of this final rule, we are finalizing the valuation for HCPCS code G2012 as proposed. We believe this valuation reflects the work time and intensity of the service relative to other PFS services and accounts for the resource costs and efficiencies associated with the use of communication technology. We recognize that the valuation of this service is relatively modest, especially compared to in-person services, however, we believe that the proposed valuation accurately reflects the resources involved in furnishing this service. We plan to monitor the utilization of this code and note that we routinely address recommended changes in values for codes paid under the PFS.

Comment: A few commenters requested that CMS allow licensed physical therapists to furnish these services. Additionally, a few commenters requested that we allow other clinical staff, such as registered nurses, to furnish this service.

Response: We are finalizing maintaining this code as part of the set of codes that is only reportable by those that can furnish E/M services. We believe this is appropriate since the service describes a check-in directly with the billing practitioner to assess whether an office visit is needed. We agree that similar check-ins provided by nurses and other clinical staff can be important aspects of coordinated patient care. We note that these kinds of non-face-to-face services by other medical professionals and clinical staff continue to be included in the RVUs for other codes, including those that describe E/M visits, and for procedures with global periods. We also note that non-face-to-face services provided by clinical staff can be explicitly and separately paid for as part of several care management services, many of which we have introduced over the past several years. However, this service is meant to describe, and account for the resources involved, when the billing practitioner directly furnishes the virtual check-in.

Comment: Several commenters requested that CMS waive the beneficiary co-payment for this service.

Response: We appreciate the commenters' request; however, we do not have the statutory authority to make specific changes to the requirements regarding beneficiary cost sharing for this service.

In summary, we are creating coding and finalizing our proposal to make separate payment for brief communication technology-based services. The code will be described as G2012 (Brief communication technology-based service, *e.g.* virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion). We are finalizing allowing real-time audio-only telephone interactions in addition to synchronous, two-way audio interactions that are enhanced with video or other kinds of data transmission. We are finalizing our proposal to limit this service to established patients.

We are finalizing that if the service originates from a related E/M service provided within the previous 7 days by the same physician or other qualified health care professional, that this service would be considered bundled into that previous E/M service and would not be separately billable. In instances when the service leads to an E/M service with the same physician or other qualified health care professional, we are finalizing that this service would be considered bundled into the pre- or post-visit time of the associated E/M service, and therefore, would not be separately billable. We plan to monitor this service with the intention of determining whether changes are necessary to the timeframes under which this service would be separately billable compared to when it would be bundled. We would consider any such changes in future rulemaking.

We are finalizing requiring verbal consent from beneficiaries that is noted in the medical record for each service. We are not implementing a frequency limitation for CY 2019, however, we plan to monitor utilization with the intention of determining whether such a limitation is warranted. In that case, we would consider that for future rulemaking.

We are finalizing the valuation for HCPCS code G2012 as proposed. We will monitor the utilization of this code and consider any potential adjustments to billing rules or valuation for this service through future rulemaking. We note that cost sharing for these services will apply.

For details related to developing utilization estimates for this service, see section VII. of this final rule, Regulatory Impact Analysis. For additional details related to valuation of this service, see section II.H. of this final rule, Valuation of Specific Codes.

2. Remote Evaluation of Pre-Recorded Patient Information (HCPCS Code G2010)

Stakeholders have requested that CMS make separate Medicare payment when a physician uses recorded video and/or images captured by a patient in order to evaluate a patient's condition. These services involve what is referred to under section 1834(m) of the Act as ''store-and-forward'' communication technology that provides for the ''asynchronous transmission of health care information.'' We noted in the proposed rule that we believe these services involve pre-recorded patient-generated still or video images. Other types of patient-generated information, such as information from heart rate monitors or other devices that collect patient health marker data, could potentially be reported with CPT codes that describe remote patient monitoring (83 FR 35724). Under section 1834(m) of

the Act, payment for telehealth services furnished using such store-and-forward technology is permitted only under federal telemedicine demonstration programs conducted in Alaska or Hawaii, and these telehealth services remain subject to the other statutory restrictions governing Medicare telehealth services. However, much like the brief communication technology-based service (''virtual check-in service'') that we are finalizing in this rule as described previously, this remote evaluation service would not be a substitute for an in-person service currently separately payable under the PFS. As such, this remote evaluation service is distinct from the telehealth services described under section 1834(m) of the Act. Effective January 1, 2019, we proposed to create specific coding that describes the remote professional evaluation of patient-transmitted information conducted via pre-recorded ''store and forward'' video or image technology. Because this service would not be considered a Medicare telehealth service, it would not be subject to the geographic and other restrictions on telehealth services under section 1834(m) of the Act; and the proposed valuation reflects the resource costs associated with furnishing services utilizing communication technology.

Also like the virtual check-in service we are finalizing as described previously, this service would be used to determine whether or not an office visit or other service is warranted. When the remote evaluation of pre-recorded patient-submitted images and/or video results in an in-person E/M office visit with the same physician or qualified health care professional, we proposed that this remote service will be considered bundled into that office visit and therefore not be separately billable. We further proposed that in instances when the remote service originates from a related E/M service provided within the previous 7 days by the same physician or qualified health care professional that this service will be considered bundled into that previous E/M service and not be separately billable. In summary, we proposed this service to be a stand-alone service that could be separately billed to the extent that there is no resulting E/M office visit and there is no related E/M office visit within the previous 7 days of the remote service being furnished. We believe the coding and separate payment for this service is consistent with the progression of technology and its impact on the practice of medicine in recent years, and would result in increased access to services for Medicare beneficiaries. We note that in the proposed rule we referred to this service as HCPCS code GRAS1, which was a placeholder code. The code for this service is G2010 (Remote evaluation of recorded video and/or images submitted by an established patient (*e.g.,* store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment). We solicited comment as to whether these services should be limited to established patients; or whether there are certain cases, like dermatological or ophthalmological services, where it might be appropriate for a new patient to receive these services. For example, when a patient seeks care for a specific skin condition from a dermatologist with whom she does not have a prior relationship, and part of the inquiry is an assessment of whether the patient needs an in-person visit, the patient could share, and the dermatologist could remotely evaluate, pre-recorded information. We also noted that this service is distinct from the virtual check-in service described previously in that this service involves the practitioner's evaluation of a patient-generated still or video image transmitted by the patient, and the subsequent communication of the practitioner's response to the patient; while the virtual check-in service describes a service that occurs in real time and does not involve the asynchronous transmission of any recorded image.

The following discussion summarizes particular definitions and billing rules we proposed for this service and the more detailed comments we received regarding these aspects of the proposal. Our responses below include information regarding the service definitions and billing requirements applicable for 2019. We additionally address comments we received regarding whether these services should be limited to established patients; or whether there are certain cases, like dermatological or ophthalmological services, where it might be appropriate for a new patient to receive these services.

Comment: Several commenters were supportive of the proposal to pay for these kinds of services. Several commenters urged CMS to take a cautious approach in paying for these services, given concerns these commenters expressed regarding potential overutilization.

Response: We appreciate the many thoughtful comments regarding this proposal. Based on our review of the comments received, especially the broad support for the proposal, we are creating coding and finalizing our proposal to make separate payment for this service. The code will be described as G2010 (Remote evaluation of recorded video and/or images submitted by an established patient (*e.g.,* store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment).

We appreciate commenters' concerns regarding the potential for overutilization of these services. We plan to monitor utilization. We note that, like all other physicians' services billed under the PFS, each of these services must be medically reasonable and necessary to be paid by Medicare.

Comment: Many commenters supported allowing this service to be furnished to new patients, noting that an established relationship is not required for the practitioner to remotely evaluate an image or video to consider whether an office visit or other service is warranted, particularly in dermatology and ophthalmology. One commenter stated that allowing new patients to receive this service would also be of value in urology, as it would provide a way to assess patients with conditions such as hematuria (that is, blood in the urine) in a timely manner. The AMA and other commenters urged CMS to limit these services to established patients. The AMA also suggested that, at some point before a physician or practitioner furnishes a virtual service, the clinician (or another clinician with whom the furnishing clinician has a cross-coverage agreement in place) should conduct a face-to-face examination (either in-person or via telehealth) with the patient, noting that the existence of a valid patient-physician relationship ensures that the treating physician or qualified health professional meets a threshold standard of care, enhances care coordination/continuity of care, and ensures that patients are afforded advance notice of when the relationship is being established and that such a patient-initiated service may result in out-of-pocket expenses including deductibles and co-insurance, and additionally serves to minimize the potential for program integrity concerns.

Response: We are persuaded by comments urging us to permit separate

payment for these services only for established patients. Since this service is furnished directly by the billing practitioner, we believe it should be furnished in the context of an existing patient-clinician relationship. Therefore, we are finalizing the reporting and billing of HCPCS code G2010 only for established patients.

Comment: Many commenters stated that it would be burdensome to obtain consent from the patient prior to each occurrence of this service. Some commenters suggested that the patient could be informed through the use of a service agreement which could be signed once and kept on file. Several commenters expressed concern about the cost to beneficiaries and therefore recommended requiring verbal consent that is documented in the medical record.

Response: As noted previously regarding HCPCS code G2012, we believe it is important for patients to consent to receive these services, especially since many beneficiaries would be financially liable for sharing in the cost of these services. We understand the potential burden regarding obtaining consent for each occurrence of this service. However, we are persuaded by those commenters who suggest that unexpected cost to beneficiaries would be particularly problematic. We are finalizing requiring beneficiary consent that could be verbal or written, including electronic confirmation that is noted in the medical record for each billed service for HCPCS code G2010.

We acknowledge that verbal consent could be obtained using more than one communication modality, especially since this service is initiated by the patient and involves submission of an image or video. Therefore, we do not intend to include the word ''verbal'' in the descriptor for the code that describes this services, since ''verbal'' could imply written or electronic consent.

Comment: Several commenters stated that the proposed payment rate is too low, citing that it is below market compared to the rate many asynchronous telemedicine companies pay their contracted/employed physician staff, and noted that new patients in particular require more resources, whereas others stated that the proposed valuation was appropriate. One commenter suggested that CMS should encourage clinicians to recommend that patients have virtual or in-person visits if the clinician has concerns about the quality of the pre-recorded patient information, such as still or video images.

Response: As discussed in section II.H. of this final rule, we are finalizing the valuation for HCPCS code G2010 as proposed. As stated previously regarding the valuation of the brief communication technology-based service code, HCPCS code G2012, we believe that the proposed valuation accurately reflects the resources involved in furnishing this service. We will monitor the utilization of this code and consider any potential adjustments to billing rules or valuation for this service through future rulemaking.

Comment: A few commenters requested that CMS clarify that the ''verbal follow-up'' that occurs after the billing practitioner evaluates the images or video submitted by the patient may take place via any mode of communication, including secure text messaging, phone call, or live/asynchronous video chat, so as not to restrict a clinician's interaction with patients. One commenter suggested that CMS should encourage clinicians to recommend that patients have a face-to-face visit (in-person or via telehealth) if the clinician has concerns about the quality of the pre-recorded patient information, such as still or video images.

Response: We are finalizing that the follow-up could take place via phone call, audio/video communication, secure text messaging, email, or patient portal communication and note that accordingly, we do not intend to include the word ''verbal'' in the code descriptor. We note that any such communications must be compliant with HIPAA and other relevant laws. Additionally, we agree that in instances in which the quality of the pre-recorded information submitted by a patient is insufficient for the clinician to assess whether an office visit or other medical service is warranted, the clinician could not fully furnish a remote evaluation service and, therefore, could not bill for the service. We anticipate that in such a circumstance, the clinician would attempt other methods of communication with the patient to either obtain sufficient images to enable a remote evaluation service or suggest other appropriate alternatives.

Comment: Several commenters suggested that we remove the language in the code descriptor for this service that states ''or soonest available appointment,'' and stated that it might be difficult to document that a subsequent visit was not the ''soonest available appointment.''

Response: As noted previously regarding similar comments on HCPCS code G2012, we appreciate the concerns regarding potential difficulty in proving that a particular visit was not the ''soonest available.'' We agree that in each individual case, it might be challenging to prove whether or not other appointments were available prior to the visit, especially since beneficiary convenience is also presumably a factor in when appointments are scheduled. However, we believe that, as written, the code description would guard against the potential for abuse that would be present if we instead adopted a purely time-based window for bundling of this service. Therefore, in response to the comments, we are finalizing retaining this language in the code descriptor for HCPCS code G2010 as proposed. However, we plan to monitor this service with the intention of determining if changes are necessary to the timeframes under which this service would be separately billable compared to when it would be bundled. We would consider any such changes in future rulemaking.

Comment: A few commenters suggested that CMS consider inclusion of email/messaging or questionnaires/assessments that do not include an image or other visual item in the scope of this code.

Response: The scope of this service is limited to the evaluation of pre-recorded video and/or images. We note that there is separate coding under the PFS for several types of formal assessments, such as CPT code 96160 (Administration of patient-focused health risk assessment instrument (*e.g.,* health hazard appraisal) with scoring and documentation, per standardized instrument), many of which can be reported when the form is completed by the patient and submitted using remote communication technology for subsequent evaluation by the clinician. Additionally, behavioral health assessments are included in coding and payment for the behavioral health integration services that were finalized for separate payment beginning in CY 2017.

In summary, we are creating coding and finalizing our proposal to make separate payment for remote evaluation of recorded video and/or images submitted by the patient. The code will be described as G2010 (Remote evaluation of recorded video and/or images submitted by an established patient (*e.g.,* store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment). We are finalizing that

HCPCS code G2010 may be billed only for established patients. We are finalizing that the follow-up with the patient could take place via phone call, audio/video communication, secure text messaging, email, or patient portal communication.

When the review of the patient-submitted image and/or video results in an in-person E/M office visit with the same physician or qualified health care professional, we are finalizing that this remote service will be considered bundled into that office visit and therefore will not be separately billable. We are further finalizing that in instances when the remote service originates from a related E/M service provided within the previous 7 days by the same physician or qualified health care professional that this service will be considered bundled into that previous E/M service and also will not be separately billable.

We are finalizing requiring beneficiary consent that could be verbal or written, including electronic confirmation that is noted in the medical record for each billed service for HCPCS code G2010.

We are finalizing the valuation for HCPCS code G2010 as proposed. We will monitor utilization of this code and consider any potential adjustments to billing rules or valuation of this service through future rulemaking. We note that cost sharing for these services will apply.

For details related to our utilization estimates for this service, see section VII. of this final rule, Regulatory Impact Analysis. For further discussion related to valuation of this service, please see the section II.H. of this final rule, Valuation of Specific Codes.

3. Interprofessional Internet Consultation (CPT Codes 99451, 99452, 99446, 99447, 99448, and 99449)

As part of our standard rulemaking process, we received recommendations from the RUC to assist in establishing values for six CPT codes that describe interprofessional consultations. In 2013, CMS received recommendations from the RUC for CPT codes 99446 (Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 5–10 minutes of medical consultative discussion and review), 99447 (Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 11–20 minutes of medical consultative discussion and review), 99448 (Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 21–30 minutes of medical consultative discussion and review), and 99449 (Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 31 minutes or more of medical consultative discussion and review). CMS declined to adopt these codes for separate payment, stating in the CY 2014 PFS final rule with comment period that these kinds of services are considered bundled (78 FR 74343). For CY 2019, the CPT Editorial Panel created two new codes to describe additional consultative services, including a code describing the work of the treating physician when initiating a consult, and the RUC recommended valuation for new codes, CPT codes 99452 (Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes) and 99451 (Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 or more minutes of medical consultative time). The RUC also reaffirmed their prior recommendations for the existing CPT codes. The six codes describe assessment and management services conducted through telephone, internet, or electronic health record consultations furnished when a patient's treating physician or other qualified healthcare professional requests the opinion and/or treatment advice of a consulting physician or qualified healthcare professional with specific specialty expertise to assist with the diagnosis and/or management of the patient's problem without the need for the patient's face-to-face contact with the consulting physician or qualified healthcare professional. Currently, the resource costs associated with seeking or providing such a consultation are considered bundled, which in practical terms means that specialist input is often sought through scheduling a separate visit for the patient when a phone or internet-based interaction between the treating practitioner and the consulting practitioner would have been sufficient. We believe that proposing payment for these interprofessional consultations performed via communications technology such as telephone or internet is consistent with our ongoing efforts to recognize and reflect medical practice trends in primary care and patient-centered care management within the PFS.

Beginning in the CY 2012 PFS proposed rule (76 FR 42793), we have recognized the changing focus in medical practice toward managing patients' chronic conditions, many of which particularly challenge the Medicare population, including heart disease, diabetes, respiratory disease, breast cancer, allergies, Alzheimer's disease, and factors associated with obesity. We have expressed concerns that the current E/M coding does not adequately reflect the changes that have occurred in medical practice, and the activities and resource costs associated with the treatment of these complex patients in the primary care setting. In the years since 2012, we have acknowledged the shift in medical practice away from an episodic treatment-based approach to one that involves comprehensive patient-centered care management, and have taken steps through rulemaking to better reflect that approach in payment under the PFS. In CY 2013, we established new codes to pay separately for transitional care management (TCM) services. Next, we finalized new coding and separate payment beginning in CY 2015 for chronic care management (CCM) services provided by clinical staff (81 FR 80226). In the CY 2017 PFS final rule, we established separate payment for complex CCM services, an add-on code to the visit during which CCM is initiated to reflect the work of the billing practitioner in assessing the beneficiary and establishing the CCM care plan, and established separate payment for Behavioral Health Integration (BHI) services (81 FR 80226 through 80227).

As part of this shift in medical practice, and with the proliferation of team-based approaches to care that are often facilitated by electronic medical record technology, we believe that making separate payment for interprofessional consultations undertaken for the benefit of treating a patient will contribute to payment accuracy for primary care and care management services. We proposed

separate payment for these services, discussed in section II.H. of this final rule, Valuation of Specific Codes.

Although we proposed to make separate payment for these services because we believe they describe resource costs directly associated with seeking a consultation for the benefit of the beneficiary, we do have concerns about how these services can be distinguished from activities undertaken for the benefit of the practitioner, such as information shared as a professional courtesy or as continuing education. We do not believe that those examples will constitute a service directly attributable to a single Medicare beneficiary, and therefore neither the Medicare program nor the beneficiary should be responsible for those costs. We therefore solicited comment on our assumption that these are separately identifiable services, and the extent to which they can be distinguished from similar services that are nonetheless primarily for the benefit of the practitioner. We noted that there are program integrity concerns around making separate payment for these interprofessional consultation services, including around CMS's or its contractors' ability to evaluate whether an interprofessional consultation is reasonable and necessary under the particular circumstances. As the beneficiary would be liable for any cost sharing associated with these services, we also sought comment on the necessity of requiring patient consent for these, and whether than consent should be written or verbal. We solicited comment on how best to minimize potential program integrity issues, and noted we were particularly interested in information on whether these types of services are paid separately by private payers and if so, what controls or limitations private payers have put in place to ensure these services are billed appropriately.

The following is a summary of the comments we received regarding how best to minimize potential program integrity issues.

Comment: Almost all commenters were very supportive of CMS proposing separate payment for these services. Commenters pointed out that these are discrete physician services undertaken for the benefit of the patient, and easily distinguished from consultations undertaken for the edification of the practitioner. One commenter stated as medical care moves toward more comprehensive patient-centered care management, frequent consultation with multiple specialists is necessary. Under the current model this means separate visits for the patients that are costly and inconvenient. Internet-based consultations between the treating practitioner and the consulting specialists provide appropriate, convenient and cost effective alternatives. Commenters were clear that, by not making separate payment for these services, CMS would not be accurately paying for the work of both the treating and consulting physicians in a consultative scenario.

Many commenters provided helpful responses to CMS' request for information on how to minimize program integrity concerns for these services. A few commenters provided suggestions as to how CMS could verify the medical necessity of the consultation, including verifying that the treating and consulting physician were of different medical specialties, requiring patient identifiers and documentation of how the interaction improved patient care, defining a time period under which an E/M visit and an Interprofessional Consultation cannot both be billed for the same diagnosis, and creating frequency limitations on billing. Others suggested that the treating physician must document that they acted on the recommendation of the consulting physician prior to billing for CPT code 99452. Commenters had a number of suggestions for items that CMS should require, including that Interprofessional Consultations should consist of focused questions that are answerable solely from information in the EMR; that they be answered in 3 business days; and that the consulting physician should restate the question in their response, provide recommendations for evaluation, management, and/or ongoing monitoring, provide a rationale for recommendations, and provide recommendations for contingencies. Other commenters suggested that CMS could make separate payment contingent upon whether the underlying condition was urgent or related to critical care and that the consultation helped avoid transfer or interruption of care or that internal expertise was sought and was not available. Many commenters also encouraged CMS to avoid imposing overly restrictive documentation requirements. One commenter stated that, due to potential program integrity concerns, these services should be subject to the Medicare telehealth restrictions on beneficiary location and site of service. Another commenter recommended that CMS delay implementation until the program integrity concerns have been addressed. Other commenters encouraged CMS to monitor utilization for abuse.

Response: We thank commenters for their support and additional information on the ways in which these services are distinct physician services. We note that because these services are inherently non face-to-face (the patient need not be present in order for the service to be furnished in its entirety), they would not be considered as potential Medicare telehealth services under section 1834(m) of the Act. We appreciate the wealth of information and suggestions from commenters; however, we also agree with the many commenters who pointed out that adding many additional billing requirements may inhibit uptake for these services. As we note below, we are requiring documentation of verbal patient consent to receive these services, and are adopting existing CPT prefatory language. We plan to monitor utilization of these services and will consider making refinements to billing rules, documentation requirements or claims edits, including those suggested by commenters, through future rulemaking as necessary.

Comment: Many commenters suggested that CMS limit or eliminate beneficiary cost sharing for these services to obviate the question of patient consent entirely.

Response: Under current statute, we do not have the authority to change the requirements for the beneficiary cost sharing for these services.

Additionally, since these codes describe services that are furnished without the beneficiary being present, we proposed to require the treating practitioner to obtain verbal beneficiary consent in advance of these services, which would be documented by the treating practitioner in the patient's medical record, similar to the conditions of payment associated with separately billable care management services under the PFS. Obtaining advance beneficiary consent includes ensuring that the patient is aware of applicable cost sharing.

The following is a summary of the comments we received regarding whether to require the treating practitioner to obtain verbal beneficiary consent in advance of these services, which would be documented by the treating practitioner in the medical record similar to the conditions of payment associated with the care management services under the PFS, as well as comments on other aspects of this proposal.

Comment: Many commenters stated that verbal patient consent was an appropriate safeguard against unnecessary utilization, while others disagreed, stating that the requirement

to obtain consent may cause unnecessary burden in cases where the patient is unresponsive or the need for the interprofessional consultation is urgent such as in a critical care or emergency setting. Other commenters stated that a single blanket patient consent to receive interprofessional consultation services would be preferable to minimize the need to obtain consent for each of what may be multiple consultations. One commenter questioned whether the consulting physician would need to verify that the beneficiary had consented, given that only the treating physician is in contact with the beneficiary.

Response: We understand the potential burden regarding obtaining consent. However, we believe that it is important for beneficiaries to consent to the service and thus be notified of their cost-sharing obligations. We note that under our current policy for several care management services, consent is required to be documented in the medical record. That policy was implemented, in part, based on feedback we received from practitioners reporting the care management services, to alleviate burdens of alternative approaches. Consequently, we believe the same requirement could be applied here, without imposition of significant burden.

We are finalizing that the patient's verbal consent is required, and that consent must be noted in the medical record for each service, consistent with the policy we are finalizing for the brief communication technology-based services (HCPCS code G2012) as noted above, as well as with the patient consent policies in place for care management services, under the PFS.

Comment: Commenters requested that CMS clarify whether billing for these services is limited to physicians or if other healthcare practitioners, such as nurses or physical therapists, may bill for these services as well.

Response: We appreciate commenters' request for clarification. We believe that billing of these services should be limited to those practitioners that can independently bill Medicare for E/M visits, as interprofessional consultations are primarily for the ongoing evaluation and management of the patient, including collaborative medical decision making among practitioners. We are therefore not finalizing any expansion of these services beyond their current scope.

Comment: A few commenters requested that CMS adopt CPT prefatory language for these services as is CMS' longstanding practice when adopting most new CPT coding.

Response: We agree with the commenters and confirm that we will be adopting existing CPT prefatory language regarding these services.

In summary, we are finalizing separate payment for CPT codes 99451, 99452, 99446, 99447, 99448, and 99449 describing Interprofessional consultations. We are finalizing a policy to require the patient's verbal consent that is noted in the medical record for each interprofessional consultation service. We note that cost sharing will apply for these services. These interprofessional services may be billed only by practitioners that can bill Medicare independently for E/M services.

For further discussion related to the valuation of these services, please see section II.H. of this final rule, Valuation of Specific Codes.

4. Medicare Telehealth Services Under Section 1834(m) of the Act

a. Billing and Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

As discussed in this rule and in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. For further details, see the full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006).

b. Adding Services to the List of Medicare Telehealth Services

In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a process for adding services to or deleting services from the list of Medicare telehealth services in accordance with section 1834(m)(4)(F)(ii) of the Act. This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed by us. Under this process, we assign any submitted request to add to the list of telehealth services to one of the following two categories:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the service; for example, the use of interactive audio and video equipment.
- *Category 2:* Services that are not similar to those on the current list of telehealth services. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

The list of telehealth services, including the proposed additions described later in this section, is included in the Downloads section to this proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Historically, requests to add services to the list of Medicare telehealth services had to be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. However, for CY 2019 and onward, we intend to accept requests through February 10, consistent with the deadline for our receipt of code valuation recommendations from the RUC. To be

considered during PFS rulemaking for CY 2020, requests to add services to the list of Medicare telehealth services must be submitted and received by February 10, 2019. Each request to add a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as the vehicle to make changes to the list of Medicare telehealth services, requesters should be advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request to add services to the list of Medicare telehealth services, including where to mail these requests, see our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.*

c. Submitted Requests To Add Services to the List of Telehealth Services for CY 2019

Under our current policy, we add services to the telehealth list on a Category 1 basis when we determine that they are similar to services on the existing telehealth list for the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 PFS final rule with comment period (76 FR 73098), we believe that the Category 1 criteria not only streamline our review process for publicly requested services that fall into this category, but also expedite our ability to identify codes for the telehealth list that resemble those services already on this list.

We received several requests in CY 2017 to add various services as Medicare telehealth services effective for CY 2019. The following presents a discussion of these requests, and our proposals for additions to the CY 2019 telehealth list. Of the requests received, we found that two services were sufficiently similar to services currently on the telehealth list to be added on a Category 1 basis. Therefore, we proposed to add the following services to the telehealth list on a Category 1 basis for CY 2019:

- HCPCS codes G0513 and G0514 (Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; first 30 minutes (list separately in addition to code for preventive service) and (Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (list separately in addition to code G0513 for additional 30 minutes of preventive service).

We found that the services described by HCPCS codes G0513 and G0514 are sufficiently similar to office visits currently on the telehealth list. We believe that all the components of this service can be furnished via interactive telecommunications technology. Additionally, we believe that adding these services to the telehealth list will make it administratively easier for practitioners who report these services in connection with a preventive service that is furnished via telehealth, as both the base code and the add-on code would be reported with the telehealth place of service.

We also received requests to add services to the telehealth list that do not meet our criteria for Medicare telehealth services. We did not propose to add to the Medicare telehealth services list the following procedures for chronic care remote physiologic monitoring, interprofessional internet consultation, and initial hospital care; or to change the requirements for subsequent hospital care or subsequent nursing facility care, for the reasons noted in the paragraphs that follow.

(1) Chronic Care Remote Physiologic Monitoring (CPT Codes 99453, 99454, and 99457)

- CPT code 99453 (Remote monitoring of physiologic parameter(s) (*e.g.,* weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment).
- CPT code 99454 (Remote monitoring of physiologic parameter(s) (*e.g.,* weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days).
- CPT code 99457 (Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month).

In the CY 2016 PFS final rule with comment period (80 FR 71064), we responded to a request to add CPT code 99490 (Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored) to the Medicare telehealth list. We discussed that the services described by CPT code 99490 can be furnished without the beneficiary's face-to-face presence and using any number of non-face-to-face means of communication. We stated that it was therefore unnecessary to add that service to the list of Medicare telehealth services. Similarly, CPT codes 99453, 99454, and 99457 describe services that are inherently non face-to-face. As discussed in section II.H. of this final rule, Valuation of Specific Codes, we instead proposed to adopt CPT codes 99453, 99454, and 99457 for payment under the PFS. Because these codes describe services that are inherently non face-to-face, we do not consider them Medicare telehealth services under section 1834(m) of the Act; therefore, we did not propose to add them to the list of Medicare telehealth services.

(2) Interprofessional Internet Consultation (CPT Codes 99451and 99452)

- CPT code 99452 (Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes).
- CPT code 99451 (Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 or more minutes of medical consultative time).

As discussed in section II.H. of this final rule, Valuation of Specific Codes, we proposed to adopt CPT codes 99452 and 99451 for payment under the PFS as these are distinct services furnished via communication technology. Because these codes describe services that are inherently non face-to-face, we do not consider them as Medicare telehealth services under section 1834(m) of the Act; therefore we did not propose to add them to the list of Medicare telehealth services for CY 2019.

(3) Initial Hospital Care Services (CPT Codes 99221–99223)

- CPT code 99221 (Initial hospital care, per day, for the evaluation and

management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity.)

- CPT code 99222 (Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity.)
- CPT code 99223 (Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity.)

We have previously considered requests to add these codes to the telehealth list. As we stated in the CY 2011 PFS final rule with comment period (75 FR 73315), while initial inpatient consultation services are currently on the list of approved telehealth services, there are no services on the current list of telehealth services that resemble initial hospital care for an acutely ill patient by the admitting practitioner who has ongoing responsibility for the patient's treatment during the course of the hospital stay. Therefore, consistent with prior rulemaking, we did not propose that initial hospital care services be added to the Medicare telehealth services list on a category 1 basis.

The initial hospital care codes describe the first visit of the hospitalized patient by the admitting practitioner who may or may not have seen the patient in the decision-making phase regarding hospitalization. Based on the description of the services for these codes, we believed it is critical that the initial hospital visit by the admitting practitioner be conducted in person to ensure that the practitioner with ongoing treatment responsibility comprehensively assesses the patient's condition upon admission to the hospital through a thorough in-person examination. Additionally, the requester submitted no additional research or evidence that the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient; therefore, we also did not propose adding initial hospital care services to the Medicare telehealth services list on a Category 2 basis.

We noted that Medicare beneficiaries who are being treated in the hospital setting can receive reasonable and necessary E/M services using other HCPCS codes that are currently on the Medicare telehealth list, including those for subsequent hospital care, initial and follow-up telehealth inpatient and emergency department consultations, as well as initial and follow-up critical care telehealth consultations.

Therefore, we did not propose to add the initial hospital care services to the list of Medicare telehealth services for CY 2019.

(4) Subsequent Hospital Care Services (CPT Codes 99231–99233)

- CPT code 99231 (Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit.).
- CPT code 99232 (Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; an expanded problem focused examination; medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the bedside and on the patient's hospital floor or unit.).
- CPT code 99233 (Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; a detailed examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit.).

CPT codes 99231–99233 are currently on the list of Medicare telehealth services, but can only be billed via telehealth once every 3 days. The requester requested that we remove the frequency limitation. We stated in the CY 2011 PFS final rule with comment period (75 FR 73316) that, although we still believed the potential acuity of hospital inpatients is greater than those patients likely to receive Medicare telehealth services that were on the list at that time, we also believed that it would be appropriate to permit some subsequent hospital care services to be furnished through telehealth in order to ensure that hospitalized patients have frequent encounters with their admitting practitioner. We also noted that we continue to believe that the majority of these visits should be in-person to facilitate the comprehensive, coordinated, and personal care that medically volatile, acutely ill patients require on an ongoing basis. Because of our concerns regarding the potential acuity of hospital inpatients, we finalized the addition of CPT codes 99231–99233 to the list of Medicare telehealth services, but limited the provision of these subsequent hospital care services through telehealth to once every 3 days. We continue to believe that admitting practitioners should continue to make appropriate in-person visits to all patients who need such care during their hospitalization. Our concerns and position on the provision of subsequent hospital care services via telehealth have not changed. Therefore, we did not propose to remove the frequency limitation on these codes.

(5) Subsequent Nursing Facility Care Services (CPT Codes 99307–99310)

- CPT code 99307 (Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering, or improving. Typically, 10 minutes are spent at the bedside and on the patient's facility floor or unit.).
- CPT code 99308 (Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; an expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 15 minutes are spent at the bedside and on the patient's facility floor or unit.).
- CPT code 99309 (Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; a detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient has developed a significant complication or a significant new problem. Typically, 25 minutes are spent at the bedside and on the patient's facility floor or unit.).
- CPT code 99310 (Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A comprehensive interval history; a comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 35 minutes are spent at the bedside and on the patient's facility floor or unit.).

CPT codes 99307–99310 are currently on the list of Medicare telehealth services, but can only be billed via telehealth once every 30 days. The requester requested that we remove the frequency limitation when these services are provided for psychiatric care. We stated in the CY 2011 PFS final rule with comment period (75 FR 73317) that we believed it would be appropriate to permit some subsequent nursing facility care services to be furnished through telehealth to ensure that complex nursing facility patients have frequent encounters with their admitting practitioner, but because of our concerns regarding the potential acuity and complexity of SNF inpatients, we limited the provision of subsequent nursing facility care services furnished through telehealth to once every 30 days. Since these codes are used to report care for patients with a variety of diagnoses, including psychiatric diagnoses, we do not think it would be appropriate to remove the frequency limitation only for certain diagnoses. The services described by these CPT codes are essentially the same service, regardless of the patient's diagnosis. We also continue to have concerns regarding the potential acuity and complexity of SNF inpatients, and therefore, we did not propose to remove the frequency limitation for subsequent nursing facility care services in CY 2019.

In summary, we proposed to add the following codes to the list of Medicare telehealth services beginning in CY 2019 on a category 1 basis:

- HCPCS code G0513 (Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; first 30 minutes (list separately in addition to code for preventive service).
- HCPCS code G0514 (Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (list separately in addition to code G0513 for additional 30 minutes of preventive service).

Comment: Commenters were unanimously supportive of our proposal to add HCPCS codes G0513 and G0514 to the Medicare telehealth list. A few commenters noted they were disappointed that we did not propose to add the initial hospital care codes to the telehealth list and that we did not propose to lift the frequency limitation on the subsequent hospital care and subsequent nursing facility care codes.

Response: We are finalizing adding HCPCS codes G0513 and G0514 to the Medicare telehealth list. We are not adding the initial hospital care codes to the telehealth list and we are not removing the frequency limitations on the subsequent hospital care and subsequent nursing facility care codes for the reasons noted above.

Comment: Several commenters suggested that CMS conduct a pilot or demonstration program to evaluate the clinical benefit of physical therapists, occupational therapists, and speech-language pathologists furnishing telehealth services to Medicare beneficiaries in states that permit such services, noting that this would improve beneficiary access to therapy services, and help to inform policymakers as they consider whether to recognize such healthcare professionals as authorized providers of telehealth under the Social Security Act.

Response: While we did not include any proposals on this topic in the proposed rule, we reiterate our commitment to expanding access to telehealth services consistent with statutory authority, and paying appropriately for services that maximize telecommunications technology. Regarding the possibility of a model or demonstration, we will consider the comments as we develop new models through the Center for Medicare and Medicaid Innovation. We note that we would need to determine whether such a model or demonstration would meet the statutory requirements, which generally require that the test be expected to reduce Medicare expenditures and preserve or enhance the quality of care for beneficiaries.

5. Expanding the Use of Telehealth Under the Bipartisan Budget Act of 2018

a. Expanding Access to Home Dialysis Therapy Under the Bipartisan Budget Act of 2018

Section 50302 of the BBA of 2018 amended sections 1881(b)(3) and 1834(m) of the Act to allow an individual determined to have end-stage renal disease receiving home dialysis to choose to receive certain monthly end-stage renal disease-related (ESRD-related) clinical assessments via telehealth on or after January 1, 2019.

The new section 1881(b)(3)(B)(ii) of the Act requires that such an individual must receive a face-to-face visit, without the use of telehealth, at least monthly in the case of the initial 3 months of home dialysis and at least once every 3 consecutive months after the initial 3 months.

As added by section 50302(b)(1) of the BBA of 2018, subclauses (IX) and (X) of section 1834(m)(4)(C)(ii) of the Act include a renal dialysis facility and the home of an individual as telehealth originating sites but only for the purposes of the monthly ESRD-related clinical assessments furnished through telehealth provided under section 1881(b)(3)(B) of the Act. Section 50302(b)(1) of the BBA of 2018, also added a new section 1834(m)(5) of the Act which provides that the geographic requirements for telehealth services under section 1834(m)(4)(C)(i) of the Act do not apply to telehealth services furnished on or after January 1, 2019 for purposes of the monthly ESRD-related clinical assessments where the originating site is a hospital-based or critical access hospital-based renal dialysis center, a renal dialysis facility, or the home of an individual. Section 50302(b)(2) of the BBA of 2018 amended section 1834(m)(2)(B)(ii) of the Act to require that no originating site facility fee is to be paid if the home of the individual is the originating site.

Our current regulation at § 410.78 specifies the conditions that must be met in order for Medicare Part B to pay for covered telehealth services included on the telehealth list when furnished by an interactive telecommunications system. In accordance with the new subclauses (IX) and (X) of section 1834(m)(4)(C)(ii) of the Act, we proposed to revise our regulation at § 410.78(b)(3) to add a renal dialysis facility and the home of an individual as Medicare telehealth originating sites, but only for purposes of the home dialysis monthly ESRD-related clinical assessment in section 1881(b)(3)(B) of the Act. We proposed to amend § 414.65(b)(3) to reflect the requirement in section 1834(m)(2)(B)(ii) of the Act that there is no originating site facility fee paid when the originating site for these services is the patient's home. Additionally, we proposed to add new § 410.78(b)(4)(iv)(A), to reflect the provision in section 1834(m)(5) of the Act, added by section 50302 of the BBA of 2018, specifying that the geographic requirements described in section 1834(m)(4)(C)(i) of the Act do not apply with respect to telehealth services furnished on or after January 1, 2019, in originating sites that are hospital-based or critical access hospital-based renal dialysis centers, renal dialysis facilities, or the patient's home, respectively under sections 1834(m)(4)(C)(ii)(VI), (IX) and (X) of the Act, for purposes of section 1881(b)(3)(B) of the Act.

Commenters supported our proposals to revise the regulation text at §§ 410.78 and 414.65 to implement the requirements of section 50302 of the BBA of 2018 for expanding access to home dialysis therapy through telehealth. We are finalizing these regulation text changes as proposed.

b. Expanding the Use of Telehealth for Individuals With Stroke Under the Bipartisan Budget Act of 2018

Section 50325 of the BBA of 2018 amended section 1834(m) of the Act by adding a new paragraph (6) that provides special rules for telehealth services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke (acute stroke telehealth services), as determined by the Secretary. Specifically, section 1834(m)(6)(A) of the Act removes the restrictions on the geographic locations and the types of originating sites where acute stroke telehealth services can be furnished. Section 1834(m)(6)(B) of the Act specifies that acute stroke telehealth services can be furnished in any hospital, critical access hospital, mobile stroke units (as defined by the Secretary), or any other site determined appropriate by the Secretary, in addition to the current eligible telehealth originating sites. Section 1834(m)(6)(C) of the Act limits payment of an originating site facility fee to acute stroke telehealth services furnished in sites that meet the usual telehealth restrictions under section 1834(m)(4)(C) of the Act.

To implement these requirements, we proposed to create a new modifier that would be used to identify acute stroke telehealth services. The practitioner and, as appropriate, the originating site, would append this modifier when clinically appropriate to the HCPCS code when billing for an acute stroke telehealth service or an originating site facility fee, respectively. We note that section 50325 of the BBA of 2018 did not amend section 1834(m)(4)(F) of the Act, which limits the scope of telehealth services to those on the Medicare telehealth list. Practitioners would be responsible for assessing whether it would be clinically appropriate to use this modifier with codes from the Medicare telehealth list. By billing with this modifier, practitioners would be indicating that the codes billed were used to furnish telehealth services for diagnosis, evaluation, or treatment of symptoms of an acute stroke. We believe that the adoption of a service level modifier is the least administratively burdensome means of implementing this provision for practitioners, while also allowing CMS to easily track and analyze utilization of these services.

In accordance with section 1834(m)(6)(B) of the Act, as added by section 50325 of the BBA of 2018, we also proposed to revise § 410.78(b)(3) to add mobile stroke unit as a permissible originating site for acute stroke telehealth services. We proposed to define a mobile stroke unit as a mobile unit that furnishes services to diagnose, evaluate, and/or treat symptoms of an acute stroke and solicited comment on this definition, as well as additional information on how these units are used in current medical practice. We therefore proposed that mobile stroke units and the current eligible telehealth originating sites, which include hospitals and critical access hospitals as specified in section 1834(m)(6)(B) of the Act, but excluding renal dialysis facilities and patient homes because they are only allowable originating sites for purposes of home dialysis monthly ESRD-related clinical assessments in section 1881(b)(3)(B) of the Act, would be permissible originating sites for acute stroke telehealth services.

We also solicited comment on other possible appropriate originating sites for telehealth services furnished for the diagnosis, evaluation, or treatment of symptoms of an acute stroke. Any additional sites would be adopted through future rulemaking. As required under section 1834(m)(6)(C) of the Act, the originating site facility fee would not apply in instances where the originating site does not meet the originating site type and geographic requirements under section 1834(m)(4)(C) of the Act. Additionally, we proposed to add § 410.78 (b)(4)(iv)(B) to specify that the requirements in section 1834(m)(4)(C) of the Act do not apply with respect to telehealth services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke.

Comment: Commenters supported the expansions to Medicare telehealth. The majority of commenters agreed with our proposed definition of a mobile stroke unit. However, the AMA suggested that CMS specify in the definition that a mobile stroke unit must include a computed tomographic (CT) scanner and a telehealth (audio and video) connection or an in-person physician who is able to interpret the CT scan and prescribe an intravenous thrombolysis and also have a qualified health

professional who is able to administer an intravenous thrombolysis if the physician interpreting the CT scan and prescribing the treatment does so via telehealth. The AMA also suggested that CMS add as an originating site Emergency Medical Service (EMS) transports equipped with a telehealth connection to stroke specialists in order to provide faster national access to patients who require an accurate stroke diagnosis and decision about eligibility for intravenous or endovascular therapy, and to determine where to take them (such as a primary stroke or comprehensive stroke center). One commenter urged CMS to distinguish between a mobile stroke unit and a standard ambulance that is equipped with telemedicine capability and to establish separate payment for each, noting that a telemedicine consult on a mobile stroke unit may involve much greater complexity and critical care treatment than on a standard ambulance that is equipped with telemedicine capability. Another commenter recommended that CMS require specially trained paramedics who can evaluate an acute ischemic stroke patient based on national standards.

Response: We are finalizing the changes to the regulation text and the definition of a mobile stroke unit as proposed without modification. We believe that clinicians are in the best position to make decisions about what equipment and professional support are required in furnishing these services. We plan to monitor utilization of these services and will consider making refinements, including those suggested by commenters, through future rulemaking as necessary. We would welcome additional information to help us understand the merits of the commenters' suggestions, including those regarding specific equipment and staffing requirements for mobile stroke units.

In summary, we are finalizing a new modifier that will be used to identify acute stroke telehealth services. The practitioner and, as appropriate, the originating site, will append this modifier to the HCPCS code as clinically appropriate when billing for an acute stroke telehealth service or an originating site facility fee, respectively. We are finalizing the regulation text changes at §§ 410.78 and 414.65 as proposed to implement the requirements of section 50325 of the BBA of 2018 for acute stroke telehealth services. Mobile stroke units, with the definition as proposed, and the current eligible telehealth originating sites, which include hospitals and critical access hospitals, but exclude renal dialysis facilities and patient homes because they are originating sites only for purposes of home dialysis monthly ESRD-related clinical assessments in section 1881(b)(3)(B) of the Act, will be permissible originating sites for acute stroke telehealth services.

6. Requirements of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

a. Expanding Medicare Telehealth Services for the Treatment of Opioid Use Disorder and Other Substance Use Disorders—Interim Final Rule With Comment Period

Section 2001(a) of the SUPPORT for Patients and Communities Act (Pub. L. 115–271, October 24, 2018) (the SUPPORT Act) makes several revisions to section 1834(m) of the Act. First, it removes the originating site geographic requirements under section 1834(m)(4)(C)(i) for telehealth services furnished on or after July 1, 2019 for the purpose of treating individuals diagnosed with a substance use disorder or a co-occurring mental health disorder, as determined by the Secretary, at an originating site described in section 1834(m)(4)(C)(ii) of the Act, other than an originating site described in subclause (IX) of section 1834(m)(4)(C)(ii) of the Act. The site described in subclause (IX) of section 1834(m)(4)(C)(ii) of the Act is a renal dialysis facility, which is only an allowable originating site for purposes of home dialysis monthly ESRD-related clinical assessments in section 1881(b)(3)(B) of the Act. It also adds the home of an individual as a permissible originating site for these telehealth services. Section 2001(a) of the SUPPORT Act for Patients and Communities Act additionally amends section 1834(m) of the Act to require that no originating site facility fee will be paid in instances when the individual's home is the originating site. Section 2001(b) of the SUPPORT for Patients and Communities Act grants the Secretary specific authority to implement the amendments made by section 2001(a) through an interim final rule.

Under the authority of section 2001(b) of the SUPPORT for Patients and Communities Act, we are issuing an interim final rule with comment period to implement the requirements of section 2001(a) of the SUPPORT for Patients and Communities Act. In accordance with section 1834(m)(2)(B)(ii)(X) of the Act, as amended by section 2001(a) of the SUPPORT for Patients and Communities Act, we are revising § 410.78(b)(3) on an interim final basis, by adding § 410.78(b)(3)(xii), which adds the home of an individual as a permissible originating site for telehealth services furnished on or after July 1, 2019 to individuals with a substance use disorder diagnosis for purposes of treatment of a substance use disorder or a co-occurring mental health disorder. We are amending § 414.65(b)(3) on an interim final basis to reflect the requirement in section 1834(m)(2)(B)(ii) of the Act that there is no originating site facility fee paid when the originating site for these services is the individual's home. Additionally, we are adding § 410.78(b)(4)(iv)(C) on an interim final basis to specify that the geographic requirements in section 1834(m)(4)(C)(i) of the Act do not apply for telehealth services furnished on or after July 1, 2019, to individuals with a substance use disorder diagnosis for purposes of treatment of a substance use disorder or a co-occurring mental health disorder at an originating site other than a renal dialysis facility.

We note that section 2001 of the SUPPORT for Patients and Communities Act did not amend section 1834(m)(4)(F) of the Act, which limits the scope of telehealth services to those on the Medicare telehealth list. Practitioners would be responsible for assessing whether individuals have a substance use disorder diagnosis and whether it would be clinically appropriate to furnish telehealth services for the treatment of the individual's substance use disorder or a co-occurring mental health disorder. By billing codes on the Medicare telehealth list with the telehealth place of service code, practitioners would be indicating that the codes billed were used to furnish telehealth services to individuals with a substance use disorder diagnosis for the purpose of treating the substance use disorder or a co-occurring mental health disorder. We note that we may issue additional subregulatory guidance in the future for billing these telehealth services.

We note that there is a 60-day period following publication of this interim final rule for the public to comment on these interim final amendments to our regulations. We invite public comment on our policies to implement section 2001 of the SUPPORT for Patients and Communities Act.

b. Medicare Payment for Certain Services Furnished by Opioid Treatment Programs (OTPs)—Request for Information

Section 2005 of the SUPPORT Act establishes a new Medicare benefit category for opioid use disorder treatment services furnished by OTPs under Medicare Part B, beginning on or after January 1, 2020. This provision requires that opioid use disorder treatment services would include FDA-approved opioid agonist and antagonist treatment medications, the dispensing and administration of such medications (if applicable), substance use disorder counseling, individual and group therapy, toxicology testing, and other services determined appropriate (but in no event to include meals and transportation). The provision defines OTPs as those that enroll in Medicare and are certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), accredited by a SAMHSA-approved entity, and meeting additional conditions as the Secretary finds necessary to ensure the health and safety of individuals being furnished services under these programs and the effective and efficient furnishing of such services.

We note that there is a 60-day period for the public to comment on the provisions of the interim final rule described previously to implement section 2001 of the SUPPORT for Patients and Communities Act. During that same comment period, we are requesting information regarding services furnished by OTPs, payments for these services, and additional conditions for Medicare participation for OTPs that stakeholders believe may be useful for us to consider for future rulemaking to implement this new Medicare benefit category.

7. Modifying § 414.65 Regarding List of Telehealth Services

In the CY 2015 PFS final rule with comment period, we finalized a proposal to change our regulation at § 410.78(b) by deleting the description of the individual services for which Medicare payment can be made when furnished via telehealth, noting that we revised § 410.78(f) to indicate that a list of Medicare telehealth codes and descriptors is available on the CMS website (79 FR 67602). In accordance with that change, we proposed a technical revision to also delete the description of individual services and exceptions for Medicare payment for telehealth services in § 414.65, by amending § 414.65(a) to note that Medicare payment for telehealth services is addressed in § 410.78 and by deleting § 414.65(a)(1).

Comment: Commenters were supportive of CMS making a technical revision to delete the description of individual services and exceptions for Medicare payment for telehealth services in § 414.65.

Response: We are finalizing the technical revision to § 414.65 as proposed.

8. Comment Solicitation on Creating a Bundled Episode of Care for Management and Counseling Treatment for Substance Use Disorders

There is an evidence base that suggests that routine counseling, either associated with medication assisted treatment (MAT) or on its own, can increase the effectiveness of treatment for substance use disorders (SUDs). According to a study in the *Journal of Substance Abuse Treatment,*[1] patients treated with a combination of web-based counseling as part of a substance abuse treatment program demonstrated increased treatment adherence and satisfaction. The federal guidelines for opioid treatment programs describe that MAT and wrap-around psychosocial and support services can include the following services: Physical exam and assessment; psychosocial assessment; treatment planning; counseling; medication management; drug administration; comprehensive care management and supportive services; care coordination; management of care transitions; individual and family support services; and health promotion (*https://store.samhsa.gov/shin/content/PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf*). Creating separate payment for a bundled episode of care for components of MAT such as management and counseling treatment for substance use disorders (SUD), including opioid use disorder, treatment planning, and medication management or observing drug dosing for treatment of SUDs under the PFS could provide opportunities to better leverage services furnished with communication technology while expanding access to treatment for SUDs.

We also believe making separate payment for a bundled episode of care for management and counseling for SUDs could be effective in preventing the need for more acute services. For example, according to the *Healthcare Cost and Utilization Project,*[2] Medicare pays for one-third of opioid-related hospital stays, and Medicare has seen the largest annual increase in the number of these stays over the past 2 decades. We believe that separate payment for a bundled episode of care could help avoid such hospital admissions by supporting access to management and counseling services that could be important in preventing hospital admissions and other acute care events.

As indicated earlier, we considered whether it would be appropriate to develop a separate bundled payment for an episode of care for treatment of SUDs. We solicited public comment on whether such a bundled episode-based payment would be beneficial to improve access, quality and efficiency for SUD treatment. Further, we solicited public comment on developing coding and payment for a bundled episode of care for treatment for SUDs that could include overall treatment management, any necessary counseling, and components of a MAT program such as treatment planning, medication management, and observation of drug dosing. Specifically, we solicited public comments related to what assumptions we might make about the typical number of counseling sessions as well as the duration of the service period, which types of practitioners could furnish these services, and what components of MAT could be included in the bundled episode of care. We were interested in stakeholder feedback regarding how to define and value this bundle and what conditions of payment should be attached. Additionally, we solicited comment on whether the concept of a global period, similar to the currently existing global periods for surgical procedures, might be applicable to treatment for SUDs.

We also solicited comment on whether the counseling portion and other MAT components could also be provided by qualified practitioners ''incident to'' the services of the billing physician who will administer or prescribe any necessary medications and manage the overall care, as well as supervise any other counselors participating in the treatment, similar to the structure of the Behavioral Health Integration codes which include

[1] Van L. King, Robert K. Brooner, Jessica M. Peirce, Ken Kolodner, Michael S. Kidorf, ''A randomized trial of Web based videoconferencing for substance abuse counseling,'' *Journal of Substance Abuse Treatment,* Volume 46, Issue 1, 2014, Pages 36–42, *http://www.sciencedirect.com/science/article/pii/S0740547213001876.*

[2] Pamela L. Owens, Ph.D., Marguerite L. Barrett, M.S., Audrey J. Weiss, Ph.D., Raynard E. Washington, Ph.D., and Richard Kronick, Ph.D. ''Hospital Inpatient Utilization Related to Opioid Overuse Among Adults 1993–2012,'' Statistical Brief #177. Healthcare Cost and Utilization Project (HCUP). July 2014. Agency for Healthcare Research and Quality, Rockville, MD, *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb177-Hospitalizations-for-Opioid-Overuse.jsp.*

services provided by other members of the care team under the direction of the billing practitioner on an ''incident to'' basis (81 FR 80231). We welcomed comments on potentially creating a bundled episode of care for management and counseling treatment for SUDs, which we will consider for future rulemaking.

Comment: We received several comments with detailed information on this topic. Some commenters expressed concern that the format of a bundled episode of care may fail to take into account the wide variability in patient needs for treatment of SUDs, especially given the chronic nature of SUDs, which like other chronic diseases, typically involves ongoing treatment without a definitive end point. Some commenters additionally noted that a global period would not lend itself to treatment of SUDs, because the treatment is not an acute intervention like surgery; rather, patients with SUDs may require increasing and decreasing access to care, depending on their progress in treatment.

Response: We thank the commenters for all of the information submitted and will consider this feedback for future rulemaking. We agree with commenters and understand that there is wide variability in patient needs for treatment of SUDs, and that unlike surgical global periods, ongoing treatment is often necessary in the treatment of SUDs. While we do not necessarily believe these characteristics preclude payment bundles and/or global periods, we do understand they would need to be taken into account. We reiterate that our intention as we consider these issues for future rulemaking is to increase access to necessary care, and that any potential bundled payment would be developed in consideration of these comments.

We note that there is a 60-day period for the public to comment on the interim final telehealth policies and revisions to our regulations we are adopting to implement statutory amendments to section 1834(m) of the Act that expand access to telehealth services used to treat substance use disorders. During that same comment period, we are requesting additional information from stakeholders and the public that we might consider for future rulemaking regarding payment structure and amounts for SUD treatment that account for ongoing treatment and wide variability in patient needs for treatment of SUDs while improving access to necessary care.

Additionally, we invited public comment and suggestions for regulatory and subregulatory changes to help prevent opioid use disorder and improve access to treatment under the Medicare program. We solicited comment on methods for identifying non-opioid alternatives for pain treatment and management, along with identifying barriers that may inhibit access to these non-opioid alternatives including barriers related to payment or coverage. Consistent with our ''Patients Over Paperwork'' Initiative, we were interested in suggestions to improve existing requirements to more effectively address the opioid epidemic.

Comment: We received several comments with detailed information on this topic.

Response: We thank the commenters for all of the information submitted and will consider this for future rulemaking.

9. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act established the Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001 through December 31, 2002, at $20.00. For telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act. The originating site facility fee for telehealth services furnished in CY 2018 is $25.76. The MEI increase for 2019 is 1.5 percent and is based on the most recent historical update of the MEI through 2018Q2 (2.0 percent), and the most recent historical multifactor productivity adjustment (MFP) through calendar year 2017 (0.5 percent). Therefore, for CY 2019, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is 80 percent of the lesser of the actual charge or $26.15. The Medicare telehealth originating site facility fee and the MEI increase by the applicable time period is shown in Table 10.

TABLE 10—THE MEDICARE TELEHEALTH ORIGINATING SITE FACILITY FEE

Time period	MEI increase	Facility fee
10/01/2001–12/31/2002	N/A	$20.00
01/01/2003–12/31/2003	3.0	20.60
01/01/2004–12/31/2004	2.9	21.20
01/01/2005–12/31/2005	3.1	21.86
01/01/2006–12/31/2006	2.8	22.47
01/01/2007–12/31/2007	2.1	22.94
01/01/2008–12/31/2008	1.8	23.35
01/01/2009–12/31/2009	1.6	23.72
01/01/2010–12/31/2010	1.2	24.00
01/01/2011–12/31/2011	0.4	24.10
01/01/2012–12/31/2012	0.6	24.24
01/01/2013–12/31/2013	0.8	24.43
01/01/2014–12/31/2014	0.8	24.63
01/01/2015–12/31/2015	0.8	24.83
01/01/2016–12/31/2016	1.1	25.10
01/01/2017–12/31/2017	1.2	25.40
01/01/2018–12/31/2018	1.4	25.76
01/01/2019–12/31/2019	1.5	26.15

E. Potentially Misvalued Services Under the PFS

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the RVUs established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.H. of this final rule, Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the RUC, MedPAC, and other stakeholders. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by law. We may also consider analyses of work time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Merit-based Incentive Payment System (MIPS) data. In addition to considering the most recently available data, we assess the results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also consider information provided by other stakeholders. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section

1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*http://www.medpac.gov/docs/default-source/reports/Mar06_Ch03.pdf?sfvrsn=0*), MedPAC discussed the importance of appropriately valuing physicians' services, noting that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PE declines. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PE rises.

As MedPAC noted in its March 2009 Report to Congress (*http://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we intend to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well.

Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed approximately 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the CY 2012 PFS final rule with comment period (76 FR 73055 through 73958), we finalized our policy to consolidate the review of physician work and PE at the same time, and established a process for the annual public nomination of potentially misvalued services.

In the CY 2013 PFS final rule with comment period, we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called ''Harvard-valued codes''). In CY 2009 (73 FR 38589), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth Five-Year Review (76 FR 32410), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 services. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as

potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time).

In the CY 2016 PFS final rule with comment period, we finalized for review a list of potentially misvalued services, which included eight codes in the neurostimulators analysis-programming family (CPT codes 95970–95982). We also finalized as potentially misvalued 103 codes identified through our screen of high expenditure services across specialties.

In the CY 2017 PFS final rule, we finalized for review a list of potentially misvalued services, which included eight codes in the end-stage renal disease home dialysis family (CPT codes 90963–90970). We also finalized as potentially misvalued 19 codes identified through our screen for 0-day global services that are typically billed with an evaluation and management (E/M) service with modifier 25.

In the CY 2018 PFS final rule, we finalized arthrodesis of sacroiliac joint (CPT code 27279) as potentially misvalued. Through the use of comment solicitations with regard to specific codes, we also examined the valuations of other services, in addition to, new potentially misvalued code screens (82 FR 53017 through 53018).

3. CY 2019 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058), we finalized a process for the public to nominate potentially misvalued codes. In the CY 2015 PFS final rule with comment period (79 FR 67606 through 67608), we modified this process whereby the public and stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10th of each year. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in peer reviewed medical literature or other reliable data that there have been changes in physician work due to one or more of the following: Technique, knowledge and technology, patient population, site-of-service, length of hospital stay, and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the MIPS data).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate for each nominated code whether we agree with its inclusion as a potentially misvalued code. The public has the opportunity to comment on these and all other proposed potentially misvalued codes. In that year's final rule, we finalize our list of potentially misvalued codes.

a. Public Nominations

We received one submission that nominated several high-volume codes for review under the potentially misvalued code initiative. In its request, the submitter noted a systemic overvaluation of work RVUs in certain procedures and tests based ''on a number of Government Accountability Office (GAO) and the Medicare Payment Advisory Commission (MedPAC) reports, media reports regarding time inflation of specific services, and the January 19, 2017 Urban Institute report for CMS.'' The submitter suggested that the times CMS assumes in estimating work RVUs are inaccurate for procedures, especially due to substantial overestimates of preservice and postservice time, including follow-up inpatient and outpatient visits that do not take place. According to the submitter, the time estimates for tests and some other procedures are primarily overstated as part of the intraservice time. Furthermore, the submitter stated that previous RUC reviews of these services did not result in reductions in valuation that adequately reflected reductions in surveyed times.

Based on these analyses, the submitter requested that the codes listed in Table 11 be prioritized for review under the potentially misvalued code initiative.

TABLE 11—PUBLIC NOMINATIONS DUE TO OVERVALUATION

CPT code	Short description
27130	Total hip arthroplasty.
27447	Total knee arthroplasty.
43239	Egd biopsy single/multiple.
45385	Colonoscopy w/lesion removal.
70450	CT head w/o contrast.
93000	Electrocardiogram complete.
93306	Tte w/doppler complete.

Another submitter requested that CPT codes 92992 (Atrial septectomy or septostomy; transvenous method, balloon (*e.g.,* Rashkind type) (includes cardiac catheterization)) and 92993 (Atrial septectomy or septostomy; blade method (Park septostomy) (includes cardiac catheterization)) be reviewed under the potentially misvalued code initiative in order to establish national RVU values for these services under the MPFS. These codes are currently priced by the Medicare Administrative Contractors (MACs).

We received several comments with regard to the nomination of several high-volume codes for review under the potentially misvalued code initiative.

Comment: One commenter stated that specific details of the nomination of the seven high-volume codes were not provided in the CY 2019 PFS proposed rule. Several other commenters, including the RUC, expressed concern that the source of the nomination of the seven high-volume codes and its entire nomination letter was not made available. These commenters requested that CMS provide greater transparency and publicly provide all nomination requests identifying potentially misvalued codes.

Response: We believe that we summarized the contents of the public nomination letter and provided the rationale in the CY 2019 PFS proposed rule with enough detail for commenters to comment substantively and provide supporting documentation or data to rebut the suggestion that these codes are potentially misvalued. We recognize the importance of transparency and note that under the public nomination process that was established in CY 2012 rulemaking, the first opportunity for the public to nominate codes was during the 60-day comment period for the CY

2012 final rule with comment period; therefore, public nominations were received via submission to *www.regulations.gov*. In the CY 2015 final rule with comment period (79 FR 67606 through 67608), we finalized a modified process for identifying potentially misvalued codes (fully effective in CY 2017), where we established a new deadline of February 10th for receipt of public nominations for potentially misvalued codes to be considered for inclusion in the proposed rule. Although stakeholders often include public nominations of misvalued codes for consideration in a subsequent year's rulemaking as part of their comments on a current year's proposed rule, the public and stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation to CMS by February 10th of each year. In the future, public nominations that CMS receives by the February 10th deadline will be made available in the form of a public use file with the proposed rule, in the downloads section on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*. We remind submitters that any information that might be considered proprietary or confidential should not be included. Additionally, we have included the submission that nominated these high-volume codes for review as potentially misvalued as a public use file for the CY 2019 PFS final rule.

Comment: One commenter stated that because CMS did not include these publicly nominated codes in Table 13 of the proposed rule, it does not appear that CMS has agreed with the commenter on the need to revisit these codes. Another commenter stated that CMS did not provide guidance on whether these nominated codes would be considered for revaluation or retained at their current value.

Response: We clarify that the codes for which we received public nominations as potentially misvalued were not included in Table 13 of the proposed rule because that table contains a list of codes for which we proposed work RVUs for CY 2019 (the list does not include codes for which we received nominations discussed in the proposed rule for consideration as potentially misvalued). As previously indicated, in the proposed rule we publish the list of codes nominated as potentially misvalued, which allows the public the opportunity to comment on these codes; then, in the final rule, we finalize our list of potentially misvalued codes. No new valuations were proposed for these codes in the CY 2019 PFS proposed rule. Any revaluation of these codes would be proposed in future rulemaking.

Comment: One commenter stated that the codes in Table 8 in the proposed rule and their respective code families should be prioritized for review as potentially misvalued. The commenter suggested revisiting two recent efforts funded by CMS, reports by Urban Institute and RAND Corporation (*https://www.urban.org/sites/default/files/publication/87771/2001123-collecting-empirical-physician-time-data-piloting-approach-for-validating-work-relative-value-units_1.pdf*, and, *https://www.rand.org/content/dam/rand/pubs/research_reports/RR600/RR662/RAND_RR662.pdf*), for prioritization of codes for review to expand the misvalued codes initiative list. The commenter referenced a June 2018 MedPAC report that stated that CMS' review of potentially misvalued codes has not addressed services that account for a substantial share of fee schedule spending and is hampered by the lack of current, accurate, and objective data on clinician work time and practice expenses. Consequently, according to the MedPAC report, work RVUs for procedures, imaging, and tests are systemically overvalued relative to other services, such as ambulatory evaluation and management (E/M) services.

Response: We appreciate the commenters' recommendations for expanding the misvalued codes list. We will consider whether to address these suggestions in future rulemaking.

Comment: One commenter recommended that additional research be conducted on the analytic products available that could be used to create transparency into the RUC process and allow for greater external participation in misvalued cost evaluation. The commenter also stated that CMS should reconsider reliance on the RUC altogether given the inherent conflicts of interest in the RUC-based process.

Response: We acknowledge that the RUC provides critically important information that factors into our review process. However, our review of recommended work RVUs and time inputs is also informed by review of various alternate sources of information, in addition to the RUC. Examples of these alternate sources of information include information provided by other public commenters, Medicare claims data, comparative databases, medical literature, as well as consultation with other physicians and healthcare professionals within CMS and the federal government. We also reiterate that we continue to be open to reviewing additional and supplemental sources of data furnished by stakeholders, and providing such information to CMS is not limited to the public nomination process for potentially misvalued codes. We encourage stakeholders to continue to provide such information for our consideration in establishing work RVUs.

Comment: One commenter stated concerns with CMS' use of a non-relative measuring approach for the seven codes nominated for review when generally the RUC-valued and CMS-approved codes are based on the concept of relativity. The commenter stated that using such an inconsistent approach on select codes will potentially cause disruption and instability in code valuations. The commenter also stated that determining reimbursement in value-based care delivery models must rely on the carefully cultivated RUC process for fairness and accountability.

Response: We are unclear about the commenter's claim that CMS is using a non-relative measuring approach for the seven high volume codes that have been nominated as potentially misvalued. We did not propose a valuation for the nominated codes, nor did we propose to use a non-relative measuring approach. Rather, as part of our statutory obligation to identify and review potentially misvalued codes, we implemented an annual process whereby the public can nominate potentially misvalued codes with supporting documentation; we then publish the list of nominated codes and the public has the opportunity to comment on these nominations. We continue to maintain that adjustments to work RVUs should be based on the resources involved with each procedure or service, and reiterate that our review of work RVUs and time inputs utilizes information from various resources, including the RUC. We continue to seek information on the best sources of objective, routinely-updated, auditable, and robust data regarding the resource costs of furnishing PFS services.

Comment: Several commenters stated that CPT codes 27130 and 27447 should not be considered potentially misvalued and do not warrant any further action because the current valuation for the codes was established after review by the RUC and CMS in 2013, and since that time there are no new data to indicate a change in the work of performing the procedure or the number of post-operative follow up visits. Another commenter stated that CMS should not subject professions to code

valuations and analysis so frequently, and that doing so calls into question the validity of the RUC process in the first place.

Response: We do not agree that recent review of a code should preclude it from being considered as potentially misvalued, nor that it calls into question the validity of the RUC process. We have a responsibility to identify and review potentially misvalued codes, and believe there is value in consistent and routine review of high-volume services, particularly considering that a minor adjustment to the work RVU of a high-volume code may have a significant dollar impact. We also note that review of high-volume services does not need to be predicated on the suspicion of overvaluation.

Comment: One commenter stated that if CMS decides to reexamine these nominated codes in the future, then the agency should provide ample opportunity for public comments, and in the event of such review, CMS should consider supplemental sources of information, including hospital anesthesia time in addition to any RUC recommendations in order to support accurate valuations of these procedures.

Response: Any revaluations of these codes would be undertaken through notice and comment rulemaking. Notice and comment rulemaking provides for an open process whereby we welcome input from all interested parties, and we encourage commenters to provide feedback including supplemental sources of information regarding potentially misvalued codes, as well as input on our annual proposed valuations.

Comment: One commenter disagreed that CPT codes 43239 and 45385 are misvalued and stated that while the Urban Institute report provides insights into potential flaws in the RUC survey process, it should not be considered proof that these codes are overvalued. The commenter stated that these code valuations were recently revised, and the RUC survey responses from gastroenterologists informed revisions to the work RVUs for both services. The commenter stated that for CPT code 43239, CMS finalized work RVUs that were less than the RUC's recommended work RVUs, and for CPT code 45385, CMS finalized the RUC-recommended work RVUs, which were lower than the work RVUs prior to reevaluation. Therefore, the commenter stated that CMS should reject the nominations of these codes as potentially misvalued.

Response: We note that the nomination referenced the Urban Institute report as only one of the sources regarding the issue of time inflation of specific services. Additionally, as previously indicated, we do not agree that recent review of a code should preclude it from being considered as potentially misvalued. We believe there is value in consistent and routine review of high-volume services, particularly considering that a minor adjustment to the work RVU of a high-volume code may have a significant dollar impact. Therefore, we do not agree that we should reject nominations of these codes as potentially misvalued because they were previously reviewed and refinements were made.

Comment: A few commenters stated that the current work RVU valuation of 0.85 for CPT code 70450 is inadequate. The commenters stated that the level of effort associated with CPT code 70450 increased between the time the code was originally valued and the 2012 survey, and this increase continued through 2016. The commenters stated that over time, advances in technology led to many more images being created than existed historically. The commenters also stated that volume acquisitions, a CT scan technique that allows for multiple two-dimensional images, has resulted in thinner reconstructions and effortless multiplanar reformats, and other technological advancements have increased the amount of professional work associated with interpreting a non-contrast head CT and should be considered in the work RVU. The commenters expressed concern that the nomination by a single entity threatens the integrity of how physician services are valued generally.

Response: We disagree with the commenter that a nomination by a single entity threatens the integrity of how physician services are valued generally, and reiterate that a public nomination process was established through rulemaking as a way for the public and stakeholders to nominate potentially misvalued codes for consideration. Any future proposed valuations of specific codes are open for public comment, and we encourage stakeholders to submit data that would indicate that the current valuation is insufficient.

Comment: One commenter stated that with regard to CPT code 70450, the times prior to survey were CMS/other times and were not subdivided into pre-service, intra-service, and post-service categories. Therefore, the commenter stated that drawing comparisons between prior RUC database times and the surveyed times is invalid because the source of the prior RUC database times are unknown and completely different from the surveyed times. The commenter also stated that selecting as potentially misvalued only certain CPT codes that have undergone the RUC process with validated surveys is not a rational approach because if the times assumed based on the RUC approved survey data are invalid for these codes, they should be invalid for the entire fee schedule so that consistent methodology is applied to all CPT codes.

Response: We typically rely on RUC survey values because we believe they are the closest to accurate values, as they are the best data available in some cases. Although we do not agree that we should not consider comparisons of RUC database times to the newly surveyed times as described by the commenter, on a case-by-case basis we can consider the existence of previous inaccuracies. However, we also note that previous valuations established based on those inaccuracies would also indicate that the payments would have been inaccurate as well. The goal of the identification and review of potentially misvalued services is to facilitate accurate payment for PFS services. We also disagree with the commenter's characterization that selecting codes that have undergone the RUC process with validated surveys is not rational, and note that just because a code has been reviewed by the RUC does not preclude it from being identified and/or publically nominated as potentially misvalued.

Comment: With regard to CPT codes 93000 and 93306, one commenter stated that while the Urban Institute report concludes that the intraservice time to interpret an electrocardiogram is 6 seconds, practitioners who furnish the service do not believe it is possible to completely interpret a study so quickly. The commenter expressed concern about the large emphasis placed on service time by CMS and some stakeholders when it comes to valuation. The commenter suggested that frequent reviews of long-established mature services like electrocardiography and echocardiography will produce two outcomes—the inputs will remain the same or circumstances at some point will align such that it appears they take less time, which will open the window for payers to try to reduce payment for services that have not actually changed, and eventually these reductive re-valuations produce underpayment. A few commenters stated that CPT code 93306 was recently reviewed and valued in CY 2018. One commenter stated that the current valuation is reflective of numerous accreditation body requirements that were implemented since the service was last valued in 2007, which increased the

work required per study. The commenter stated that the Urban Institute report should not be considered proof that the CPT code is overvalued, and given the recent RUC review of this service, CMS' acceptance of the RUC recommendation, and no change in the physician work of performing the service in the past year, this code should not be included in the potentially misvalued codes list.

Response: We reiterate that it is our practice to consider all elements of the relative work when we are reviewing and determining work RVU valuations. Additionally, our review of recommended work RVUs and time inputs generally includes review of various sources such as information provided by the RUC, and other public commenters, medical literature, and comparative databases. As previously stated, we believe there is great value in consistent and routine review of high-volume services. Additionally, as previously indicated, we do not agree that recent review of a code should preclude it from being considered as potentially misvalued, and therefore, do not agree that CMS should not include a code in the list of potentially misvalued services because it was previously reviewed.

Comment: One commenter disagreed that the time allocated to CPT code 93306 is overstated. The commenter stated that the Intersocietal Accreditation Commission for Echocardiography Guidelines regarding time standards indicated that more time is necessary from patient encounter to departure than is stipulated in the CMS time file. The commenter also stated there is more and more information being gathered with the introduction of technology that is labor and time intensive. The commenter suggested that if anything is revised, CMS times should be increased, not decreased.

Response: We reiterate that we are interested in receiving resource-based data from stakeholders and not just the RUC and we encourage stakeholders to submit data that would indicate that the current valuations are insufficient.

Although we appreciate the comments that were received regarding the seven high-volume codes, we believe that the nominator presented some concerns that have merit, such as the observation that in many cases time is reduced substantially but the work RVU only minimally, which results in an implied increase in the intensity of work that does not appear to be valid, and ultimately creates work intensity anomalies that are difficult to defend, and further review of these high-volume codes is the best way to determine the validity of the concerns articulated by the submitter. Therefore, we are adding CPT codes 27130, 27447, 43239, 45385, 70450, 93000, and 93306 to the list of potentially misvalued codes and anticipate reviewing recommendations from the RUC and other stakeholders. We reiterate that we do not believe that the inclusion of a code on a potentially misvalued code list necessarily means that a particular code is misvalued. Instead, the list is intended to prioritize codes to be reviewed under the misvalued code initiative.

In addition to comments on the nomination of the seven high-volume codes, we also received comments on the nomination of two contractor-priced codes for review under the potentially misvalued code initiative.

Comment: We received a few comments with regard to CPT codes 92992 and 92993, which were requested for review under the potentially misvalued code initiative in order to establish national RVU values for these services under the PFS. One of the commenters, the RUC, stated that these contractor-priced services, which are typically performed on children, would be discussed at the October 2018 Relativity Assessment Workgroup meeting.

Response: We appreciate the information from the RUC on their plans to discuss these codes. Given the plans by the RUC to consider CPT codes 92992 and 92993 we will wait for the RUC's review and will not add these codes to the list of potentially misvalued codes.

b. Update on the Global Surgery Data Collection

Payment for postoperative care is currently bundled within 10 or 90 days after many surgical procedures. Historically, we have not collected data on how many postoperative visits are actually performed during the global period. Section 523 of the MACRA added a new paragraph 1848(c)(8) to the Act, and section 1848(c)(8)(B) required CMS to use notice and comment rulemaking to implement a process to collect data on the number and level of postoperative visits and use these data to assess the accuracy of global surgical package valuation. In the CY 2017 PFS final rule, we adopted a policy to collect postoperative visit data. Beginning July 1, 2017, we required practitioners in groups with 10 or more practitioners in nine states (Florida, Kentucky, Louisiana, Nevada, New Jersey, North Dakota, Ohio, Oregon, and Rhode Island) to use the no-pay CPT code 99024 (Postoperative follow-up visit, normally included in the surgical package, to indicate that an E/M service was performed during a postoperative period for a reason(s) related to the original procedure) to report postoperative visits. Practitioners who only practice in groups with fewer than 10 practitioners are exempted from required reporting, but are encouraged to report if feasible. The 293 procedures for which reporting is required are those furnished by more than 100 practitioners, and either are nationally furnished more than 10,000 times annually or have more than $10 million in annual allowed charges. A list of the procedures for which reporting is required is updated annually to reflect any coding changes and is posted on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-.html*.

In these nine states, from July 1, 2017 through December 31, 2017, there were 990,581 postoperative visits reported using CPT code 99024. Of the 32,573 practitioners who furnished at least one of the 293 procedures during this period and who, based on Tax Identification Numbers in claims data, were likely to meet the practice size threshold, only 45 percent reported one or more visit using CPT code 99024 during this 6-month period. The share of practitioners who reported any CPT code 99024 claims varied by specialty. Among surgical oncology, hand surgery, and orthopedic surgeons, reporting rates were 92, 90, and 87 percent, respectively. In contrast, the reporting rate for emergency medicine physicians was 4 percent.

Among 10-day global procedures performed from July 1, 2017 through December 31, 2017, where it is possible to clearly match postoperative visits to specific procedures, only 4 percent had one or more matched visit reported with CPT code 99024. The percentage of 10-day global procedures with a matched visit reported with CPT code 99024 varied by specialty. Among procedures with 10-day global periods performed by hand surgeons, critical care, and obstetrics/gynecology, 44, 36, and 23 percent, respectively, of procedures had a matched visit reported using CPT code 99024. In contrast, less than 5 percent of 10-day global procedures performed by many other specialties had a matched visit reported using CPT code 99024. Among 90-day global procedures performed from July 1, 2017 through December 31, 2017, where it is possible to clearly match postoperative visits to specific procedures, 67 percent had one or more matched visits reported using CPT code 99024.

In the CY 2019 PFS proposed rule, we suggested one potential explanation for

these findings is that many practitioners are not consistently reporting postoperative visits using CPT code 99024. We sought comment on how to encourage reporting to ensure the validity of the data without imposing undue burden. Specifically, we sought comment on whether we need to do more to make practitioners aware of their obligation and whether we should consider implementing an enforcement mechanism.

We sought comment on several other issues. Given the very small number of postoperative visits reported using CPT code 99024 during 10-day global periods, we sought comment on whether or not it might be reasonable to assume that many visits included in the valuation of 10-day global packages are not being furnished, or whether there are alternative explanations for what could be a significant level of underreporting of postoperative visits. Alternatively, we sought comment on whether it is possible that some or all of the postoperative visits are occurring after the global period ends and are, therefore, reported and paid separately.

We sought comment on whether we should consider requiring use of modifiers -54 and -55 in cases where the surgeon does not expect to perform the postoperative visits, regardless of whether or not the transfer of care is formalized. We also sought comment on the best approach to 10-day global codes for which the preliminary data suggest that postoperative visits are rarely performed by the practitioner reporting the global code and whether we should consider changing the global period and reviewing the code valuation.

The following is a summary of the comments we received on collecting data on global surgery and reporting.

Comment: The majority of commenters, including the RUC, noted that more time was needed for physicians to become aware of reporting and prepare for reporting. Moreover, they opposed implementing an enforcement mechanism, but supported more efforts by CMS to make physicians aware of the requirement. A few commenters objected to reporting and noted that CMS had complied with the statute. MedPAC, which supported converting all 10- and 90-day global codes to 0-day global codes and revaluing these codes as 0-day codes, suggested that these findings are consistent with the OIG's three studies that showed post-operative visits were not occurring at the rate that we estimated. MedPAC noted support for converting all codes with 10- and 90-day global periods to 0-day global codes and revaluing these codes as 0-day codes, most other commenters were opposed to creating 0-day global services out of 10-day global services. Of those who commented on reporting of post-operative visits, most suggested that improving reporting of these visits is essential if the data is to be used to improve the accuracy of the existing codes.

Response: We will evaluate the public comments received and consider whether to propose action at a future date. For the comment calling for additional efforts to make physicians aware of the requirement, we sent a letter describing the requirement to practitioners who are required to report in the 9 affected states and we plan to send another such letter to these practitioners. We will also consider other actions to make sure affected practitioners are aware of the requirement.

F. Radiologist Assistants

In accordance with § 410.32(b)(3), except as otherwise provided, all diagnostic X-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the PFS must be furnished under at least a general level of physician supervision as defined in paragraph (b)(3)(i) of that regulation. In addition, some of these tests require either direct or personal supervision as defined in paragraphs (b)(3)(ii) or (iii) of § 410.32, respectively. We list the required minimum physician supervision level for each diagnostic X-ray and other diagnostic test service along with the codes and relative values for these services in the PFS Relative Value File, which is posted on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files.html.* For most diagnostic imaging procedures, this required physician supervision level applies only to the technical component (TC) of the procedure.

In response to the Request for Information on CMS Flexibilities and Efficiencies (RFI) that was issued in the CY 2018 PFS proposed rule (82 FR 34172 through 34173), many commenters recommended that we revise the physician supervision requirements at § 410.32(b) for diagnostic tests with a focus on those that are typically furnished by a radiologist assistant (RA) under the supervision of a physician. Specifically, the commenters stated that all diagnostic tests, when performed by RAs, can be furnished under direct supervision rather than personal supervision of a physician, and that we should revise the Medicare supervision requirements so that when RAs conduct diagnostic imaging tests that would otherwise require personal supervision, they only need to do so under direct supervision. In addition to increasing efficiency, stakeholders suggested that the current supervision requirements for certain diagnostic imaging services unduly restrict RAs from conducting tests that they are permitted to do under current law in many states.

After consideration of these comments on the RFI, as well as information provided by stakeholders, we proposed to revise our regulations to specify that all diagnostic imaging tests may be furnished under the direct supervision of a physician when performed by an RA in accordance with state law and state scope of practice rules. Stakeholders representing the radiology community have provided us with information showing that the RA designation includes registered radiologist assistants (RRAs) who are certified by The American Registry of Radiologic Technologists, and radiology practitioner assistants (RPAs) who are certified by the Certification Board for Radiology Practitioner Assistants. We proposed to revise our regulation at § 410.32 to add a new paragraph (b)(4) to state that diagnostic tests performed by an RRA or an RPA require only a direct level of physician supervision, when permitted by state law and state scope of practice regulations. We noted that for diagnostic imaging tests requiring a general level of physician supervision, this proposal would not change the level of physician supervision to direct supervision. Otherwise, the diagnostic imaging tests must be performed as specified elsewhere under § 410.32(b). We based this proposal on recommendations from the practitioner community that included specific recommendations on how to implement the change. Representatives of the practitioner community submitted information on the education and clinical experience of RAs, which we took into consideration in determining whether the proposal would pose a significant risk to patient safety, and we determined that it would not. In addition, we considered information provided by stakeholders that indicated that 28 states have statutes or regulations that recognize RAs, and these states have general or direct supervision requirements for RAs.

Comment: Many commenters supported our proposed changes to the regulations and stated that they agreed that diagnostic tests performed by RAs be performed under at most direct supervision rather than personal

supervision where permitted by state law and state scope of practice regulations. According to these commenters, the change would allow for greater efficiency, improved patient access, more dedicated time with patients, increased quality of care, and increased patient satisfaction.

Response: We appreciate the comments received in support of this proposal. As discussed in the proposed rule, for diagnostic imaging tests requiring a general level of physician supervision, we are not changing the level of physician supervision to direct supervision. Otherwise, the diagnostic imaging tests must be performed as specified elsewhere under § 410.32(b). In order to provide further clarity, we are modifying the regulation to clarify that diagnostic tests performed by an RRA who is certified and registered by the American Registry of Radiologic Technologists or an RPA who is certified by the Certification Board for Radiology Practitioner Assistants, and that would otherwise require a personal level of supervision as specified in § 410.32(b)(3), may be furnished under a direct level of physician supervision to the extent permitted by state law and state scope of practice regulations.

Comment: Many commenters requested that CMS ensure that the proposed policy be effective January 1, 2019 by providing any necessary administrative guidance. Many commenters requested that CMS clarify in its final regulation that all services within the RA scope of practice, including procedures, may be performed under direct supervision.

Response: In implementing these changes to the regulation, we will be updating guidance contained in Pub. 100–04, Medicare Claims Processing Manual, Chapter 23 (available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/Pub100_23.html*). Medicare supervision rules are only directly applicable to diagnostic tests, not procedures. We note that for procedures provided by auxiliary personnel (such as a radiologist assistant) incident to the services of the billing physician or practitioner, Medicare generally requires direct supervision in accordance with the regulation at § 410.26(b)(5).

Comment: One commenter suggested that CMS require verbal assurances to patients as to the credentials of the health care professional conducting the procedure, when the procedure is performed by an RA. The commenter stated that requiring this verbal assurance will minimize confusion about who the physician is when there are multiple individuals furnishing the procedure.

Response: We believe such a requirement would be unwarranted and overly restrictive. We do not generally require practitioners to provide such assurances to Medicare beneficiaries, nor did we propose such a requirement in the proposed rule.

Comment: Several commenters suggested that CMS should operationalize the proposal starting January 1, 2019 by using a radiologist supervision indicator to recognize the RA under direct supervision rather than personal supervision when they provide Medicare services under their state scope of practice. These commenters requested the creation of a new supervision indicator that would be applied to specific codes and would indicate that the procedure may be performed under the direct supervision of a radiologist when performed by an RRA who is certified by The American Registry of Radiologic Technologists, and an RPA who is certified by the Certification Board for Radiology Practitioner Assistants.

Response: Our approach to effectuating this policy change was based on recommendations we received from the practitioner community. Under this approach, we allow for direct supervision for tests performed in part by an RA, which avoids the need to identify which CPT codes would be appropriate for inclusion under a new indicator. We believe our approach offers the most flexibility, ease of implementation, and subsequently reduces burden for billing practitioners and radiologist assistants.

After consideration of the public comments received, we are finalizing, with refinements for further clarity, our proposed revisions to § 410.32, by adding a new paragraph (b)(4) that states that diagnostic tests that are performed by a registered radiologist assistant (RRA) who is certified and registered by the American Registry of Radiologic Technologists or a radiology practitioner assistant (RPA) who is certified by the Certification Board for Radiology Practitioner Assistants, and that would otherwise require a personal level of supervision as specified in paragraph (3), may be furnished under a direct level of physician supervision to the extent permitted by state law and state scope of practice regulations.

G. Payment Rates Under the Medicare PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital

1. Background

Sections 1833(t)(1)(B)(v) and (t)(21) of the Act require that certain items and services furnished by certain off-campus provider-based departments (PBDs) (collectively referenced here as nonexcepted items and services furnished by nonexcepted off-campus PBDs) shall not be considered covered outpatient department (OPD) services for purposes of payment under the Hospital Outpatient Prospective Payment System (OPPS), and payment for those nonexcepted items and services furnished on or after January 1, 2017 shall be made under the applicable payment system under Medicare Part B if the requirements for such payment are otherwise met. These requirements were enacted in section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74, enacted November 2, 2015).

In the CY 2017 OPPS/Ambulatory Surgical Center (ASC) final rule with comment period (81 FR 79699 through 79719), we established several policies and provisions to define the scope of nonexcepted items and services in nonexcepted off-campus PBDs. We also finalized the PFS as the applicable payment system for most nonexcepted items and services furnished by nonexcepted off-campus PBDs. At the same time, we issued an interim final rule with comment period (81 FR 79720 through 79729) in which we established payment policies under the PFS for nonexcepted items and services furnished on or after January 1, 2017. In the following paragraphs, we summarize the policies that we adopted for CY 2017 and CY 2018. We also summarize proposals for CY 2019, respond to public comments, and finalize payment policies for CY 2019. For issues related to the excepted status of off-campus PBDs or the excepted status of items and services, please see the CY 2019 OPPS/ASC final rule.

2. Payment Mechanism

In establishing the PFS as the applicable payment system for most nonexcepted items and services in nonexcepted off-campus PBDs under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, we recognized that there was no technological capability, at least in the near term, to allow off-campus PBDs to bill under the PFS for those nonexcepted items and services. Off-campus PBDs bill under the OPPS for their services on an institutional claim,

while physicians and other suppliers bill under the PFS on a practitioner claim. The two systems that process these different types of claims, the Fiscal Intermediary Standard System (FISS) and the Multi-Carrier System (MCS) system, respectively, were not designed to accept or process claims of a different type. To permit an off-campus PBD to bill directly under a different payment system than the OPPS would have required significant changes to these complex systems as well as other systems involved in the processing of Medicare Part B claims. Consequently, we proposed and finalized a policy for CY 2017 and CY 2018 in which nonexcepted off-campus PBDs continue to bill for nonexcepted items and services on the institutional claim utilizing a new claim line modifier ''PN'' to indicate that an item or service is a nonexcepted item or service.

We implemented requirements under section 1833(t)(1)(B) of the Act for CY 2017 and CY 2018 by applying an overall downward scaling factor, called the PFS Relativity Adjuster to payments for nonexcepted items and services furnished in nonexcepted off-campus PBDs. The PFS Relativity Adjuster generally reflects the average (weighted by claim line volume times rate) of the site-specific rate under the PFS compared to the rate under the OPPS (weighted by claim line volume times rate) for nonexcepted items and services furnished in nonexcepted off-campus PBDs. As we have discussed extensively in prior rulemaking (81 FR 97920 through 97929 and 82 FR 53021), we established a new set of site-specific payment rates under the PFS that reflect the relative resource cost of furnishing the technical component (TC) of services furnished in nonexcepted off-campus PBDs. For the majority of HCPCS codes, these rates are based on either (1) the difference between the PFS nonfacility payment rate and the PFS facility rate, (2) the TC, or (3) in instances where payment would have been made only to the facility or to the physician, the full nonfacility rate. The PFS Relativity Adjuster refers to the percentage of the OPPS payment amount paid under the PFS for a nonexcepted item or service to the nonexcepted off-campus PBD.

To operationalize the PFS Relativity Adjuster as a mechanism to pay for nonexcepted items and services furnished by nonexcepted off-campus PBDs, we adopted the packaging payment rates and multiple procedure payment reduction (MPPR) percentage that applies under the OPPS. We also incorporated the claims processing logic that is used for payments under the OPPS for comprehensive Ambulatory Payment Classifications (C–APCs), conditionally and unconditionally packaged items and services, and major procedures. As we noted in the CY 2017 PFS final rule (82 FR 53024), we believe that this maintains the integrity of the cost-specific relativity of current payments under the OPPS compared with those under the PFS.

In CY 2017, we implemented a PFS Relativity Adjuster of 50 percent of the OPPS rate for nonexcepted items and services furnished in nonexcepted off-campus PBDs. For a detailed explanation of how we developed the PFS Relativity Adjuster of 50 percent for CY 2017, including assumptions and exclusions, we refer readers to the CY 2017 OPPS/ASC interim final rule with comment period (81 FR 79720 through 79729). Beginning for CY 2018, we adopted a PFS Relativity Adjuster of 40 percent of the OPPS rate. For a detailed explanation of how we developed the PFS Relativity Adjuster of 40 percent, we refer readers to the CY 2018 PFS final rule (82 FR 53019 through 53042). A brief overview of the general approach we took for CY 2018 and how it differs from the proposal for CY 2019 appears in this section.

3. The PFS Relativity Adjuster

The PFS Relativity Adjuster reflects the overall relativity of the applicable payment rate for nonexcepted items and services furnished in nonexcepted off-campus PBDs under the PFS compared with the rate under the OPPS. To develop the PFS Relativity Adjuster for CY 2017, we did not have all of the claims data needed to identify the mix of items and services that would be billed using the ''PN'' modifier. Instead, we analyzed hospital outpatient claims data from January 1 through August 25, 2016, that contained the ''PO'' modifier, which was a new mandatory reporting requirement for CY 2016 for claims that were billed by an off-campus department of a hospital. We limited our analysis to those claims billed on the 13X Type of Bill because those claims were used for Medicare Part B billing under the OPPS. We then identified the 25 most frequently billed major codes that were billed by claim line; that is, items and services that were separately payable or conditionally packaged. Specifically, we restricted our analysis to codes with OPPS status indicators (SI) ''J1'', ''J2'', ''Q1'', ''Q2'', ''Q3'', ''S'', ''T'', or ''V''. The most frequently billed service with the ''PO'' modifier in CY 2016 was described by HCPCS code G0463 (Hospital outpatient clinic visit for the assessment and management of a patient), which, in CY 2016, was paid under APC 5012 at a rate of $102.12; the total number of claim lines for this service was approximately 6.7 million as of August 2016. Under the PFS, there are 10 CPT codes describing different levels of office visits for new and established payments. We compared the payment rate under OPPS for HCPCS code G0463 ($102.12) to the average of the difference between the nonfacility and facility rates for CPT code 99213 (Level III office visit for an established patient) and CPT code 99214 (Level IV office visit for an established patient) in CY 2016 and found that the relative payment difference was approximately 22 percent. We did not include HCPCS code G0463 in our calculation of the PFS Relativity Adjuster for CY 2017 because we were concerned that there was no single, directly comparable code under the PFS. As we stated in the CY 2017 PFS final rule (81 FR 79723), we wanted to mitigate the risk of underestimating the overall relativity between the PFS and OPPS rates. From the remaining top 24 most frequently billed codes, we excluded HCPCS code 36591 (Collection of blood specimen from a completely implantable venous access device) because, under PFS policies, the service was only separately payable under the PFS when no other code was on the claim. We also removed HCPCS code G0009 (Administration of Pneumococcal Vaccine) because there was no payment for this code under the PFS. For the remaining top 22 codes furnished with the ''PO'' modifier in CY 2016, the average (weighted by claim line volume times rate) of the nonfacility payment rate estimate for the PFS compared to the estimate for the OPPS was 45 percent. We indicated that, because of our inability to estimate the effect of the packaging difference between the OPPS and the PFS, we would assume a 5 percentage point adjustment upward from the calculated amount of 45 percent; therefore, we established the PFS Relativity Adjuster of 50 percent for CY 2017.

In establishing the PFS Relativity Adjuster for CY 2018, we still did not have claims data for items and services furnished reported with a ''PN'' modifier. However, we updated the list of the 25 most frequently billed HCPCS codes using an entire year (CY 2016) of claims data for services submitted with a ''PO'' modifier and we updated the corresponding utilization weights for the codes used in the analysis. The order and composition of the top 25 separately payable HCPCS codes, based on the full year of claims from CY 2016

submitted with the ''PO'' modifier, changed minimally from the codes we used in our original analysis for the CY 2017 OPPS/ASC interim final rule with comment period. For a detailed list of the HCPCS codes we used in calculating the CY 2017 PFS Relativity Adjuster and the CY 2018 PFS Relativity Adjuster, we refer readers to the CY 2018 PFS final rule (82 FR 53030 through 53031). As noted earlier, in establishing the PFS Relativity Adjuster of 50 percent for CY 2017, we did not include in the weighted average code comparison, the relative rate for the most frequently billed service furnished in off-campus PBDs, HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), in part to ensure that we were not underestimating the overall relativity between the PFS and the OPPS. In contrast, in the CY 2018 PFS final rule, we stated that our objective for CY 2018 was to ensure that we did not overestimate the appropriate overall payment relativity, and that the payment made to nonexcepted off-campus PBDs better aligned with the services that are most frequently furnished in the setting. Therefore, in addition to using updated claims data, we revised the PFS Relativity Adjuster to incorporate the relative payment rate for HCPCS code G0463 into our analysis. We followed all other exclusions and assumptions that were made in calculating the CY 2017 PFS Relativity Adjuster. Our analysis resulted in a 35 percent relative difference in payment rates. Similar to our stated rationale in the CY 2017 PFS final rule, we increased the PFS Relativity Adjuster to 40 percent, acknowledging the difficulty of estimating the effect of the packaging differences between the OPPS and the PFS.

4. Payment Policies for CY 2019

In prior rulemaking, we stated our expectation that our general approach of adjusting OPPS payments using a single scaling factor, the PFS Relativity Adjuster, would continue to be an appropriate payment mechanism to implement provisions of section 603 of the Bipartisan Budget Act of 2015, and would remain in place until we are able to establish code-specific reductions that represent the TC of services furnished under the PFS or until we are able to implement system changes needed to enable nonexcepted off-campus PBDs to bill for nonexcepted items and services under the PFS directly (82 FR 53029). As we continue to explore alternative options related to requirements under section 1833(t)(21)(C) of the Act, we believed that this overall approach is still appropriate, and we are finalizing our proposal to continue to allow nonexcepted off-campus PBDs to bill for nonexcepted items and services on an institutional claim using a ''PN'' modifier until we identify a workable alternative mechanism to improve payment accuracy.

We made several adjustments to our methodology for calculating the PFS Relativity Adjuster for CY 2019. Most importantly, we had access to a full year of claims data from CY 2017 for services submitted with the ''PN'' modifier. Incorporating these data allows us to improve the accuracy of the PFS Relativity Adjuster by accounting for the specific mix of nonexcepted items and services furnished in nonexcepted off-campus PBDs. In analyzing the CY 2017 claims data, we identified just under 2,000 unique OPPS HCPCS/OPPS status indicator (SI) code pairs reported in CY 2017 with status indicators ''J1'', ''J2'', ''Q1'', ''Q2'', ''Q3'', ''S'', ''T'', or ''V''. The data reinforce our previous observation that the single most frequently reported service furnished in nonexcepted off-campus PBDs is HCPCS code G0463. Approximately half of all claim lines for separately payable or conditionally packaged services furnished by nonexcepted off-campus PBDs included HCPCS code G0463 in CY 2017, representing over 30 percent of total Medicare payments for separately payable or conditionally packaged services. The top 30 HCPCS/SI code combinations accounted for over 80 percent of all claim lines and approximately 70 percent of Medicare payments for services that are separately billable or conditionally packaged. In contrast with prior analyses, we also looked at claims units, which reflect HCPCS/SI code combinations that are billed more than once on a claim line. Certain HCPCS codes are much more frequently billed in multiple units than others. The largest differences between the number of claim lines and the number of claims units are for injections and immunizations, which are not typically separately payable or conditionally packaged under the OPPS. For instance, HCPCS code Q9967 (Low osmolar contrast material, 300–399 mg/ml iodine concentration, per ml) was reported in 12,268 claim lines, but 1,168,393 times (claims units) in the aggregate. HCPCS code Q9967 has an OPPS status indicator of ''N'', meaning that there is no separate payment under OPPS (items and services are packaged into APC rates). To calculate the PFS Relativity Adjuster using the full range of claims data submitted with a ''PN'' modifier in CY 2017, we first established site-specific rates under the PFS that reflect the TC of items and services furnished by nonexcepted off-campus PBDs in CY 2017. These HCPCS-level rates reflect our best current estimate of the amount that would have been paid for the service in the office setting under the PFS for practice expenses (PEs) not associated with the professional component (PC) of the service. As discussed in prior rulemaking (81 FR 79720 through 79729), we believe the most appropriate code-level comparison would reflect the TC of each HCPCS code under the PFS. However, we do not currently calculate a separate TC rate for all HCPCS codes under the PFS—only for those for which the PC and TC of the service are distinct and can be separately billed by two different practitioners or other suppliers under the PFS. For most of the remainder of services that do not have a separately payable TC under the PFS, we estimated the site-specific rate as (1) the difference between the PFS nonfacility rate and the PFS facility rate, or (2) in instances where payment would have been made only to the facility or only to the physician, the full nonfacility rate. As with the PFS rates that we developed when calculating the PFS Relativity Adjuster for CY 2017 and CY 2018, there were large code-level differences between the applicable PFS rate and the OPPS rate.

In calculating the proposed PFS Relativity Adjuster for CY 2019, we employed the same fundamental methodology that we used to calculate the PFS Relativity Adjuster for CY 2017 and CY 2018. We began by limiting our analysis to the items and services billed in CY 2017 with a ''PN'' modifier that are separately payable or conditionally packaged under the OPPS (status indicator = ''J1'', ''J2'', ''Q1'', ''Q2'', ''Q3'', ''S'', ''T'', or ''V'') and compared the rates for these codes under the OPPS with the site-specific rates under the PFS. Next, we imputed PFS rates for a limited number of items and services that are separately payable or conditionally packaged under the OPPS but are contractor priced under the PFS. We also imputed PFS rates for some HCPCS codes that are not separately payable under the OPPS (SI = ''N''), but are separately payable under the PFS. This includes items and services with an indicator status of ''X'' under the PFS, which are statutorily excluded from payment under the PFS, but may be paid under a different fee schedule, such as the Clinical Lab Fee Schedule (CLFS). We summed the HCPCS-level

rates under the PFS across all nonexcepted items and services, weighted by the number of HCPCS code claims units for each service. Next, we calculated the sum of the HCPCS-level OPPS rate for items and services that are separately payable or conditionally packaged, also weighted by the number of HCPCS code claims units. We compared the weighted sum of the site-specific PFS rate with the weighted sum of the OPPS rate for items and services reported in CY 2017 and we found that our updated analysis supports maintaining a PFS Relativity Adjuster of 40 percent. In view of this analysis, we proposed to continue applying a PFS Relativity Adjuster of 40 percent for CY 2019. Moreover, we proposed to maintain this PFS Relativity Adjuster for future years until updated data or other considerations indicate that an alternative adjuster or a change to our approach is warranted, which we will then propose through notice and comment rulemaking. We discuss some of our ongoing data analyses and future plans regarding implementation of section 603 of the Bipartisan Budget Act of 2015 in this section.

Comment: Several commenters were disappointed that CMS did not provide the same level of detail regarding the data and methodology used in calculating the PFS Relativity Adjuster for CY 2019 as we had in prior rulemaking (CY 2017 and CY 2018). In particular, these commenters noted that we had previously included specific HCPCS codes that comprised the top 25 reported, the number of claims lines for each HCPCS code, and the associated PFS payment rates we used to estimate the appropriate adjuster. Some commenters maintained that the lack of specific HCPCS codes and associated PFS payment rates prevented them from replicating our analysis and commenting on the merits of maintaining the 40 percent PFS Relativity Adjuster.

Response: We understand and appreciate commenters' interest in replicating our analysis using the full set of claims data and PFS payment rates we used to conduct our analysis. However, we do not agree that commenters were not able to conduct their own analysis for purposes of evaluating our proposal. The principal data sources in the analysis are the OPPS CY 2017 rates, the CY 2017 PFS rates, and institutional claims data for items and services furnished in CY 2017 that included the ''PN'' modifier, which are publicly available resources. We did not receive specific inquiries indicating that commenters tried to reproduce our results using these data sources (or other data sources), nor did we receive any specific alternatives for consideration. As we noted in the proposed rule, the methodological aspects of our proposed PFS Relativity Adjuster calculation for CY 2019 differ from the calculation for CY 2017 and CY 2018 by the following two adjustments: (1) Development of site specific technical-equivalent rates under the PFS for all HCPCS codes reported on a claim with the ''PN'' modifier in CY 2017; and (2) the addition of OPPS SI ''N'' claims data to the PFS component of the PFS Relativity Adjuster equation to reflect items and services that are packaged under OPPS but paid separately under the PFS. We imputed certain PFS rates, such as for codes that are contractor priced under the PFS, because those would be paid at the contractor price if the claim had been submitted in a freestanding office. We remind commenters that adding PFS rates to the analysis, where such rates would not have otherwise been included, has the effect of increasing the PFS Relativity Adjuster since the aggregate PFS payment amount increases relative to the aggregate OPPS payment amount. Nonetheless, we appreciate the commenters' interest in validating the results of our analysis. For the convenience of commenters wishing to conduct analysis of differences in payment rates between off-campus PBDs and freestanding offices for similar services, we are providing a public use file (PUF), available on the CMS website under the ''downloads'' section for this final rule containing the CY 2017 PFS technical-equivalent payment rates for all HCPCS codes reported on an institutional claim with the ''PN'' modifier, as well as the OPPS payment rate and the number of claims units by OPPS SI (see *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched*).

Comment: Commenters posed specific questions about our PFS Relativity Adjuster calculations and requested that CMS provide additional detail about the calendar year we used for OPPS and PFS rates, the specific HCPCS codes for which we imputed PFS rates, our rationale for weighting the data using claims units instead of claims lines, and if our analysis accounted for the more extensive packaging that occurs under the OPPS compared with the PFS.

Response: Although we addressed much, if not all, of the information requested by these commenters in the discussion of our methodology in the proposed rule, we provide the following summary, along with additional detail on specific aspects of our analysis to respond explicitly to commenters' questions. We began our analysis to identify the proposed CY 2019 PFS Relativity Adjuster by examining a full year of claims data for services furnished in CY 2017 that were reported on an institutional claim form and appended with the ''PN'' modifier. Because claims processed through the institutional setting are adjudicated based on the OPPS SI, our unit of analysis was the number of claims units at the HCPCS/SI code level. We used claim units instead of claim lines because this metric accounts for instances when a HCPCS code is reported multiple times on the same claim line. We made this methodological change in formulating our proposal for CY 2019 in large part to address commenters' concerns from prior years that our calculations may underrepresent PFS payment for HCPCS codes that would have been paid multiple times under the PFS if they were reported separately. For the majority of HCPCS/SI code combinations that were reported with the ''PN'' modifier, there is little difference between the number of claim lines and claim units. However, because more units are separately paid under the PFS than under the OPPS, using claims units rather than claims lines yielded a slightly higher PFS Relativity Adjuster.

For CY 2019, our proposed PFS Relativity Adjuster was based on all HCPCS codes that were submitted on an institutional claim form in CY 2017, appended with the ''PN'' modifier in order to improve the accuracy of the overall payment comparison using the best data available regarding the actual mix of services furnished in nonexcepted off-campus PBDs. In contrast, for CYs 2017 and 2018, we used only a subset of claims from CY 2016 because of known limitations regarding the data available at the time. In particular, the data from CY 2016 were based on claims that were appended with the ''PO'' modifier, which was a new reporting requirement for CY 2016. Although the ''PO'' modifier allowed us to distinguish items and services furnished in off-campus PBDs in CY 2016, it did not allow us to distinguish between excepted and nonexcepted off-campus PBDs. The ''PN'' modifier, which was a new reporting requirement for CY 2017, allows us to make the distinction between excepted and nonexcepted off-campus PBDs.

In updating our analysis for calculating the proposed PFS Relativity Adjuster for CY 2019 to include all HCPCS codes that were reported on an institutional claim with the ''PN'' modifier, we also extended to all HCPCS

codes our earlier logic with regard to calculating the site specific rates that represent the technical-equivalent of the resource costs of furnishing a service under the PFS. This amount, as we discussed in the proposed rule, generally reflected: (1) The difference between the PFS nonfacility payment rate and the PFS facility rate; (2) the TC; or (3) in instances where payment would have been made only to the facility or only to the physician, the full nonfacility rate. Applying the same logic to the fuller range of HCPCS codes, we developed site specific rates for all HCPCS codes that are nationally priced under the PFS and we referred to them as the technical-equivalent rates.

To continue with our analysis, we combined the CY 2017 OPPS rates at the HCPCS code level with the CY 2017 claims data representing nonexcepted items and services furnished in nonexcepted off-campus PBDs. Next, we added the technical-equivalent PFS rates for each HCPCS code, calculated using the approach described above. For both the OPPS and the PFS portions of the PFS Relativity Adjuster calculations, we weighted our analysis of HCPCS/SI code combinations by the number of claims units. For the OPPS component of the calculation, we restricted our analysis to HCPCS/SI code combinations that had OPPS SI indicators ''J1'', ''J2'', ''Q1'', ''Q2'', ''Q3'', ''S'', ''T'', or ''V'', which are separately payable or conditionally packaged codes under the OPPS. We multiplied the number of claims units for each HCPCS/SI code combination by the OPPS rate for each HCPCS/SI code combination and summed across the weighted rates. To calculate the PFS component of the PFS Relativity Adjuster, we used the same OPPS/SI code combinations, but we also included claims for HCPCS codes with OPPS SI ''N'', which indicates that, under the OPPS, payment for these services is packaged into payment for other services. We multiplied the number of claims units for each HCPCS/SI code combination by the technical-equivalent PFS rate for each HCPCS code and summed across the HCPCS/SI code combinations. We believe that adding weighted rates for HCPCS codes with OPPS SI ''N'' to the PFS allows us to better adjust, although imprecisely, for the packaging under the OPPS of nonexcepted items and services for which separate payment would typically be made under the PFS in the office setting. Although we did not conduct code-level analysis to estimate packaging under the OPPS, we believe that the combination of using the full range of claims data for nonexcepted items and services furnished in nonexcepted off-campus PBDs, using claim units rather than claim lines to weight rates on both the OPPS and PFS, and adding PFS rates for HCPCS codes with OPPS status indicator ''N'' is an improved approach to the PFS Relativity Adjuster that better accounts for OPPS packaging policies.

To increase the precision of our analysis, we imputed payment rates under the PFS for certain HCPCS codes for which payment is based on rates other than national PFS pricing. For services that are contractor-priced under the PFS, as indicated by a PFS status indicator of ''C'', we applied the national median allowed charge for these services in CY 2017. For a limited number of other services, where appropriate, we incorporated rates from the applicable fee schedule under which the service may have been paid if furnished in a freestanding office. For instance, HCPCS codes with a PFS status indicator of either ''X'' (service is statutorily excluded for payment under PFS) or ''E'' (service is excluded from payment under PFS by regulation), may be paid under the CLFS or the National Limitation Amount (NLA). The imputed values that we used, both from contractor priced codes and other fee schedules, are included in the data file that will be posted with this final rule, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Although there remains a certain level of imprecision inherent in our analysis, we believe the margin of error is relatively small and would likely affect the PFS and OPPS amounts similarly. For instance, we did not take into account the several MPPRs that would reduce payment on the PFS side when multiple codes are billed together. In many cases, these codes are packaged under the OPPS, so not including the PFS MPPRs in our analysis has the effect of increasing the PFS component of the calculation by a marginal amount. Likewise, we recognize that because of existing packaging rules under the OPPS, there is likely to be underreporting of codes on institutional claims for which the hospital does not receive separate payment, but for which the practitioner might receive separate payment if furnished in a freestanding office and reported on a professional claim form. This would effectively reduce the PFS Relativity Adjuster, but only to the extent hospitals are not appropriately reporting furnished items and services.

Comment: Many commenters expressed that the appropriate point of comparison for PFS technical-equivalent rates is the full nonfacility rate rather than the difference between the nonfacility rate and the facility rate. The commenters stated that since hospitals, like freestanding offices, incur both direct and indirect costs when services are furnished in nonexcepted off-campus PBDs, the difference between the nonfacility rate and the facility rate does not appropriately account for indirect costs incurred by the facility.

Response: We believe the commenters misunderstood the methodology for allocating direct and indirect costs as part of the PFS ratesetting process. Under the PFS algorithm for allocating indirect costs, nonfacility PFS rates include indirect PE that is directly related to the resources associated with the professional portion of the service alone. In other words, this is the indirect PE that is also paid by Medicare to professionals like physicians when they report services in the hospital setting. In addition to these indirect PE RVUs, nonfacility PFS rates include indirect PE RVUs allocated based on the direct PE inputs. We believe these indirect costs, those associated with provision of the technical aspects of the service alone, are analogous to those incurred by facilities when professionals furnish services there. To be clear, even when the total nonfacility rates are reduced by the facility rates, there are remaining PE RVUs that result from both direct inputs and indirect allocations under the established PFS methodology. We agree with the commenters that nonexcepted off-campus PBDs incur indirect costs, but we believe our calculation for the technical-equivalent PFS rates includes the relative resource costs of indirect expenses involved in furnishing the services. We also note that CMS makes corresponding payments under the PFS at the facility rate for nonexcepted items and services furnished in nonexcepted off-campus PBD settings, meaning that CMS is already paying for some of the indirect expenses associated with the PCs of the service. If CMS were to use the full nonfacility PE RVUs as the basis for comparing PFS rates to OPPS rates, we would effectively be paying twice for a portion of indirect costs, once under the PFS for the PC of services and again through the PFS Relativity Adjusted payment under the OPPS to off-campus PBDs for the facility part of the same service.

We recognize that the process of allocating indirect costs under the PFS is built on assumptions about

organizational practices and healthcare payment structures that may not fully reflect the current health care delivery environment, especially where physicians and other professionals are paid under salaried arrangements by institutions such as hospitals. Under the current PFS payment methodology, we assume that indirect costs associated with professional services furnished in institutions like hospital PBDs are incurred by the individual practitioners and not by the institutions. We may consider this issue for future rulemaking.

Comment: A commenter requested that CMS clarify how, in calculating the PFS Relativity Adjuster, CMS treated codes that are valued under the PFS only in a facility setting. Because these HCPCS codes do not have PE inputs reflecting the specific costs of furnishing a service in a freestanding office, the commenter stated concern that these codes may have been incorrectly incorporated in the analysis at a PFS payment rate of zero.

Response: We appreciate the commenter's concern and the opportunity to clarify the way we treated services not priced in the nonfacility setting in calculating the PFS Relativity Adjuster. Because there are no PFS payment rates for these services in the nonfacility setting, we incorporated the OPPS rate as the technical equivalent rate under the PFS.

Comment: Several commenters were opposed to our proposal to maintain the PFS Relativity Adjuster at 40 percent, citing both the lack of transparency in our methodology and prior analyses provided by the American Hospital Association (AHA) in earlier notice and comment rulemaking, suggesting that a 65 percent PFS Relativity Adjuster would appropriately incorporate into the Adjuster the additional packaging that occurs under the OPPS. Two commenters urged CMS to implement a 75 percent PFS Relativity Adjuster for CY 2019, although no specific rationale was given.

Response: We accounted for packaging under the OPPS by including PFS payment rates for HCPCS codes that were reported with OPPS SI ''N''. Our analysis does not support a PFS Relativity Adjuster of 65 or 75 percent, but rather indicates that a PFS Relativity Adjuster of 40 percent appropriately accounts for packaging of services under the OPPS. For additional discussion of the challenges related to incorporating the effect of packaging into the PFS Relativity Adjuster, we refer readers to the CY 2018 PFS final rule (82 FR 53024 through 53022).

Comment: A commenter stated that CMS has not provided sufficient justification for continuation of a reduction in payment of 60 percent for nonexcepted items and services furnished in nonexcepted off campus PBDs. Commenters noted that the first 2017 claims from the initial period of implementation of this policy are only now being incorporated into CMS claims files. The commenter indicated that there is an insufficient volume of claims to determine the impact this policy is having on beneficiary access to services in the PBD setting, particularly at the 40 percent Relativity Adjuster. The commenter stated that CMS should, at minimum, restore the 50 percent PFS Relativity Adjuster that was in place for CY 2017.

Response: We appreciate the commenter's suggestions, but we do not agree that there is insufficient data to support the PFS Relativity Adjuster of 40 percent. We have no reason to believe that the CY 2017 claims data are not as robust as any other claims based analysis and, to the extent that we recognize, acknowledge, and try to account for difference in payment policies between the PFS and OPPS, we believe our analysis demonstrates that a PFS Relativity Adjuster of 40 percent is appropriate.

Comment: Several commenters supported the 40 percent PFS Relativity Adjuster for CY 2019 and future years because this will provide stability for clinicians practicing in these settings and not disrupt patient access to care. One commenter cited the importance of making gradual changes to site neutrality policies to ensure alignment with other rapid changes in Medicare and the private sector regarding provider payment, including the movement to value-based purchasing and alternative payment systems.

Response: We agree with the commenter that there is value in the stability of maintaining the PFS Relativity Adjuster at 40 percent, particularly to the extent that this enables continuity of care for beneficiaries. We appreciate the support from commenters.

Comment: Some commenters, rather than opposing any particular PFS Relativity Adjuster, expressed disappointment that CMS did not propose to make broader changes to implement site-neutrality under section 603 of the Bipartisan Budget Act of 2015. Commenters were displeased that CMS is continuing to implement the requirements of the legislation using a single scaling factor applied to payment rates under the OPPS. Instead, they stated CMS should revise the applicable payment rates to appropriately reimburse for services provided by off-campus PBDs. Commenters did not provide specific suggestions for implementing alternative policies, but several commenters noted that a single overall scaling factor was intended by CMS to be an interim, not a long term policy solution. A few commenters suggested that the PFS Relativity Adjuster as a mechanism for implementing section 603 of the Bipartisan Budget Act of 2015 is not consistent with the requirement under that section to pay for nonexcepted items and services under the applicable payment system because this approach is still fundamentally based on OPPS payment rates. Other commenters stated that nonexcepted off-campus PBDs differ from one another in the mix of services furnished and the beneficiary population and that CMS payment policies should reflect those variances.

Despite concerns about the appropriateness of the PFS Relativity Adjuster for implementing requirements under section 603 of the Bipartisan Budget Act of 2015, several of the same commenters pointed out that there are significant advantages of continuing to allow hospitals to bill for items and services furnished in nonexcepted PBDs using the institutional claim form. In particular, they stated, this allows PBDs to properly use cost reporting procedures and to accurately reconcile the cost report to hospital ledgers for all services and departments and to correctly allow revenue for nonexcepted PBDs to flow through the Provider Statistical and Reimbursement (PS&R) report.

Response: We previously expressed interest in exploring how hospitals might report and receive payment for nonexcepted items and services furnished in nonexcepted off-campus PBDs using the standard PFS payment rates based on HCPCS-specific RVUs. However, CMS does not currently develop as part of the PFS ratesetting process separate payment rates for the technical aspects of the full range of nonexcepted items and services furnished in nonexcepted off-campus PBDs specifically for services for which there are not separately valued PCs and TCs. As such, we do not have a consistent way for nonexcepted off-campus PBDs and the professionals who furnish services in those settings to bill for the respective portions of the services for which they incurred costs. Additionally, while the statute was amended to change the nature and payment of nonexcepted items and services furnished in nonexcepted off-campus PBDs, the amendments did not

alter the status of non-excepted off-campus PBDs as parts of hospitals. Nonexcepted off-campus PBDs are still required to follow all reporting and regulatory policies consistent with hospital settings.

We continue to explore options that would allow hospitals to report nonexcepted items and services on an institutional claim form but receive payments that more directly reflect the technical aspect of services under the PFS. In general, we believe there may be additional utility, especially in the context of improving price transparency for Medicare beneficiaries, in establishing and displaying a set of payment rates, recalculated annually as part of the annual PFS rulemaking cycle, that reflect the relative resource costs of the technical aspects of furnishing PFS services.

Along with this final rule, we are including the technical-equivalent rates that we developed specifically for calculating the PFS Relativity Adjuster for CY 2019, which is the current mechanism for implementing the PFS as the applicable payment system for nonexcepted items and services furnished in nonexcepted off-campus PBDs. This information is being made available under the downloads section for this final rule on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

Comment: Several commenters supported our ongoing efforts to implement site neutral payments in the context of section 603 of the Bipartisan Budget Act of 2015. Several commenters indicated their support for additional policies that would equalize payment across freestanding offices and hospital PBDs, both on-campus and off-campus.

Response: We recognize that this is a topic of great interest to many commenters and we welcome the range of perspectives and ideas posed by commenters.

Comment: Some commenters disagreed with our view that the amendments under section 603 of the Bipartisan Budget Act of 2015 were intended to produce site neutral payments between freestanding offices and off-campus PBDs with the goal of removing incentives for hospitals to purchase physician offices. These commenters noted that hospital PBDs face higher costs than freestanding offices, such as those associated with regulatory requirements, and reducing payment to nonexcepted off-campus PBDs threatens the viability of hospitals that serve a vital role in providing services to rural and underserved communities in these off-campus settings. We received several comment letters from Medicare beneficiaries expressing concern about reduced payments to their community's major medical hospital offsite locations. The commenters stated that without the hospital's offsite locations community members would be forced to drive unreasonable distances to seek basic and immediate care.

Response: We understand the commenters' concerns, especially with regard to maintaining access to appropriate care. CMS continues to evaluate data regarding beneficiary access to care to identify possible issues. We also agree that hospitals face additional regulatory and operational costs not generally incurred by physician offices, and that OPDs of a hospital function as an important and integral part of the Medicare care delivery infrastructure. However, many off-campus PBDs are similar to physician's offices and do not necessarily have the same operational costs as the main hospital. We believe that the amendments made to the statute by section 603 of the Bipartisan Budget Act of 2015 were intended to reduce Medicare payment incentives for hospitals to purchase physician offices, convert them to off-campus PBDs, and bill under the OPPS for items and services furnished there.

Comment: Several commenters opposed our inclusion of the proposal related to payment for nonexcepted off-campus PBDs under the CY 2019 PFS rule instead of the CY 2019 OPPS/ASC rule. They suggested that proposals related to the payment rate for nonexcepted items and services furnished in nonexcepted off-campus PBDs are inseparable from proposals and comment solicitations in the OPPS/ASC rule related to service line expansions and other payment policies related to implementation of the amendments under section 603 of the Bipartisan Budget Act of 2015. Some commenters suggested that, for purposes of administrative simplification, the discussion of any changes to site-of-service payments regarding PBDs of a hospital should be fully maintained within a single rule and recommended this be included in the OPPS rule. Some commenters expressed concern that the PFS and OPPS proposed rules were not released at the same time and that this presents challenges for them in reconciling and preparing their comments on each rule.

Response: We appreciate commenters' concerns about responding to two separate rules for policies associated with payment for nonexcepted items and services furnished in nonexcepted off-campus PBDs. However, we note that in finalizing the PFS as the applicable payment system for most nonexcepted items and services, proposals related to the implementation of payment rates under the PFS fall reasonably under the purview of PFS rulemaking, while proposals related to the applicability of those rates are more appropriately addressed in OPPS/ASC rulemaking. We will consider these concerns for future rulemaking.

We believe that our proposal to maintain the PFS Relativity Adjuster at 40 percent for CY 2019 and for future years reflects an analysis that accounts for many of the concerns expressed by commenters regarding the PFS Relativity Adjuster in prior rules. Therefore, we are finalizing the proposal to maintain the PFS Relativity Adjuster at 40 percent for CY 2019 and beyond until there is an appropriate reason and process for implementing an alternative to our current policy, at which time we will make a proposal through notice and comment rulemaking.

5. Policies Related to Supervision, Beneficiary Cost-Sharing, and Geographic Adjustments

In the CY 2018 PFS final rule (81FR 53019 through 53031), we finalized policies related to supervision rules, beneficiary cost sharing, and geographic adjustments. We finalized that supervision rules in nonexcepted off-campus PBDs that furnish nonexcepted items and services are the same as those that apply for hospitals, in general. We also finalized that all beneficiary cost sharing rules that apply under the PFS in accordance with sections 1848(g) and 1866(a)(2)(A) of the Act continue to apply when payment is made under the PFS for nonexcepted items and services furnished by nonexcepted off-campus PBDs, regardless of cost sharing obligations under the OPPS. Lastly, we finalized the policy to apply the same geographic adjustments used under the OPPS to nonexcepted items and services furnished in nonexcepted off-campus PBDs. We are maintaining these policies for CY 2019, as finalized in the CY 2018 PFS final rule.

6. Partial Hospitalization

a. Partial Hospitalization Services

Partial hospitalization programs (PHPs) are intensive outpatient psychiatric day treatment programs furnished to patients as an alternative to inpatient psychiatric hospitalization, or as a stepdown to shorten an inpatient stay and transition a patient to a less intensive level of care. Section

1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital, to its outpatients, or by a community mental health center (CMHC). In the CY 2017 OPPS/ASC proposed rule (81 FR 45690), in the discussion of the proposed implementation of section 603 of Bipartisan Budget Act of 2015, we noted that because CMHCs also furnish PHP services and are ineligible to be provider-based to a hospital, a nonexcepted off-campus PBD would be eligible for PHP payment if the entity enrolls and bills as a CMHC for payment under the OPPS. We further noted that a hospital may choose to enroll a nonexcepted off-campus PBD as a CMHC, provided it meets all Medicare requirements and conditions of participation.

In response to that rule, commenters expressed concern that without a clear payment mechanism for PHP services furnished by nonexcepted off-campus PBDs, access to partial hospitalization services would be limited, and pointed out the critical role PHPs play in the continuum of mental health care. Many commenters noted that the Congress did not intend for partial hospitalization services to no longer be paid for by Medicare when such services are furnished by nonexcepted off-campus PBDs. Several commenters disagreed with the notion of enrolling as a CMHC in order to receive payment for PHP services. The commenters stated that hospital-based PHPs and CMHCs are inherently different in structure, operation, and payment, and noted that the conditions of participation for hospital departments and CMHCs are different. Several commenters requested that CMS find a mechanism to pay hospital-based PHPs in nonexcepted off-campus PBDs.

We agreed with the commenters' concerns and adopted payment for partial hospitalization items and services furnished by nonexcepted off-campus PBDs under the PFS in the CY 2017 OPPS/ASC final rule with comment period and interim final rule with comment period (81 FR 79715, 79717, and 79727). When billed in accordance with the CY 2017 PFS final rule, these partial hospitalization services are paid at the CMHC per diem rate for APC 5853, for providing three or more partial hospitalization services per day (81 FR 79727).

In the CY 2017 OPPS/ASC proposed rule (81 FR 45681), and the CY 2017 OPPS/ASC final rule with comment period/interim final rule with comment period (81 FR 79717 and 79727), we noted that when a beneficiary receives outpatient services in an off-campus department of a hospital, the total Medicare payment for those services is generally higher than when those same services are provided in a physician's office. Similarly, when partial hospitalization services are provided in a hospital-based PHP, Medicare pays more than when those same services are provided by a CMHC. Our rationale for adopting the CMHC per diem rate for APC 5853 as the PFS payment amount for nonexcepted off-campus PBDs providing PHP services is because CMHCs are freestanding entities that are not part of a hospital, but they provide the same PHP services as hospital-based PHPs (81 FR 79727). This is similar to the differences between freestanding entities paid under the PFS that furnish other services also provided by hospital-based entities. Similar to other entities currently paid for their TC services under the PFS, we believe CMHCs would typically have lower cost structures than hospital-based PHPs, largely due to lower overhead costs and other indirect costs such as administration, personnel, and security. We believe that paying for nonexcepted hospital-based partial hospitalization services at the lower CMHC per diem rate aligns with section 603 of Bipartisan Budget Act of 2015, while also preserving access to PHP services. In addition, nonexcepted off-campus PBDs will not be required to enroll as CMHCs in order to bill and be paid for providing partial hospitalization services. However, a nonexcepted off-campus PBD that wishes to provide PHP services may still enroll as a CMHC if it chooses to do so and meets the relevant requirements. Finally, we recognize that because hospital-based PHPs are providing partial hospitalization services in the hospital outpatient setting, they can offer benefits that CMHCs do not have, such as an easier patient transition to and from inpatient care, and easier sharing of health information between the PHP and the inpatient staff.

In the CY 2018 PFS final rule, we did not require these PHPs to enroll as CMHCs but instead we continued to pay nonexcepted off-campus PBDs providing PHP items and services under the PFS. Further, in that CY 2018 PFS final rule (82 FR 53025 to 53026), we continued to adopt the CMHC per diem rate for APC 5853 as the PFS payment amount for nonexcepted off-campus PBDs providing three or more PHP services per day in CY 2018.

For CY 2019, we proposed to continue to identify the PFS as the applicable payment system for PHP services furnished by nonexcepted off-campus PBDs, and proposed to continue to set the PFS payment rate for these PHP services as the per diem rate that will be paid to a CMHC in CY 2019. We further proposed to maintain these policies for future years until updated data or other considerations indicate that a change to our approach is warranted, which we will then propose through notice and comment rulemaking.

We received no comments on our PHP proposals for CY 2019 and future years, and are finalizing our policies as proposed.

7. Future Years

We continue to believe the amendments made by section 603 of the Bipartisan Budget Act of 2015 were intended to reduce the Medicare payment incentive for hospitals to purchase physician offices, convert them to off-campus PBDs, and bill under the OPPS for items and services they furnish there. Therefore, we continue to believe the payment policy under this provision should ultimately equalize payment rates between nonexcepted off-campus PBDs and physician offices to the greatest extent possible, while allowing nonexcepted off-campus PBDs to bill in a straightforward way for services they furnish.

In developing our proposal for CY 2019 as described previously, we incorporated all HCPCS codes that appeared in CY 2017 claims data from nonexcepted off-campus PBDs. We also expanded the number of site specific, technical-equivalent rates for nonexcepted items and services furnished in nonexcepted off-campus PBDs, in order to ensure that Medicare payment to hospitals billing for nonexcepted items and services furnished by nonexcepted off-campus PBDs reflects the relative resources involved in furnishing the items and services. We recognize that for certain specialties, service lines, and nonexcepted off-campus PBDs, total Medicare payments for the same services might be either higher or lower when furnished by a nonexcepted off-campus PBD rather than in a physician office.

We intend to continue to examine the claims data in order to assess whether a different PFS Relativity Adjuster is warranted and also to consider whether additional adjustments to the methodology are appropriate. In particular, we are monitoring claims for shifts in the mix of services furnished in nonexcepted off-campus PBDs that may affect the relativity between the PFS and OPPS. An increase over time in the share of nonexcepted items and services with lower technical-equivalent rates under the PFS compared with APC rates

under the OPPS might result in a lower PFS Relativity Adjuster, for example. We will also carefully assess annual payment policy updates to the PFS and OPPS, respectively, to identify changes in overall relativity resulting from any new or modified policies, such as expanded packaging under the OPPS or an increase in the number of HCPCS codes with global periods under the PFS. As part of these ongoing efforts, we are also analyzing PFS claims data to identify patterns of services furnished together on the same day. We anticipate that this will ultimately allow us to make refinements to the PFS Relativity Adjuster to better account for the more extensive packaging of services under the OPPS and the potential underreporting of services that are not separately payable under the OPPS but are paid separately under the PFS.

Another dimension of our ongoing efforts to improve implementation of section 603 of the Bipartisan Budget Act of 2015 is the development and refinement of a new set of payment rates under the PFS that reflect the relative resource costs of furnishing the TC of items and services furnished in nonexcepted off-campus PBDs. Although we believe that our site-specific HCPCS code-level rates reflect the best available estimate of the amount that would have been paid for the service in the office setting under the PFS for practice expenses not associated with the PC of the service, for the majority of HCPCS codes there is no established methodology for separately valuing the resource costs incurred by a provider while furnishing a service from those incurred exclusively by the facility in which the service is furnished. We continue to explore alternatives to our current estimates that would better reflect the TC of services furnished in nonexcepted off-campus PBDs. We are broadly interested in stakeholder feedback and recommendations for ways in which CMS can improve pricing and transparency with regard to the differences in the payment rates across sites of service.

We expect that our continued analyses of claims data and our ongoing exploration of systems changes that are needed to allow nonexcepted off-campus PBDs to bill directly for the TC portion of nonexcepted items and services may lead us to consider a different approach for implementing section 603 of the Bipartisan Budget Act of 2015. On the whole, however, we believe that a PFS Relativity Adjuster for CY 2019 of 40 percent advances efforts to equalize payment rates in the aggregate between physician offices and nonexcepted off-campus PBDs. Maintaining our policy of applying an overall scaling factor to OPPS payments allows hospitals to continue billing through a facility claim form and permits continued use of the packaging rules and cost report-based relative payment rate determinations for nonexcepted services.

H. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011, and revised MP RVUs in CY 2010 and CY 2015. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the RUC identified a number of potentially misvalued codes each year using various identification screens, as discussed in section II.E. of this final rule, Potentially Misvalued Services under the PFS. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accepted public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values, and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period, we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule, the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we established interim final values in the CY 2016 PFS final rule with comment period, we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period, and re-proposed values for those codes in the CY 2017 PFS proposed rule.

We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values. For CY 2017, we did not identify any new codes that described such wholly new services. Therefore, we did not establish any code values on an interim final basis.

For CY 2018, we generally proposed the RUC-recommended work RVUs for new, revised, and potentially misvalued codes. We proposed these values based on our understanding that the RUC generally considers the kinds of concerns we historically raised regarding appropriate valuation of work RVUs. However, during our review of these recommended values, we identified some concerns similar to those we recognized in prior years. Given the relative nature of the PFS and our obligation to ensure that the RVUs reflect relative resource use, we included descriptions of potential alternative approaches we might have taken in developing work RVUs that differed from the RUC-recommended values. We sought comment on both the RUC-recommended values, as well as the alternatives considered. Several commenters generally supported the proposed use of the RUC-recommended work RVUs, without refinement. Other commenters expressed concern about the effect of the misvalued code reviews on particular specialties and settings and disappointment with our proposed

approach for valuing codes for CY 2018. A detailed summary of the comments and our responses can be found in the CY 2018 PFS final rule (82 FR 53033–53035).

We clarified in response to commenters that we are not relinquishing our obligation to independently establish appropriate RVUs for services paid under the PFS. We will continue to thoroughly review and consider information we receive from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparative databases, comparison with other codes within the PFS, as well as consultation with other physicians and healthcare professionals within CMS and the federal government as part of our process for establishing valuations. Although generally proposing the RUC-recommended work RVUs for new, revised, and potentially misvalued codes was our approach for CY 2018, we note that we also included alternative values where we believed there was a possible opportunity for increased precision. We also clarified that as part of our obligation to establish RVUs for the PFS, we annually make an independent assessment of the available recommendations, supporting documentation, and other available information from the RUC and other commenters to determine the appropriate valuations. Where we concur that the RUC's recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we propose those values as recommended. Additionally, we will continue to engage with stakeholders, including the RUC, with regard to our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process.

2. Methodology for Establishing Work RVUs

For each code identified in this section, we conducted a review that included the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs generally included, but had not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assessed the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process.

Components that we used in the building block approach may have included preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. We used the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. The statute specifically defines the work component as the resources in time and intensity required in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refined the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently, there are preservice time packages for services typically furnished in the facility setting (for example, preservice time packages reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the nonfacility setting.

We developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an evaluation and management (E/M) service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjusted the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we removed 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also removed a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we did not believe the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

The following paragraphs contain a general discussion of our approach to reviewing RUC recommendations and developing proposed values for specific codes. When they exist we also include a summary of stakeholder reactions to

our approach. We note that many commenters and stakeholders have expressed concerns over the years with our ongoing adjustment of work RVUs based on changes in the best information we had regarding the time resources involved in furnishing individual services. We have been particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we used to make the adjustments is derived from their survey process. We are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We have observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for a significant portion of codes for which we recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we have adjusted work RVUs to account for significant changes in time, we have started by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we have employed the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these, we sometimes used the relationship between the old time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we have used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe were not otherwise reflected in the RUC-recommended value. If we believed that such changes in time were already accounted for in the RUC's recommendation, then we did not make such adjustments. Likewise, we did not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We used the ratios to identify potential work RVUs and considered these work RVUs as potential options relative to the values developed through other options.

We do not imply that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we have believed that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC's recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we have generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several stakeholders, including the RUC, have expressed general objections to our use of these methodologies and deemed our actions in adjusting the recommended work RVUs as inappropriate; other stakeholders have also expressed general concerns with CMS refinements to RUC recommended values in general. In the CY 2017 PFS final rule (81 FR 80272 through 80277) we responded in detail to several comments that we received regarding this issue. In the CY 2017 PFS proposed rule, we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives. As described earlier in this section, crosswalks to key reference or similar codes is one of the many methodological approaches we have employed to identify potential values that reconcile the RUC-recommend work RVUs with the recommended time values when the RUC-recommended work RVUs did not appear to account for significant changes in time.

Following the publication of the CY 2019 PFS proposed rule, we received several comments noting that there was some confusion in the terminology between ''reference services'' and ''crosswalks.'' Commenters stated that ''reference services'' are services indicated by the specialty society or the RUC as a good comparator that demonstrates relativity using magnitude estimation as requiring similar physician work, time, intensity and complexity. ''Key reference services'' are the top two services selected by the survey respondents as most similar to the code being surveyed. By contrast, ''crosswalks'' are services that have similar or exact intraservice time and require the same physician work (that is, have the same work RVU), and the term ''crosswalk'' should only be used when making a comparison to a CPT code with the identical work RVU. The commenters noted that these terms were used interchangeably in the proposed rule when they have distinct and separate meanings.

In response to the commenters, we would like to clarify that the terms ''reference services'', ''key reference services'', and ''crosswalks'' as described by the commenters are part of the RUC's process for code valuation. These are not terms that we created, and we do not agree that we necessarily must employ them in the identical fashion for the purposes of discussing our valuation of individual services that come up for review. However, in the interest of minimizing confusion and providing clear language to facilitate stakeholder feedback, we will seek to limit the use of the term, ''crosswalk,'' to those cases where we are making a comparison to a CPT code with the identical work RVU.

We look forward to continuing to engage with stakeholders and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes; and will continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process. We refer readers to the detailed discussion in this section of the final valuation considered for specific codes. Table 13 contains a list of codes for which we are finalizing work RVUs; this includes all codes for which we received RUC recommendations by February 10, 2018. The finalized work RVUs, work time and other payment information for all CY 2019 payable codes are available on the CMS website under downloads for the CY 2019 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*). Table 13 also contains the CPT code descriptors for all new, revised, and potentially misvalued codes discussed in this section.

3. Methodology for the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code by code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table 14 details our refinements of the RUC's direct PE recommendations at the code-specific level. In this final rule, we address several refinements that are common across codes, and refinements to particular codes are addressed in the portions of this section that are dedicated to particular codes. We note that for each refinement, we indicate the impact on direct costs for that service. We note that, on average, in any case where the impact on the direct cost for a particular refinement is $0.30 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. We also note that nearly half of the refinements listed in Table 14 result in changes under the $0.30 threshold and are unlikely to result in a change to the RVUs.

We also note that the finalized direct PE inputs for CY 2019 are displayed in the CY 2019 direct PE input database, available on the CMS website under the downloads for the CY 2019 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. The inputs displayed there have been used in developing the final CY 2019 PE RVUs as displayed in Addendum B.

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time would also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also note that we believe these same assumptions would apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question would be available if the room is not being occupied by a particular patient. For additional information, we refer readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of this final rule, Determination of Practice

Expense Relative Value Units (PE RVUs), for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC's recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. Some recommendations, however, include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2019, we received invoices for several new supply and equipment items. Tables 14 and 15 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this final rule, we encouraged stakeholders to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encouraged stakeholders to submit invoices or other information to improve the accuracy of pricing for these items in the direct PE database by February 10th of the following year for consideration in future rulemaking, similar to our process for consideration of RUC recommendations.

We remind stakeholders that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 14 and 15 also include the number of invoices received and the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that stakeholders will note the impact the particular price might have on PE relativity, as well as to identify items that are used frequently, since we believe that stakeholders are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs and we encourage stakeholders to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we included the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the final PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our direct PE inputs do not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address proposed code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We note that the public use files for the PFS proposed and final rules for each year display the services subject to the MPPR lists on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services. We also include a list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap for the upcoming calendar year. The public use files for CY 2019 are available on the CMS website under downloads for the CY 2019 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* For more information regarding the history of the MPPR policy, we refer readers to the CY 2014 PFS final rule with comment period (78 FR 74261–74263). For more information regarding the history of the OPPS cap, we refer readers to the CY 2007 PFS final rule with comment period (71 FR 69659–69662).

4. Valuation of Specific Codes for CY 2019

(1) Fine Needle Aspiration (CPT Codes 10021, 10004, 10005, 10006, 10007, 10008, 10009, 10010, 10011, 10012, 76492, 77002 and 77021)

CPT code 10021 was identified as part of the OPPS cap payment proposal in CY 2014 (78 FR 74246–74248), and it was reviewed by the RUC for direct PE inputs only as part of the CY 2016 rule cycle. Afterwards, CPT codes 10021 and 10022 were referred to the CPT Editorial Panel to consider adding additional clarifying language to the code descriptors and to include bundled imaging guidance due to the fact that imaging had become typical with these services. In June 2017, the CPT Editorial Panel deleted CPT code 10022, revised CPT code 10021, and created nine new codes to describe fine needle aspiration procedures with and without imaging guidance. These ten codes were surveyed and reviewed for the October 2017 and January 2018 RUC meetings. Several imaging services were also reviewed along with the rest of the code family, although only CPT code 77021 was subject to a new survey.

For CY 2019, we proposed the RUC-recommended work RVU for seven of the ten codes in this family. Specifically, we proposed a work RVU of 0.80 for CPT code 10004 (Fine needle aspiration biopsy; without imaging guidance; each additional lesion), a work RVU of 1.00 for CPT code 10006 (Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion), a work RVU of 1.81 for CPT code 10007 (Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion), a work RVU of 1.18 for CPT code 10008 (Fine needle aspiration biopsy, including fluoroscopic guidance; each additional lesion), and a work RVU of

1.65 for CPT code 10010 (Fine needle aspiration biopsy, including CT guidance; each additional lesion). We also proposed to assign the recommended contractor-priced status to CPT codes 10011 (Fine needle aspiration biopsy, including MR guidance; first lesion) and 10012 (Fine needle aspiration biopsy, including MR guidance; each additional lesion) due to low utilization until these services are more widely utilized. In addition, we proposed the recommended work RVU of 1.50 for CPT code 77021 (Magnetic resonance guidance for needle placement (*e.g.,* for biopsy, fine needle aspiration biopsy, injection, or placement of localization device) radiological supervision and interpretation), as well as proposed to reaffirm the current work RVUs of 0.67 for CPT code 76942 (Ultrasonic guidance for needle placement (*e.g.,* biopsy, fine needle aspiration biopsy, injection, localization device), imaging supervision and interpretation) and 0.54 for 77002 (Fluoroscopic guidance for needle placement (*e.g.,* biopsy, fine needle aspiration biopsy, injection, localization device)).

We disagreed with the RUC-recommended work RVU of 1.20 for CPT code 10021 (Fine needle aspiration biopsy; without imaging guidance; first lesion) and proposed a work RVU of 1.03 based on a direct crosswalk to CPT code 36440 (Push transfusion, blood, 2 years or younger). CPT code 36440 is a recently reviewed code with the same intraservice time of 15 minutes and 2 additional minutes of total time. In reviewing CPT code 10021, we noted that the recommended intraservice time is decreasing from 17 minutes to 15 minutes (12 percent reduction), and the recommended total time is decreasing from 48 minutes to 33 minutes (32 percent reduction); however, the RUC-recommended work RVU is only decreasing from 1.27 to 1.20, which is a reduction of just over 5 percent. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 10021, we believed that it was more accurate to propose a work RVU of 1.03 based on a crosswalk to CPT code 36440 to account for these decreases in the surveyed work time.

We disagreed with the RUC-recommended work RVU of 1.63 for CPT code 10005 (Fine needle aspiration biopsy, including ultrasound guidance; first lesion) and proposed a work RVU of 1.46. Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference in work between CPT codes 10021 and 10005 is equivalent to the recommended interval of 0.43 RVUs. Therefore, we proposed a work RVU of 1.46 for CPT code 10005, based on the recommended interval of 0.43 additional RVUs above our proposed work RVU of 1.03 for CPT code 10021. The proposed increment of 0.43 RVUs above CPT code 10021 was also based on the use of two crosswalk codes: CPT code 99225 (Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of 3 key components); and CPT code 99232 (Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of 3 key components). Both of these codes have the same intraservice time and 1 additional minute of total time as compared with CPT code 10005, and both crosswalk codes share a work RVU of 1.39.

We disagreed with the RUC-recommended work RVU of 2.43 for CPT code 10009 (Fine needle aspiration biopsy, including CT guidance; first lesion) and we proposed a work RVU of 2.26. Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference in work between CPT codes 10021 and 10009 is equivalent to the recommended interval of 1.23 RVUs. Therefore, we proposed a work RVU of 2.26 for CPT code 10009, based on the recommended interval of 1.23 additional RVUs above our proposed work RVU of 1.03 for CPT code 10021. The proposed use of the recommended increment from CPT code 10021 was also based on the use of a crosswalk to CPT code 74263 (Computed tomographic (CT) colonography, screening, including image postprocessing), another CT procedure with 38 minutes of intraservice time and 50 minutes of total time at a work RVU of 2.28.

We noted that the recommended work pool is increasing by approximately 20 percent for the Fine Needle Aspiration family as a whole, while the recommended work time pool for the same codes is only increasing by about 2 percent. Since time is defined as one of the two components of work, we believed that this indicated a discrepancy in the recommended work values. We do not believe that the recoding of the services in this family has resulted in an increase in their intensity, only a change in the way in which they will be reported, and therefore, we do not believe that it would serve the interests of relativity to propose the recommended work values for all of the codes in this family. We believe that, generally speaking, the recoding of a family of services should maintain the same total work pool, as the services themselves are not changing, only the coding structure under which they are being reported. We also noted that through the bundling of some of these frequently reported services, it is reasonable to expect that the new coding system will achieve savings via elimination of duplicative assumptions of the resources involved in furnishing particular servicers. For example, a practitioner will not be carrying out the full preservice work twice for CPT codes 10022 and 76942, but preservice times were assigned to both of the codes under the old coding. We believe the new coding assigns more accurate work times and thus reflects efficiencies in resource costs that existed regardless of how the services were previously reported.

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Prepare room, equipment and supplies'' (CA013) activity to 3 minutes and to refine the clinical labor time for the ''Confirm order, protocol exam'' (CA014) activity to 0 minutes for CPT code 77021. This code did not previously have clinical labor time assigned for the ''Confirm order, protocol exam'' clinical labor task, and we do not have any reason to believe that the services being furnished by the clinical staff have changed, only the way in which this clinical labor time has been presented on the PE worksheets. We also noted that there is no effect on the total clinical labor direct costs in these situations, since the same 3 minutes of clinical labor time is still being furnished. We also proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving the Fine Needle Aspiration family of codes.

Comment: Several commenters disagreed with the CMS statement in the proposed rule that the RUC-recommended work pool was increasing by approximately 20 percent for this family of codes. Commenters stated that the work pool based on the RUC-recommended values would actually decrease by 15 percent and that the CMS work valuations were based on a flawed methodology that did not account for the associated savings with bundling the image guidance codes. One of the commenters supplied a table with data to support the claim that the work

pool based on the RUC-recommended values would decrease by 15 percent rather than increasing by 20 percent.

Response: We disagree with the commenters that the work pool would decrease by 15 percent if we were to finalize the RUC recommendations. We investigated the data in the table submitted by the commenters, and we believe that there are several methodological flaws in the analysis it contains. First, there are a number of 0.00 work RVUs listed in the ''RUC Recommended RVUs'' column for the new codes, which results in an incorrect amount of ''New/Rev Total RVUs'' when multiplied by the utilization for the new codes. As an example, CPT code 10005 has approximately 135,000 services that are counted as having a work RVU of 0.00 in this table instead of the RUC-recommended work RVU of 1.63, which undercounts the total number of RVUs by a wide margin. Second, the values in the ''Total Source RVUs'' include the ratios from the utilization crosswalk (listed on the table as ''Percent''). We do not understand why these ratios would be used to calculate the total source RVUs, as this side of the work pool comparison is calculated from the utilization of the source codes times the work RVUs of the source codes. Third, the imaging guidance codes are not fully included in both sides of the comparison on this table, with their work RVUs included in the source RVU total but not in the new/revised RVU total. This uneven comparison results in an inaccurate tally of the work pools from before and after the coding revisions take place.

In the interest of providing transparency, we are including Table 12 with our work pool comparison for the Fine Needle Aspiration code family.

TABLE 12—FINE NEEDLE ASPIRATION WORK POOL COMPARISON

HCPCS code	Utilization source	Utilization destination	Work RVU source	Work pool source	Work RVU destination	Work pool destination	Work pool RVU change	Work pool % change
10021	23,755	21,380	1.27	30,169	1.20	25,655	−4,513	−15
10004	0	2,376	0.00	0	0.80	1,900	1,900	
10005	0	270,753	0.00	0	1.63	441,327	441,327	
10006	0	30,621	0.00	0	1.00	30,621	30,621	
10007	0	6,857	0.00	0	1.81	12,411	12,411	
10008	0	873	0.00	0	1.18	1,030	1,030	
10009	0	60,665	0.00	0	2.43	147,416	147,416	
10010	0	6,831	0.00	0	1.65	11,271	11,271	
10011	0	83	0.00	0	C	0	0	
10012	0	3	0.00	0	C	0	0	
10022	186,455	0	1.27	236,798	0.00	0	−236,798	−100
76942	558,081	488,321	0.67	373,914	0.67	327,175	−46,739	−13
7694226	641,346	561,178	0.67	429,702	0.67	375,989	−53,713	−13
76942TC	8,588	7,515	0.00	0	0.00	0	0	
77002	311,280	308,790	0.54	168,091	0.54	166,746	−1,345	−1
7700226	180,964	179,516	0.54	97,721	0.54	96,939	−782	−1
77002TC	7,936	7,873	0.00	0	0.00	0	0	
77012	9,343	7,792	1.16	10,838	1.50	11,688	850	8
7701226	194,611	162,306	1.16	225,749	1.50	243,458	17,710	8
77012TC	469	391	0.00	0	0.00	0	0	
77021	1,481	1,432	1.50	2,222	1.50	2,148	−73	−3
7702126	1,038	1,004	1.50	1,557	1.50	1,506	−51	−3
77021TC	67	65	0.00	0	0.00	0	0	
Totals	2,125,414	2,126,622		1,576,760		1,897,282	320,523	20

We continue to believe that the RUC-recommended work pool is increasing by approximately 20 percent for the Fine Needle Aspiration family as a whole, and that this percentage increase suggests that CPT codes 10021, 10005, and 10009 are more accurately valued at the CMS proposed work RVUs.

Comment: Several commenters disagreed that this code family will achieve savings via elimination of duplicative assumptions of the resources involved in furnishing particular services. Commenters stated that there is no overlap between the current descriptions of work for the bundled codes, and that CPT code 10022 is never performed on the same patient without an image guidance code and the image guidance codes are never performed on the same patient without a corresponding procedure code. The commenters stated that any associated reduction in payment would be due to other factors, not due to the code bundling.

Response: We disagree with the commenters that there would be no savings achieved via elimination of duplicative assumptions of the resources involved in furnishing particular services. As we stated in the proposed rule, a practitioner will not be carrying out the full preservice work twice for CPT codes 10022 and 76942, but preservice times were assigned to both of the codes under the old coding. In similar fashion, these codes both separately include immediate postservice work time for dictating a report in their clinical vignettes. This is an example of how savings are achieved via elimination of duplicative assumptions of resources, as the practitioner will only dictate a single report in the newly created CPT code 10005 that bundles these two services together. We continue to believe that the new coding assigns more accurate work times and thus reflects efficiencies in resource costs that existed regardless of how the services were previously reported.

Comment: One commenter stated that while it may be true mathematically that the work pool for this family of codes was increasing by 20 percent, using this observation as the sole basis to implement work value relies on incorrect assumptions which do not adhere to current relativity-based RUC methodologies. The commenter stated that the rationale proposed by CMS incorrectly implies that the decrease in time as reflected in survey values must equate to a one to one or linear decrease in the valuation of work RVUs and fails to recognize changes in intensity that have taken place over time.

Response: We disagree with the commenter that our analysis of changes in the work pool for this family of codes was the sole basis for the proposed refinements to the work RVUs. While

this was an important factor in our analysis of the work valuation of individual codes, we also detailed in the proposed rule our use of time ratios, increments, and crosswalk codes as part of our larger methodology to determine work RVUs. We specifically stated that we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, but rather that we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. We do consider changes in intensity that have taken place over time as part of our analysis of work valuation, as demonstrated by the fact that we proposed the RUC-recommended work RVUs for seven of the ten codes in this family.

Comment: One commenter disagreed that the work pool for a family of revised codes should be similar before and after the valuation of the new codes. The commenter stated that by separating different modalities into their own codes, the appropriate time and intensity differences for these services were more accurately reflected in the recommended RVUs, and the work pool appropriately expanded to reflect these differences. The commenter cited the example of CPT code 10022 being unable to account for different patients receiving a biopsy using ultrasound or CT technology.

Response: We agree with the commenter that the work pool for a revised code family does not always need to be similar before and after the valuation of the new codes. However, the commenter did not address our rationale for why we believe that an increase in the work pool would be inaccurate for this particular family of codes, which was based on the observation that the RUC-recommended work pool was increasing by approximately 20 percent while the RUC-recommended work time pool for the same codes was only increasing by about 2 percent. In a situation where prior coding was unable to account for newer and more complex forms of treatment, we would expect the work time pool to expand alongside the work pool, since these more complex and intensive procedures would take more time to furnish.

Comment: A few commenters stated that since CMS changed the multiple procedure indicator from ''0'' to ''2'' for all Fine Needle Aspiration biopsy initial lesion codes for CY 2019, the commenter believes that using XXX global codes as references was incorrect. The commenter instead recommended that CMS review similar minor procedures that have a 0-day global designation, which suggested that a higher work RVU could have been supported.

Response: We continue to believe that codes should generally be compared to codes with the same global period. Codes with a 0-day global period bundle other services that take place on the same day as the procedure into the valuation of the code, whereas such bundling is not included in codes with an XXX global period. We do not agree that it would have been more accurate to use codes with a 0-day global period as references for the codes in this family.

Comment: Many commenters disagreed with the proposed work RVU of 1.03 for CPT code 10021 and stated that CMS should finalize the RUC-recommended work RVU of 1.20. Commenters stated that this service has a new coding structure as compared to the past, and that the prior review was last carried out in 1995 when physician work time was evaluated with much less rigor. Commenters stated that the old time values were also based on a crosswalk and not a survey, and that therefore the drop in work time did not warrant a proportional change in work RVU as the previous times were inaccurate.

Response: We agree that it is important to use the most recent data available regarding time, and we note that when many years have passed between when time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The times currently associated with codes play a very important role in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had routinely been overestimated, this would undermine the relativity of the work RVUs on the PFS in general, given the process under which codes are often valued by comparisons to codes with similar times, and it also would undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS. Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times used in the PFS ratesetting processes are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we want to reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of prior work time values in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: Several commenters stated the CMS rationale for the proposed work RVU for CPT code 10021 incorrectly implies that the decreased time reflected in survey values should have a one-to-one decrease in value, or a linear decrease in the valuation of work RVUs. Commenters stated that CMS incorrectly assumed that there are no differences in how work was valued in 1995 and how it is valued now.

Response: We do not agree with the commenters' characterization of our statements, and believe it misinterprets our view on this matter. We specifically stated in the CY 2019 PFS proposed rule that we were not implying that the decrease in time as reflected in survey values must necessarily equate to a one-to-one or linear decrease in the valuation of work RVUs, both generally speaking and with regards to this particular CPT code (83 FR 35747). We recognize that intensity for any given procedure may change over several years or within the intraservice period. Nevertheless, since the two components of work are time and intensity, we believe that absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has specifically increased or the reduction in time occurs disproportionally in the less-intensive portions of the procedure, significant decreases in time should generally be reflected as decreases to work RVUs.

Comment: Several commenters disagreed with the use of CPT code 36440 as a crosswalk for the work RVU of CPT code 10021. Commenters stated that there were differences in site of service, patient population, and utilization between these two codes, which made CPT code 36440 a poor choice to use for work valuation. One commenter stated that CPT code 36440 is used to report a push transfusion of blood through an already established

access in a vessel, and does not carry the same risk and intensity as CPT code 10021, which involves accessing a lesion in the neck multiple times to aspirate biopsy specimens. Commenters supplied a chart depicting several comparator codes for 10021 that they stated were more appropriate choices for a crosswalk.

Response: We disagree with the commenters that CPT code 36440 is an inappropriate choice for a crosswalk code. While it is true that this code is typically performed on an inpatient basis and the patient population comprises neonates instead of adults, we note that these factors suggest that the patient population for CPT code 36440 is likely sicker and more complex than the patient population for CPT code 10021. These differences would, if anything, be grounds for a lower work RVU for CPT code 10021, not a higher work RVU. We continue to believe that CPT code 36440 is an appropriate choice for a crosswalk due to the highly similar work times and intensity as compared to CPT code 10021. As for the other comparator codes provided by the commenters, we do not agree that they would be more appropriate choices for a crosswalk as we believe that they have a higher intensity than the service described by CPT code 10021. In more general terms, we continue to believe that the nature of the PFS relative value system necessarily involves comparisons of all services to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: Many commenters disagreed with the proposed work RVU of 1.46 for CPT code 10005 and stated that CMS should finalize the RUC-recommended work RVU of 1.63. Commenters stated that CMS should use valid methods of evaluating services, such as survey data and magnitude estimation, instead of relying on an incremental difference in work RVUs between CPT codes 10021 and 10005.

Response: We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. We note that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service. We further note that we did not rely solely on an increment for our proposed work RVU for CPT code 10005, supporting our proposed valuation with the use of two reference codes: CPT codes 99225 and 99232. Both of these codes have the same intraservice time and 1 additional minute of total time as compared with CPT code 10005, and both reference codes share a work RVU of 1.39.

Comment: One commenter stated that they did not object to the CMS designation of 0.43 RVUs as the increment over CPT code 10021 for adding ultrasound guidance; however, the commenter objected to the assumption that the work value for CPT code 36440 offers an acceptable baseline.

Response: We continue to believe that a crosswalk to the work RVU of CPT code 36440 produces the most accurate valuation for baseline CPT code 10021.

Comment: Commenters disagreed with the proposed work RVU of 2.26 for CPT code 10009 and stated that CMS should finalize the RUC-recommended work RVU of 2.43. Commenters provided similar comments for CPT code 10009 as they provided for CPT code 10005, suggesting that the use of an incremental methodology was inaccurate and that CMS should use more valid methods of evaluating services, such as survey data and magnitude estimation.

Response: We continue to disagree with the commenters that the use of an increment is a less valid methodology for valuing services. As detailed in the response to the comment summary above for CPT code 10005, we believe the use of an incremental difference is appropriate, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. We further note that we did not rely solely on an increment for our proposed work RVU for CPT code 10009, supporting our proposed valuation with the use of a reference to CPT code 74263.

Comment: A commenter stated that in the CMS refinements to the direct PE inputs for CPT codes 77012 and 77021, CMS proposed to remove 1 minute from the CA014 activity code and proposed to add 1 minute to the CA013 activity code. The commenter stated that this refinement was inaccurate and encouraged CMS to modify this proposal by finalizing the RUC-recommended direct PE inputs for clinical labor.

Response: We address this subject in detail in the PE section of this final rule under the Changes to Direct PE Inputs for Specific Services heading (section II.B.3. of this final rule). For CPT codes 77012 and 77021, we are finalizing these clinical labor refinements as proposed.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for all of the codes in the Fine Needle Aspiration family as proposed.

(2) Biopsy of Nail (CPT Code 11755)

CPT code 11755 (Biopsy of nail unit (*e.g.,* plate, bed, matrix, hyponychium, proximal and lateral nail folds) (separate procedure)) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. For CY 2019, the HCPAC recommended a work RVU of 1.25 based on the survey median value.

We disagreed with the recommended value and proposed a work RVU of 1.08 for CPT code 11755 based on the survey 25th percentile value. We noted that the recommended intraservice time for CPT code 11755 is decreasing from 25 minutes to 15 minutes (40 percent reduction), and the recommended total time for CPT code 11755 is decreasing from 55 minutes to 39 minutes (29 percent reduction); however, the recommended work RVU is only decreasing from 1.31 to 1.25, which is a reduction of less than 5 percent. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 11755, we believed that it would be more accurate to propose the survey 25th percentile work RVU than the survey median to account for these decreases in the surveyed work time.

The proposed work RVU of 1.08 is also based on a crosswalk to CPT code 11042 (Debridement, subcutaneous tissue (includes epidermis and dermis, if performed); first 20 sq cm or less), which has a work RVU of 1.01, the same intraservice time of 15 minutes, and a similar total time of 36 minutes. We also noted that, generally speaking, working with extremities like nails tends to be less intensive in clinical terms than other services, especially as compared to surgical procedures. We believe that

this further supports our proposal of a work RVU of 1.08 for CPT code 11755.

We proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving CPT code 11755.

Comment: A few commenters stated that section 1848(c)(7) of the Act, as amended by section 220(e) of the Protecting Access to Medicare Act of 2014 (PAMA), specifies that for services that are not described by new and revised codes, if the total RVU for a service would be decreased by 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments must be phased in over a 2-year period. These commenters stated that, according to this requirement, CPT code 11755 should be subject to the phase-in for CY 2019.

Response: We agree that CPT code 11755 should be subject to the phase-in for CY 2019. Due to a technical error, we inadvertently neglected to apply the phase-in to the total RVU of this code in the facility setting for the proposed rule, and we are correcting this for the final rule.

Comment: Many commenters disagreed with the proposed work RVU of 1.08 for CPT code 11755 and stated that CMS should finalize the RUC-recommended work RVU of 1.25. Commenters urged CMS to view the survey and the HCPAC's recommendation for the survey median work value of 1.25 apart from the current work time and work RVU because the primary specialty that currently performs the service was not included in the prior survey conducted in 1993.

Response: We disagree with the commenters that the current work time and work RVU for CPT code 11755 should be viewed separately from the new recommended values. We do not pay differentially for services on the basis of specialty, and a change in the dominant specialty since the time of the last survey is not a reason to disregard the current work time and work RVUs in developing proposed work RVUs.

Comment: Commenters compared the proposed work RVU of CPT code 11755 to the work valuation of the top key reference service, CPT code 11730 (Avulsion of nail plate, partial or complete, simple; single). Commenters stated that the increment of work between CPT code 11730 of 1.05 and the CMS proposed value for CPT code 11755 of 1.08 was only 0.03 RVUs, which was not enough to account for the additional work involved in CPT code 11755 given that the latter code also had 50 percent more intraservice time. Commenters also expressed concerns with the CMS reference to CPT code 11042 at a work RVU of 1.01, stating that it required less physician work time and a less refined technique. Commenters stated that the service described by CPT code 11755 was more intense to perform because the physician has to be extremely careful not to accidentally hit the patient's bone while taking the biopsy. Commenters stated that the nail plate is typically difficult to remove during the process of the biopsy performed in the service described by CPT code 11755, and that the biopsy must be performed with extreme care to avoid injury to the surgeon or extension of the incision to the underlying bone, which carries the potential for an osteomyelitis and significant post-operative pain. Commenters again urged CMS to finalize the RUC-recommended values for this code.

Response: After reviewing the additional information about the risks inherent in the service provided by the commenters, we agree that it would be more accurate to finalize the RUC-recommended work RVU of 1.25 for CPT code 11755 to reflect the intensity of the procedure.

Comment: One commenter stated that CMS did not indicate what amount of service period time was removed from the calculation of the equipment time, and that this made it difficult to determine the accuracy of the refinements. The commenter requested more information about this change.

Response: For the basic instrument pack (EQ137) equipment, we removed the clinical labor for the CA024, CA027, CA029, and CA035 clinical labor activities in accordance with our standard equipment time formula for surgical instrument packs. For the other three equipment items, we removed the clinical labor for the CA027 and CA035 clinical labor activity codes in accordance with our standard equipment time formula for non-highly technical equipment.

After consideration of the public comments, we are finalizing the RUC-recommended work RVU of 1.25 for CPT code 11755. We are finalizing the direct PE inputs for this code as proposed.

(3) Skin Biopsy (CPT Codes 11102, 11103, 11104, 11105, 11106, and 11107)

In CY 2016, CPT codes 11100 (Biopsy of skin, subcutaneous tissue and/or mucous membrane (including simple closure), unless otherwise listed; single lesion) and 11101 (Biopsy of skin, subcutaneous tissue and/or mucous membrane (including simple closure), unless otherwise listed; each separate/additional lesion) were identified as potentially misvalued using a high expenditure services screen across specialties with Medicare allowed charges of $10 million or more. Prior to the January 2016 RUC meeting, the specialty society notified the RUC that its survey data displayed a bimodal distribution of responses with more outliers than usual. The RUC referred CPT codes 11100 and 11101 to the CPT Editorial Panel. In February 2017, the CPT Editorial Panel deleted these two codes and created six new codes for primary and additional biopsy based on the thickness of the sample and the technique utilized.

For CY 2019, we proposed the RUC-recommended work RVUs for five of the six codes in the family. We proposed a work RVU of 0.66 for CPT code 11102 (Tangential biopsy of skin, (*e.g.,* shave, scoop, saucerize, curette), single lesion), a work RVU of 0.83 for CPT code 11104 (Punch biopsy of skin, (including simple closure when performed), single lesion), a work RVU of 0.45 for CPT code 11105 (Punch biopsy of skin, (including simple closure when performed), each separate/additional lesion), a work RVU of 1.01 for CPT code 11106 (Incisional biopsy of skin (*e.g.,* wedge), (including simple closure when performed), single lesion), and a work RVU of 0.54 for CPT code 11107 (Incisional biopsy of skin (*e.g.,* wedge), (including simple closure when performed), each separate/additional lesion).

For CPT code 11103 (Tangential biopsy of skin, (*e.g.,* shave, scoop, saucerize, curette), each separate/additional lesion), we disagreed with the RUC-recommended work RVU of 0.38 and proposed a work RVU of 0.29. When we compared the RUC-recommended work RVU of 0.38 to other add-on codes in the RUC database, we found that CPT code 11103 would have the second-highest work RVU for any code with 7 minutes or less of total time, with the recommended work RVU noticeably higher than other related add-on codes, and we did not agree that the tangential biopsy service being performed should have an anomalously high work value in comparison to other similar add-on codes. Our proposed work RVU of 0.29 was based on a crosswalk to CPT code 11201 (Removal of skin tags, multiple fibrocutaneous tags, any area; each additional 10 lesions, or part thereof), a clinically related add-on procedure with 5 minutes of intraservice and total time as opposed to the surveyed 6 minutes for

CPT code 11103. We also noted that the intraservice time ratio between CPT code 11103 and the recommended reference code, CPT code 11732 (Avulsion of nail plate, partial or complete, simple; each additional nail plate), was 75 percent (6 minutes divided by 8 minutes). This 75 percent ratio when applied to the work RVU of CPT code 11732 also produced a work RVU of 0.29 (0.38 * 0.75 = 0.29). Finally, we also supported the proposed work RVU through a crosswalk to CPT code 33508 (Endoscopy, surgical, including video-assisted harvest of vein(s) for coronary artery bypass procedure), which has a higher intraservice time of 10 minutes but a similar work RVU of 0.31. We believed that our proposed work RVU of 0.29 for CPT code 11103 better serves the interests of relativity, as well as better fitting with the other recommended work RVUs within this family of codes.

For the direct PE inputs, we proposed to remove the 2 minutes of clinical labor time for the ''Review home care instructions, coordinate visits/prescriptions'' (CA035) activity for CPT codes 11102, 11104, and 11106. These codes are typically billed with a same day E/M service, and we believe that it would be duplicative to assign clinical labor time for reviewing home care instructions given that this task would typically be done during the same day E/M service. We also proposed to refine the equipment times in accordance with our standard equipment time formulas.

We proposed to refine the quantity of the ''gown, staff, impervious'' (SB024) and the ''mask, surgical, with face shield'' (SB034) supplies from 2 to 1 for CPT codes 11102, 11104, and 11106. We proposed to remove one gown and one surgical mask from these codes as duplicative since these supplies are also included within the surgical instrument cleaning pack (SA043). We also proposed to remove all of the supplies in the three add-on procedures (CPT codes 11103, 11105, and 11107) that were not contained in the previous add-on procedure for this family, CPT code 11101. We do not believe that the use of these supplies would be typical for the ''each additional lesion'' add-on codes, as these supplies are all included in the base codes and are not currently utilized in CPT code 11101. We noted that the recommended direct PE costs for the three new add-on codes represent an increase of approximately 500 percent from the direct PE costs for CPT code 11101, and believe that this is largely due to the addition of these new supplies.

The following is a summary of the public comments we received on our proposals involving the Skin Biopsy family of codes.

Comment: Many commenters disagreed with the proposed work RVU of 0.29 for CPT code 11103 and stated that CMS should finalize the RUC-recommended work RVU of 0.38. Commenters disagreed that CPT code 11103 would have the second-highest work RVU for any code with 7 minutes or less of total time, stating that the total number of add-on codes with RUC total time of 7 minutes or less is 18. Commenters stated that only five of these services have total time of 6 or 7 minutes and the rest were lower, thus the majority of the work RVUs among these services were lower and not comparable. Commenters stressed that the RUC-recommended work RVU of 0.38 for CPT code 11103 was appropriate since the service is performed on a separate site than the base code and there is additional physician work to transition to a different site. Commenters stated that the RUC's direct crosswalk to CPT code 11732 (Avulsion of nail plate, partial or complete, simple; each additional nail plate), which describes procedures with significant physician effort in removing a nail plate with its anesthesia and hemostasis challenges, was a much better comparator to CPT code 11103 which involves the biopsy of a vascular tumor, typically on the face. Commenters stated that the proposed crosswalk to CPT code 11201 at a work RVU of 0.29 was too low to maintain relativity within the family of codes. One commenter stated that the type of skin biopsies performed in CPT code 11103 can result in the detection of carcinoma, melanoma, sarcoma/lymphoma, and other dangerous pathologies, and that making these diagnoses can save lives and ultimately decrease Medicare spending.

Response: After reviewing the additional information provided by the commenters, we agree that it would be more accurate to finalize the RUC-recommended work RVU of 0.38 for CPT code 11103 as the proposed work RVU was too low to maintain relativity within the family of codes.

Comment: Commenters disagreed with many of the refinements made by CMS to the direct PE inputs for this family of codes. Commenters stated that it was not appropriate to only include equipment and supply items in the new biopsy add-on codes that were included in the old add-on code (CPT code 11101) because the old codes were not specific enough to accurately distinguish between the three types of biopsies. Commenters cited as an example the fact that the predecessor CPT code 11101 did not include supply items that are necessary for the performance of the incisional biopsy.

Response: We appreciate the feedback from the commenters clarifying some of the differences between the predecessor code and the newly created add-on codes. We evaluated these differences on an individual case-by-case basis when determining whether or not to finalize the proposed refinements to the direct PE inputs.

Comment: Several commenters disagreed with the proposed refinements to the ''Review home care instructions, coordinate visits/prescriptions'' (CA035) clinical labor time. Commenters stated that home care instructions furnished in an E/M visit do not typically include wound care instructions, and that this instruction would be above and beyond instructions proved during an E/M visit in which no procedure is performed.

Response: We disagree with the commenters that wound care instructions would not be provided during the same day E/M visit. We continue to believe that it would be duplicative to assign clinical labor time for this task given the fact that a same day E/M visit is typical for these services. We believe that these instructions would be provided during the same day E/M visit.

Comment: Several commenters disagreed with the CMS proposal to refine the quantity of the ''gown, staff, impervious'' (SB024) and the ''mask, surgical, with face shield'' (SB034) supplies from 2 to 1 for CPT codes 11102, 11104, and 11106 since these supplies are also included within the surgical instrument cleaning pack (SA043). Commenters stated that the SA043 instrument cleaning pack is used in the dirty instrument room as part of the instrument cleaning and sterilization process and therefore cannot be used during a patient procedure as the instrument cleaning occurs after the procedure has been completed. Commenters stated that the personal protective equipment used during the patient procedure is considered contaminated after the procedure is concluded, and that personal protective equipment must be removed and disposed of prior to leaving the procedure room. As a result, these supplies were not duplicative and should not be removed.

Response: We disagree with the commenter and we continue to believe that the impervious staff gown and the surgical mask with face shield would be duplicative supplies given that they are also contained within the instrument cleaning pack. We do not believe that it

would be typical to remove the staff gown and face shield used during a procedure and put on new items afterwards for the purposes of cleaning instruments.

Comment: Commenters also disagreed with the CMS proposal to remove all of the supplies in the three add-on procedures (CPT codes 11103, 11105, and 11107) that were not contained in the previous add-on procedure for this family, CPT code 11101. For the ''drape, sterile, fenestrated 16in x 29in'' (SB011) supply, commenters stated that draping the new body site with a new sterile disposable drape was clinically indicated and would be typically done rather than take a drape used on one body site and then reposition it to a new body site for a new procedure. Commenters made the same claim for the sterile gloves (SB024) supply. For the ''needle, OSHA compliant (SafetyGlide)'' (SC080) and the ''scalpel, safety, surgical, with blade (#10–20)'' (SF047) supplies, commenters stated that the add-on represented a completely new body site and completely new skin lesion which would not allow the needle or scalpel to be un-sheathed and then reused at a separate body site out of fear of contamination. For the ''dressing, 12–7mm (Gelfoam)'' (SG033), ''dressing, 3in x 4in (Telfa, Release)'' (SG035), and ''gauze, sterile 4in x 4in (10 pack uou)'' (SG056) supplies, commenters stated that the add-on procedure is a second biopsy of a completely different body location and that these dressings/gauze pads would not be retained and then used on the second procedure out of fear of contamination. For the ''tape, surgical paper 1in (Micropore)'' (SG079) supply, commenters stated that the quantity of this supply in the base code was sufficient for one lesion, but not more than one lesion due to the simple fact that two lesions required more surgical tape than one lesion. Finally, for the ''swab, patient prep, 1.5 ml (chloraprep)'' (SJ081) supply, commenters stated that the process of skin prep starts with the center of the lesion and moves outward in concentric circles to avoid bringing pathogens back into the field. Commenters stated that the prep sponge cannot be reused on a separate area of skin as it will contaminate that area by transporting pathogens from the last concentric circle of the prior area, and that the supply quantity in the base code contained an amount insufficient to prep more than one area. Commenters requested CMS not to finalize the proposal to remove these supplies from the add-on codes.

Response: After considering the new information provided by the commenters regarding the clinical use of these supplies, we will not finalize our proposal to remove these supplies from the three add-on procedures (CPT codes 11103, 11105, and 11107). We will restore the RUC-recommended supplies for these three codes.

Comment: Several commenters disagreed with the refinements to the equipment time in CPT codes 11102, 11104, and 11106. The commenters stated that the removal of 2 minutes of equipment time was not appropriate and that equipment time needs to match clinical staff time.

Response: We agree with the commenter that changes in clinical labor time should be matched with corresponding changes in equipment time. However, since we continue to believe that the clinical labor to the ''Review home care instructions, coordinate visits/prescriptions'' (CA035) clinical labor time should be removed as duplicative with the same day E/M visit, we also continue to believe that the equipment times are accurate as proposed.

After consideration of the public comments, we are finalizing the RUC-recommended work RVUs for all of the codes in the Skin Biopsy family. We are finalizing the direct PE inputs as proposed, with the exception of the supplies from the three add-on procedures (CPT codes 11103, 11105, and 11107) as detailed above.

(4) Injection Tendon Origin-Insertion (CPT Code 20551)

CPT code 20551 (Injection(s); single tendon origin/insertion) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. For CY 2019, we proposed the RUC-recommended work RVU of 0.75 for CPT code 20551.

We proposed to maintain the current work RVU for many of the CPT codes identified as potentially misvalued on the screen of 0-day global services reported with an E/M visit 50 percent of the time or more. We noted that regardless of the proposed work valuations for individual codes, which may or may not retain the same work RVU, we continue to have reservations about the valuation of 0-day global services that are typically billed with a separate E/M service with the use of Modifier 25 (indicating that a significant and separately identifiable E/M service was provided on the same day). As we stated in the CY 2017 PFS final rule (81 FR 80204), we continue to believe that the routine billing of separate E/M services in conjunction with a particular code may indicate a possible problem with the valuation of the code bundle, which is intended to include all the routine care associated with the service. We will continue to consider additional ways to address the appropriate valuation for these services.

For the direct PE inputs, we proposed to remove the clinical labor time for the ''Provide education/obtain consent'' (CA011) and the ''Review home care instructions, coordinate visits/prescriptions'' (CA035) activities for CPT code 20551. This code is typically billed with a same day E/M service, and we believe that it will be duplicative to assign clinical labor time for obtaining consent or reviewing home care instructions given that these tasks will typically be done during the same day E/M service. We also proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving CPT code 20551.

Comment: A few commenters supported our proposal to maintain the current work RVU for this code, as recommended by the RUC.

Response: We appreciate the support for our proposal from the commenters.

Comment: Several commenters disagreed with the proposed direct PE refinements to CPT code 20551. Commenters stated that they did not agree that the clinical labor taking place in activity codes CA011 and CA035 were duplicative and that the RUC is careful to remove any duplication with E/M visits. Commenters stated that the home care instructions in activity code CA035 refer directly to the tendon injection and may include discussion of care for the affected area and home restrictions. Commenters stated that this injection is more involved and invasive than a vaccination such as the ones taking place in CPT codes 90470 and 90471, which were allowed 3 minutes for ''F/u on physician's discussion w/ patient/parent & obtain actual consent signature'' and an additional 3 minutes for home care instructions and recording vaccine information.

Response: For the CA011 clinical labor activity, we agree with the commenters that there would be a need for some additional time to obtain consent for the injection, but we do not agree that it would be typical to require the full 3 minutes because we believe there would be some overlap with the same day E/M visit. In similar fashion, we believe that there would also be some overlap with the same-day E/M

visit for the home care instructions described in activity code CA035. We also note that there is 1 minute of clinical labor time assigned to the ''Check dressings & wound/home care instructions/coordinate office visits/ prescriptions'' clinical labor task for CPT code 90471 referenced by the commenters. As a result, we are finalizing the assignment of 1 minute of clinical labor time to both of the CA011 and CA035 activities for CPT code 20551. We are also finalizing an increase of 1 minute in the equipment time for the exam table (EF023) to a total of 15 minutes, in accordance with our standard time formula for non-highly technical equipment.

After consideration of the public comments, we are finalizing our proposal to maintain the current work RVU for CPT code 20551. We are finalizing the direct PE inputs with the refinements detailed above.

(5) Structural Allograft (CPT Codes 20932, 20933, and 20934)

In February 2017, the CPT Editorial Panel created three new codes to describe allografts. These codes were designated as add-on codes and revised to more accurately describe the structural allograft procedures they represent. For CY 2019, we proposed the RUC-recommended work RVUs for all three codes. We proposed a work RVU of 13.01 for CPT code 20932 (Allograft, includes templating, cutting, placement and internal fixation when performed; osteoarticular, including articular surface and contiguous bone), a work RVU of 11.94 for CPT code 20933 (Allograft, includes templating, cutting, placement and internal fixation when performed; hemicortical intercalary, partial (*i.e.,* hemicylindrical)), and a work RVU of 13.00 for CPT code 20934 (Allograft, includes templating, cutting, placement and internal fixation when performed; intercalary, complete (*i.e.,* cylindrical)).

These three new codes are all facility-only procedures with no recommended direct PE inputs.

We did not receive any comments on our proposals involving the Structural Allograft family of codes. Therefore we are finalizing the work RVUs for the codes in this family as proposed.

(6) Knee Arthrography Injection (CPT Code 27369)

CPT code 27370 (Injection of contrast for knee arthrography) repeatedly appeared on high volume growth screens between 2008 and 2016, and the RUC expressed concern that the high volume growth for this procedure was likely due to its being reported incorrectly as arthrocentesis or aspiration. In June 2017, the CPT Editorial Panel deleted CPT code 27370 and replaced it with a new code, 27369, to report injection procedure for knee arthrography or enhanced CT/MRI knee arthrography.

The RUC recommended a work RVU of 0.96 for CPT code 27369, which is identical to the work RVU for CPT code 27370 (Injection of contrast for knee arthrography). The RUC's recommendation is based on key reference service, CPT code 23350 (Injection procedure for shoulder arthrography or enhanced CT/MRI shoulder arthrography), with identical intraservice time (15 minutes) and total time (28 minutes) as the new CPT code and a work RVU of 1.00. The RUC notes that its recommendation is lower than the 25th percentile from the survey results, but that the work described by the service should be valued identically with the CPT code being replaced. We disagreed with the RUC's recommended work RVU for CPT code 27369. Both the total (28 minutes) and intraservice (15 minutes) times for the new CPT code are considerably lower than the deleted CPT code 27370. Based on the reduced times and the projected work RVU from the reverse building block methodology (0.60 work RVUs), we believe this CPT code should be valued at 0.77 work RVUs, supported by a crosswalk to CPT code 29075 (Application, cast; elbow to finger (short arm)), with total time of 27 minutes and intraservice time of 15 minutes. Therefore, we proposed a work RVU of 0.77 for CPT code 27369.

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Prepare room, equipment and supplies'' (CA013) activity to 3 minutes and to refine the clinical labor time for the ''Confirm order, protocol exam'' (CA014) activity to 0 minutes. The predecessor code for 27369, CPT code 27370, did not have clinical labor time assigned for the ''Confirm order, protocol exam'' clinical labor task, and we do not have any reason to believe that the services being furnished by the clinical staff have changed, only the way in which this clinical labor time has been presented on the PE worksheets. We also noted that there is no effect on the total clinical labor direct costs in these situations, since the same 3 minutes of clinical labor time is still being furnished.

We proposed to remove the clinical labor time for the ''Scan exam documents into PACS. Complete exam in RIS system to populate images into work queue'' (CA032) activity. CPT code 27369 does not include a PACS workstation among the recommended equipment, and the predecessor code 27370 did not previously include time for this clinical labor activity. We believe that data entry activities such as this task would be classified as indirect PE, as they are considered administrative activities and are not individually allocable to a particular patient for a particular service. We also proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving CPT code 27369.

Comment: We received one comment regarding our proposed work RVU for CPT code 27369 of 0.77 RVUs. The commenter disagreed with CMS's reference to CPT code 27370, which is being deleted, as a basis for evaluating whether the RUC's proposed work RVU for this CPT code (0.96) adequately accounts for the large reduction in time between the deleted code, CPT code 27370 and the new code, CPT code 27369. The commenter noted that it is particularly inappropriate for CMS to value codes on the basis of time differences when the comparison code had not been previously surveyed by the RUC. The commenter urged CMS to finalize the RUC-recommended work RVU for CPT code 27369 of 0.96.

Response: We use several parameters to review the work RVU for codes including, where applicable, refining the work RVUs in direct proportion to either total time or intraservice time based on the best available information regarding the time resources involved in furnishing particular services. We note that the reason the CPT Editorial Panel was asked to review the code was to prevent incorrect reporting of the code, not to reflect a fundamentally different service. The work involved in furnishing the service described by CPT code 27369 is not fundamentally different from the work involved in furnishing the service described by the deleted code. In such cases we do not believe it is inappropriate to compare the survey times for the new code to the existing time for the code that it is intended to replace as one of several parameters we consider in our review. We are finalizing a work RVU for CPT code 27369 of 0.77 as proposed.

Comment: A commenter stated that in the CMS refinements to the direct PE inputs for CPT code 27369, CMS proposed to remove 1 minute from the CA014 activity code and proposed to add 1 minute to the CA013 activity code. The commenter stated that this refinement was inaccurate and encouraged CMS to modify this proposal by finalizing the RUC-

recommended direct PE inputs for clinical labor.

Response: We addressed this subject in detail in the PE section of this final rule under the Changes to Direct PE Inputs for Specific Services heading (section II.B.3. of this final rule). For CPT code 27369, we are finalizing these clinical labor refinements as proposed.

Comment: One commenter agreed with the proposed CMS refinement to the CA032 clinical labor activity.

Response: We appreciate the support for our proposal from the commenter.

After consideration of the public comments, we are finalizing the direct PE inputs for CPT code 27369 as proposed.

(7) Application of Long Arm Splint (CPT Code 29105)

CPT code 29105 (Application of long arm splint (shoulder to hand)) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. For CY 2019, we proposed the RUC-recommended work RVU of 0.80 for CPT code 29105. For the direct PE inputs, we proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving CPT code 29105.

Comment: Some commenters expressed support for our proposal to accept the RUC-recommended work RVU for this code.

Response: We appreciate the support for our proposal from the commenters.

Comment: One commenter stated that CMS did not indicate what amount of service period time was removed from the calculation of the equipment time, and that this made it difficult to determine the accuracy of the refinements. The commenter requested more information about this change.

Response: For the five equipment items utilized in CPT code 29105, we removed the clinical labor for the CA035 clinical labor activity code in accordance with our standard equipment time formula for non-highly technical equipment.

After consideration of the public comments, we are finalizing the work RVU and direct PE inputs for CPT code 29105 as proposed.

(8) Strapping Lower Extremity (CPT Codes 29540 and 29550)

CPT codes 29540 (Strapping; ankle and/or foot) and 29550 (Strapping; toes) were identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. For CY 2019, we proposed the HCPAC-recommended work RVU of 0.39 for CPT code 29540 and the HCPAC-recommended work RVU of 0.25 for CPT code 29550.

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Provide education/obtain consent'' (CA011) activity from 3 minutes to 2 minutes for both codes, as this is the standard clinical labor time assigned for patient education and consent. We also proposed to remove the 2 minutes of clinical labor time for the ''Review home care instructions, coordinate visits/prescriptions'' (CA035) activity for both codes. CPT codes 29540 and 29550 are both typically billed with a same day E/M service, and we believe that it would be duplicative to assign clinical labor time for reviewing home care instructions given that this task would typically be done during the same day E/M service. We also proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving the Strapping Lower Extremity family of codes.

Comment: A few commenters supported our proposal to accept the HCPAC-recommended work RVUs.

Response: We appreciate the support for our proposal from the commenters.

Comment: Several commenters disagreed with the proposed direct PE refinements to CPT codes 29540 and 29550. Commenters stated that CMS mistakenly cited a standard for this activity of 2 minutes, however there is no set standard for CA011, and that 3 minutes is needed for clinical staff to perform this clinical activity.

Response: We disagree with the commenters that 3 minutes would be typically needed for the clinical staff to provide education and obtain consent in these procedures. We have typically assigned 2 minutes for this clinical labor activity unless we had a specific rationale for a higher amount of clinical labor time, and we continue to believe that this standard amount of clinical labor time would be the most accurate value for CPT codes 29540 and 29550.

Comment: Several commenters disagreed that the clinical labor for home care instructions and coordinating visits/prescriptions would be duplicative with the same day E/M office visit in these services. Commenters stated that these home care instructions directly pertain to the strapping procedure and would not be provided during an evaluation of the patient. Commenters stated that the strappings do not work unless left alone and taken care of in a specific manner, and that this important information is included in the home care instructions that the patient receives from clinical staff.

Response: We disagree with the commenters and we continue to believe that this clinical labor would be duplicative with the same day E/M visit. We believe that this clinical labor would take place during the same day E/M visit. Due to the way patients typically present in these procedures, we do not believe that the patients would typically need additional home care instructions above and beyond the E/M visit. We also note that these strapping procedures are frequently repeated for the same patient multiple times, and there would not be a need for repeated home care instructions for subsequent strapping procedures for the same patient. Any home care instructions taking place outside of the same day E/M visit would only be needed the first time that these procedures are performed on a patient, and as a result they would not be typical. As a result, we continue to believe that this clinical labor would not be typical.

Comment: One commenter stated that CMS did not indicate what amount of service period time was removed from the calculation of the equipment time, and that this made it difficult to determine the accuracy of the refinements. The commenter requested more information about this change.

Response: For the two equipment items utilized in these CPT codes, we removed the clinical labor for the CA035 clinical labor activity code in accordance with our standard equipment time formula for non-highly technical equipment.

After consideration of the public comments, we are finalizing the work RVU and direct PE inputs for CPT codes 29540 and 29550 as proposed.

(9) Bronchoscopy (CPT Codes 31623 and 31624)

CPT code 31623 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with

brushing or protected brushings) was identified on a high growth screen of services with total Medicare utilization of 10,000 or more that have increased by at least 100 percent from 2009 through 2014. CPT code 31624 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial alveolar lavage) was also included for review as part of the same family of codes. For CY 2019, we proposed the RUC-recommended work RVU of 2.63 for CPT codes 31623 and 31624.

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Complete post-procedure diagnostic forms, lab and x-ray requisitions'' (CA027) activity from 4 minutes to 2 minutes for CPT codes 31623 and 31624. Two minutes is the standard time, as well as the current time for this clinical labor activity, and we have no reason to believe that the time to perform this task has increased since the codes were last reviewed. We did not receive any explanation in the recommendations as to why the time for this activity would be doubling over the current values. We also proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving the Bronchoscopy family of codes.

Comment: Several commenters disagreed with the proposal to refine the clinical labor time for the ''Complete post-procedure diagnostic forms, lab and x-ray requisitions'' (CA027) activity from 4 minutes to 2 minutes for CPT codes 31623 and 31624. Commenters stated that there is no standard for the CA027 clinical labor activity and that the CMS logic to conform to such a standard lacks merit. Commenters also stated that these services require verification of samples, and completion of several lab forms and clearly requires more than the standard time for completing forms.

Response: We disagree with the commenters. While it is true that we have not formalized 2 minutes as a standard through rulemaking for this clinical labor activity code, we have typically assigned 2 minutes for the CA027 activity across a wide variety of codes. Out of the 168 HCPCS codes that have clinical labor time for the CA027 clinical labor activity in our database, 64 codes have 2 minutes of assigned clinical labor time while only 9 codes have 4 minutes of assigned clinical labor time, which indicates that 2 minutes is far more typical for this activity. More importantly, commenters did not address our statement that 2 minutes is the current time for this clinical labor activity, and we had no reason to believe that the time to perform this task has increased since the codes were last reviewed. As a result, we are finalizing our refinement to 2 minutes of clinical labor time for the CA027 activity.

After consideration of the public comments, we are finalizing the work RVU and direct PE inputs for CPT codes 31623 and 31624 as proposed.

(10) Pulmonary Wireless Pressure Sensor Services (CPT Codes 33289 and 93264)

In September 2017, the CPT Editorial Panel created a code to describe pulmonary wireless sensor implantation and another code for remote care management of patients with an implantable, wireless pulmonary artery pressure sensor monitor. For CY 2019, we proposed the RUC-recommended work RVU of 6.00 for CPT code 33289 (Transcatheter implantation of wireless pulmonary artery pressure sensor for long term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed), and the RUC-recommended work RVU of 0.70 for CPT code 93264 (Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional).

We did not propose any direct PE refinements for this code family.

The following is a summary of the public comments we received on our proposals involving the Pulmonary Wireless Pressure Sensor Services family of codes.

Comment: Commenters were supportive of our proposal of the RUC-recommended work RVUs.

Response: We thank commenters for their support.

After consideration of the public comments, we are finalizing the RUC-recommended work RVUs for CPT codes 33289 and 93264 as proposed.

(11) Cardiac Event Recorder Procedures (CPT Codes 33285 and 33286)

In February 2017, the CPT Editorial Panel created two new codes replacing cardiac event recorder codes to reflect new technology. For CY 2019, we proposed the RUC-recommended work RVU of 1.53 for CPT code 33285 (Insertion, subcutaneous cardiac rhythm monitor, including programming) and the RUC-recommended work RVU of 1.50 for CPT code 33286 (Removal, subcutaneous cardiac rhythm monitor).

We did not propose any direct PE refinements for this code family.

The following is a summary of the public comments we received on our proposals involving the Cardiac Event Recorder Procedures family of codes.

Comment: Commenters were supportive of our proposal of the RUC-recommended work RVUs.

Response: We thank commenters for their support.

After consideration of the public comments, we are finalizing the RUC-recommended work RVUs and direct PE inputs for CPT codes 33285 and 33286 as proposed.

(12) Aortoventriculoplasty With Pulmonary Autograft (CPT Code 33440)

In September 2017, the CPT Editorial Panel created one new code to combine the efforts of aortic valve and root replacement with subvalvular left ventricular outflow tract enlargement to allow for an unobstructed left ventricular outflow tract.

For CY 2019, we proposed the RUC-recommended work RVU of 64.00 for CPT code 33440 (Replacement, aortic valve; by translocation of autologous pulmonary valve and transventricular aortic annulus enlargement of the left ventricular outflow tract with valved conduit replacement of pulmonary valve (Ross-Konno procedure)). When this code is re-reviewed in a few years as part of the new technology screen, we look forward to receiving new recommendations on the whole family, including the related Ross and Konno procedures (CPT codes 33413 and 33412 respectively) that were used as references for CPT code 33440.

For the direct PE inputs, we proposed to refine the preservice clinical labor times to match our standards for 90-day global procedures. We proposed to refine the clinical labor time for the ''Coordinate pre-surgery services (including test results)'' (CA002) activity from 25 minutes to 20 minutes, to refine the clinical labor time for the ''Schedule space and equipment in facility'' (CA003) activity from 12 minutes to 8 minutes, and to refine the clinical labor time for the ''Provide pre-service education/obtain consent'' (CA004) activity from 26 minutes to 20 minutes. We also proposed to add 15 minutes of clinical labor time for the ''Perform regulatory mandated quality assurance activity (pre-service)'' (CA008) activity. We agreed with the recommendation that the total preservice clinical labor

time for CPT code 33440 is unchanged from the two reference codes at 75 minutes. However, we believed that the clinical labor associated with additional coordination between multiple specialties prior to patient arrival is more accurately described through the use of the CA008 activity code than by distributing this 15 minutes amongst the other preservice clinical labor activities. We previously established standard preservice times for 90-day global procedures, and did not want to propose clinical labor times above those standards for CPT code 33440. We also noted that there is no effect on the total clinical labor direct costs in this situation, since the same 15 minutes of preservice clinical labor time is still being furnished.

The following is a summary of the public comments we received on our proposals involving CPT code 33440.

Comment: A few commenters stated that they had no objections to the CMS proposal to refine the preservice clinical labor times for the direct PE inputs for code 33440 to match the 90-day global procedure standards and to add 15 minutes of clinical labor time to clinical labor activity code CA008. The commenters stated that they believed the RUC-recommended allocation of the preservice activities was appropriate, whereas activity code CA008 was not an accurate description of the additional work being done, and hoped that CMS would not use the allocation of time to CA008 as a way to reduce the preservice time in future rulemaking.

Response: We appreciate the feedback on our proposed direct PE refinements from the commenters.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for CPT code 33440 as proposed.

(13) Hemi-Aortic Arch Replacement (CPT Code 33866)

At the September 2017 CPT Editorial Panel meeting, the Panel created one new add-on code to report hemi-aortic arch graft replacement. For CY 2019, we proposed the RUC-recommended work RVU of 19.74 for CPT code 33866 (Aortic hemiarch graft including isolation and control of the arch vessels, beveled open distal aortic anastomosis extending under one or more of the arch vessels, and total circulatory arrest or isolated cerebral perfusion). CPT code 33866 is a facility-only procedure with no recommended direct PE inputs.

The following is a summary of the public comments we received on our proposals involving CPT code 33866.

Comment: We received several comments, including comments from the RUC. The RUC noted in its comment letter that at the April 2018 RUC meeting, the specialty societies determined that the family of services encompassing CPT code 33866 should be submitted to the CPT Editorial Panel for the following revisions: (1) To develop distinct codes for ascending aortic report for dissection and ascending aortic repair for other ascending aortic disease such as aneurysms and congenital anomalies. The specialties noted that there is a difference in the work associated with these procedures and now there is sufficient volume to allow for more accurate capture of the work and outcomes data for these distinct patient populations, which was not the case when the code was first developed, (2) Revise the descriptor for transverse arch code, CPT code 33870, to further clarify the difference in work between the new add on code, CPT code 33866, and (3) Revise the guidelines to provide additional instructions on the appropriate use of these codes. The RUC further noted that the specialty societies had already submitted a new coding proposal for consideration at the May 2018 CPT Editorial Panel for CPT 2020, which the RUC supported. Following the April 2018 RUC meeting, the RUC rescinded its interim value recommendation (work RVU of 19.74) to us for CPT code 33866 for CY 2019. One commenter noted, that although the RUC rescinded the interim work RVU of 19.74 due to a specialty societies' recommendation to submit the family of services to the CPT Editorial Panel, they encouraged CMS to consider using the work RVU of 19.74 as an interim value until the code can be re-surveyed and reviewed by the RUC. The commenter further noted that using the RUC-recommended value would allow physicians to be paid for the service in CY 2019, decreasing the burden of reporting a carrier-priced service to both the carriers and providers.

Response: While we recognize that the RUC rescinded its work RVU recommendation, we note that we proposed the RUC-recommended work RVU for valuation in CY 2019. We also want to remind commenters that we no longer establish interim valuations on a routine basis, and we are not convinced that establishing an interim valuation for CPT code 33866 is necessary. We will review any new coding that the CPT Editorial Panel provides for 2020, and will review any recommendations we receive timely from the RUC or other stakeholders for valuation through CY 2020 rulemaking.

After consideration of the public comments received, we are finalizing the RUC-recommended work RVUs for CPT code 33866 as proposed.

(14) Leadless Pacemaker Procedures (CPT Codes 33274 and 33275)

At the September 2017 CPT Editorial Panel meeting, the Panel replaced the five leadless pacemaker services, Category III codes, with the addition of two new CPT codes to report transcatheter leadless pacemaker procedures and revised five codes to include evaluation and interrogation services of leadless pacemaker systems.

For CPT code 33274 (Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (*e.g.,* fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (*e.g.,* interrogation or programming), when performed), we disagreed with the recommended work RVU of 8.77 and we proposed a work RVU of 7.80 based on a direct crosswalk to one of the top reference codes selected by the RUC survey participants, CPT code 33207 (Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular). This code has the same 60 minutes of intraservice time as CPT code 33274 and an additional 61 minutes of total time at a work RVU of 7.80. In our review of CPT code 33274, we noted that this reference code had an additional inpatient hospital visit of CPT code 99232 (Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of 3 key components) and a full instead of a half discharge visit of CPT code 99238 (Hospital discharge day management; 30 minutes or less) included in its 90-day global period. The combined work RVU of these two visits would be equal to 2.03. However, the recommended work RVU for CPT code 33274 was 0.97 work RVUs higher than CPT code 33207, despite having fewer of these visits and significantly less surveyed total time. While we acknowledge that CPT code 33274 is a more intense procedure than CPT code 33207, we do not believe that it should be valued almost a full RVU higher than the reference code given the fewer visits in the global period and the lower surveyed work time.

Therefore, we proposed to crosswalk CPT code 33274 to CPT code 33207 at the same work RVU of 7.80. The proposed work RVU was also supported through a reference crosswalk to CPT code 38542 (Dissection, deep jugular node(s)), which has 60 minutes of intraservice time, 198 minutes of total time, and a work RVU of 7.95. We believe that our proposed work RVU of

7.80 is a more accurate valuation for CPT code 33274, while still recognizing the greater intensity of this procedure in comparison to its reference code.

For CPT code 33275 (Transcatheter removal of permanent leadless pacemaker, right ventricular), we disagreed with the RUC-recommended work RVU of 9.56 and we proposed a work RVU of 8.59. Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference in work between CPT codes 33274 and 33275 is equivalent to the recommended interval of 0.79 RVUs. Therefore, we proposed a work RVU of 8.59 for CPT code 33275, based on the recommended interval of 0.79 additional RVUs above our proposed work RVU of 7.80 for CPT code 33274. We also noted that our proposed work RVU for CPT code 33275 situates it approximately halfway between the two reference codes from the survey, with CPT code 33270 (Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed) having an intraservice time of 90 minutes and a work RVU of 9.10, and CPT code 33207 having an intraservice time of 60 minutes and a work RVU of 7.80. CPT code 33275 has a surveyed intraservice time of 75 minutes and nearly splits the difference between them at our proposed work RVU of 8.59.

We did not propose any direct PE refinements for this code family.

The following is a summary of the public comments we received on our proposals involving the Leadless Pacemaker Procedures family of codes.

Comment: One commenter recommended that CMS adopt the RUC-recommended RVUs for both codes due to the newness of the procedures. The commenter stated that there might not be sufficient evidence or rationale for CMS to disagree with the RUC-recommended values, and again cited the newness of these procedures.

Response: We disagree with the commenter that the newness of a procedure would provide a sufficient rationale for finalizing the RUC-recommended work RVU for a new CPT code without any further consideration. Establishing valuations for newly created CPT codes is a routine part of maintaining the PFS, and we have historically valued new services since the inception of the resource-based relative value system. We also believe that RUC surveys are less likely to be representative of practitioners when evaluating new services, due to the fact that practitioners are not yet sufficiently experienced with the services to provide accurate evaluations, which is why we have been supportive of the RUC's policy to resurvey new services a few years after their creation when typical practice patterns have been more firmly established.

Comment: Many commenters disagreed with the proposed work RVUs for CPT codes 33274 and 33275 and stated that CMS should instead finalize the RUC-recommended work RVUs for these services. Commenters stated that CMS provided no qualitative or quantitative rationale to support their assumption that the difference in time between CPT codes 33274 and the top key reference from the survey (CPT code 33207) completely reflects the difference in intensity. Commenters stated that patients receiving leadless pacemakers are more complex and have more comorbidities and contraindications than transvenous patients, with more significant groin complications and more commonly present tamponade. Commenters stated that there were other issues that make CPT code 33274 more challenging, including: (1) Capture thresholds tend to change more than with transvenous devices; (2) There is a higher risk for complications including embolization and groin complications, which are not associated with tranvenous implants; and (3) Patients undergoing leadless pacemaker procedures are more likely to have chronic atrial fibrillation and poor venous access. Commenters emphasized that they believed the leadless pacemaker procedure described by CPT code 33274 was more intensive than the CMS crosswalk to CPT code 33207.

Response: We disagree with the commenters' assertion that we provided no qualitative or quantitative rationale to support our choice of a crosswalk to CPT code 33207. We stated in the proposed rule that in our review of CPT code 33274, we noted that this reference code had an additional inpatient hospital visit of CPT code 99232 and a full, instead of a half, discharge visit of CPT code 99238 included in its 90-day global period. We acknowledged that CPT code 33274 is a more intense procedure than CPT code 33207; however, we did not believe that it should be valued almost a full RVU higher than the reference code. We also supported the proposed work RVU through the use of a reference code, CPT code 38542, which was not addressed by the commenters.

We also disagree with the commenters that CPT code 33274 has so much additional intensity and complexity as compared to key reference CPT code 33207 that they should be valued at the same work RVU of 8.77. We note that the RUC's research panel selected preservice package 3, ''a straightforward patient and a difficult procedure'' for CPT code 33274. We believe this indicates that the patient population for CPT code 33274 would not be unusually difficult or complex as suggested by the commenters. We further note that the summary of recommendations for CPT code 33274 states that these patients are typically sent home from the facility the next day. In contrast, reference CPT code 33207 includes a full hospital inpatient day of post procedure care associated with CPT code 99322, as well as a full discharge visit instead of half of a discharge visit. We believe that this further suggests that the patient population for CPT code 33274 would not be more difficult or complex than the patient population for CPT code 33207. As we stated in the proposed rule, we continue to acknowledge that CPT code 33274 is a more intense procedure than CPT code 33207, but we do not believe that it should be valued almost a full RVU higher than the reference code given the fewer visits in the global period and the lower surveyed work time.

Comment: Commenters stated that CMS should use valid methods of evaluating services, such as survey data and magnitude estimation, instead of relying on an incremental difference in work RVUs between CPT codes 33274 and 33275.

Response: We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. We note that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service. We further note that we did not rely solely on an increment for our proposed work RVU for CPT code 33275, supporting our proposed valuation by noting that the CMS work RVU of 8.59 situated the code approximately halfway between the two reference codes from the survey, with CPT code 33270 having an intraservice time of 90 minutes and a work RVU of 9.10, and CPT code 33207 having an intraservice

time of 60 minutes and a work RVU of 7.80.

Comment: Several commenters stated that while these procedures described in CPT code 33275 will be rare, these patients will still have the elevated risk factors mentioned in discussion of CPT code 33274 and warranted the additional work indicated by survey respondents at the 25th percentile of the survey.

Response: We continue to believe that the patients in CPT code 33274 would not be more difficult or complex than the patients in CPT code 33207 for the reasons detailed above. We continue to believe that the relative difference in work between CPT codes 33274 and 33275 is equivalent to the recommended interval of 0.79 RVUs.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Leadless Pacemaker Procedures family as proposed.

(15) PICC Line Procedures (CPT Codes 36568, 36569, 36572, 36573, and 36584)

In CY 2016, CPT code 36569 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, without imaging guidance; age 5 years or older) was identified as potentially misvalued using a high expenditure services screen across specialties with Medicare allowed charges of $10 million or more. CPT code 36569 is typically reported with CPT codes 76937 (Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent real-time ultrasound visualization of vascular needle entry, with permanent recording and reporting) and 77001 (Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal) and was referred to the CPT Editorial Panel to have the two common imaging codes bundled into the code. In September 2017, the CPT Editorial Panel revised CPT codes 36568 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump; younger than 5 years of age), 36569 and 36584 (Replacement, complete, of a peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, through same venous access, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the replacement) and created two new CPT codes to specify the insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion.

For CY 2019, we proposed the RUC-recommended work RVU for two of the CPT codes in the family. We proposed the RUC-recommended work RVU of 2.11 for CPT code 36568 and the RUC-recommended work RVU of 1.90 for CPT code 36569.

For CPT code 36572 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; younger than 5 years of age), we disagreed with the RUC-recommended work RVU of 2.00 and proposed a work RVU of 1.82 based on a direct crosswalk to CPT code 50435 (Exchange nephrostomy catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation). CPT code 50435 is a recently reviewed code that also includes radiological supervision and interpretation with similar intraservice and total time values. In our review of CPT code 36572, we were concerned about the possibility that the recommended work RVU of 2.00 could create a rank order anomaly in terms of intensity with the other codes in the family. We noted that the recommended intraservice time for CPT code 36572 as compared to CPT code 36568, the most similar code in the family, is decreasing from 38 minutes to 22 minutes (42 percent), and the recommended total time is decreasing from 71 minutes to 51 minutes (38 percent); however, the recommended work RVU is only decreasing from 2.11 to 2.00, which is a reduction of just over 5 percent. We also noted that CPT code 36572 has a lower recommended intraservice time and total time as compared to CPT code 36569, yet has a higher recommended work RVU. Although we did not imply that the decreases in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs.

In the case of CPT code 36572, we believed that it would be more accurate to propose a work RVU of 1.82 based on a crosswalk to CPT code 50435 to better fit with the recommended work RVUs for CPT codes 36568 and 36569. The proposed work valuation was also based on the use of three additional crosswalk codes: CPT code 32554 (Thoracentesis, needle or catheter, aspiration of the pleural space; without imaging guidance), CPT code 43198 (Esophagoscopy, flexible, transnasal; with biopsy, single or multiple), and CPT code 64644 (Chemodenervation of one extremity; 5 or more muscles). All of these codes were recently reviewed with similar intensity, intraservice time, and total time values, and all three of them share a work RVU of 1.82.

For CPT code 36573 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; age 5 years or older), we disagreed with the RUC-recommended work RVU of 1.90 and proposed a work RVU of 1.70 based on maintaining the current work RVU of CPT code 36569. In our review of CPT code 36573, we were again concerned about the possibility that the recommended work RVU of 1.90 could create a rank order anomaly in terms of intensity with the other codes in the family. We noted that the recommended intraservice time for CPT code 36573 as compared to CPT code 36569, the most similar code in the family, was decreasing from 27 minutes to 15 minutes (45 percent), and the recommended total time was decreasing from 60 minutes to 40 minutes (33 percent); however, the RUC-recommended work RVU was exactly the same for these two codes at 1.90. Although we did not imply that the decreases in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs.

In the case of CPT code 36573, we believed that it would be more accurate to propose a work RVU of 1.70 based on maintaining the current work RVU of CPT code 36569. These two CPT codes describe the same procedure done with (CPT code 36573) and without (CPT code 35659) imaging guidance and radiological supervision and interpretation. Because the inclusion of the imaging described by CPT code 36573 has now become the typical case for this service, we believe that it is more accurate to maintain the current work RVU of 1.70 as opposed to

increasing the work RVU to 1.90, especially considering that the new surveyed work time for CPT code 36573 is lower than the current work time for CPT code 36569. The proposed work RVU of 1.70 was also based on a crosswalk to CPT code 36556 (Insertion of non-tunneled centrally inserted central venous catheter; age 5 years or older). This is a recently reviewed code with the same 15 minutes of intraservice time and the same 40 minutes of total time with a work RVU of 1.75.

For CPT code 36584, we disagreed with the RUC-recommended work RVU of 1.47 and proposed a work RVU of 1.20 based on maintaining the current work RVU. We noted that the recommended intraservice time for CPT code 36584 was decreasing from 15 minutes to 12 minutes (20 percent reduction), and the recommended total time was decreasing from 45 minutes to 34 minutes (25 percent reduction); however, the recommended work RVU was increasing from 1.20 to 1.47, an increase of approximately 23 percent. Although we did not imply that the decreases in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believed that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. We were especially concerned when the recommended work RVU is increasing despite survey results indicating that the work time is decreasing due to a combination of improving technology and greater efficiencies in practice patterns.

In the case of CPT code 36584, we believed that it would be more accurate to propose a work RVU of 1.20 based on maintaining the current work RVU for the code. Because the inclusion of the imaging has now become the typical case for this service, we believed that it was more accurate to maintain the current work RVU of 1.20 as opposed to increasing the work RVU to 1.47, especially considering that the new surveyed work time for CPT code 36584 was decreasing from the current work time. The proposed work RVU of 1.20 was also based on a crosswalk to CPT code 40490 (Biopsy of lip), which has the same total time of 34 minutes and slightly higher intraservice time at a work RVU of 1.22.

We noted that the RUC-recommended work pool was increasing by approximately 68 percent for the PICC Line Procedures family as a whole, while the RUC-recommended work time pool for the same codes was only increasing by about 22 percent. Since time is defined as one of the two components of work, we believe that this indicated a discrepancy in the recommended work values. We do not believe that the recoding of the services in this family has resulted in an increase in their intensity, only a change in the way in which they will be reported, and therefore, we did not believe that it would serve the interests of relativity to propose the RUC-recommended work values for all of the codes in this family. We believe that, generally speaking, the recoding of a family of services should maintain the same total work pool, as the services themselves are not changing, only the coding structure under which they are being reported. We also noted that, through the bundling of some of these frequently reported services, it is reasonable to expect that the new coding system will achieve savings via elimination of duplicative assumptions of the resources involved in furnishing particular servicers. For example, a practitioner would not be carrying out the full preservice work three times for CPT codes 36568, 76937, and 77001, but preservice times were assigned to all of the codes under the old coding. We believed the new coding assigns more accurate work times and thus reflects efficiencies in resource costs that existed but were not reflected in the services as they were previously reported.

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' (CA016) activity from 4 minutes to 2 minutes for CPT codes 36572 and 36573. We noted that the two reference codes for the two new codes, CPT codes 36568 and 36569, currently have 2 minutes assigned for this activity, and CPT code 36584 also has a recommended 2 minutes assigned to this same activity. We did not agree that the patient positioning would take twice as long for CPT codes 36572 and 36573 as compared to the rest of the family, and therefore proposed to refine both of them to the same 2 minutes of clinical labor time. We also proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving the PICC Line Procedures family of codes.

Comment: One commenter stated that CMS believes it is not accurate to ''increase'' work RVUs when survey results indicate that work time is ''decreasing'' due to improving technology and greater efficiencies in practice patterns. The commenter disagreed that the difference between the current codes (without imaging guidance) and the new bundled codes (with imaging guidance) could be characterized as an ''increase'' or a ''decrease,'' as it was inappropriate simply to compare the RVUs of the bundled codes to the existing codes, because the bundled codes include imaging services that involve significantly more intense physician work than PICC line insertion without imaging guidance.

Response: We disagree with the commenter that it is methodologically inappropriate to characterize changes in surveyed work time as ''increases'' or ''decreases''. As we stated in the proposed rule, we do not believe that the revised coding of the services in this family has changed the services themselves or resulted in an increase in their intensity, only changed in the way in which they will be reported under the new coding. CPT code 36572 is a new code resulting from the bundling together of CPT code 36568 with imaging guidance. The same services that were previously reported through a combination of CPT codes 36568 and 76397 will now be reported under CPT code 36572. We believe that it is highly relevant to note how the recommended work times for CPT code 36572 compare to the recommended work times for CPT code 36568, which includes noting that the intraservice time is decreasing from 38 minutes to 22 minutes (42 percent), and the recommended total time is decreasing from 71 minutes to 51 minutes (38 percent). We also do not agree that it is inappropriate to compare the RVUs of the bundled codes to the existing codes, as all of these procedures describe clinically similar procedures that together comprise a family of codes. In more general terms, we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes with clinically similar services are sometimes stronger comparator codes, we do not agree that codes must both include imaging guidance or not include imaging guidance to be used as a crosswalk.

Comment: Several commenters disagreed that the recoding of the services in the PICC line code family had only resulted in a change in the way that services will be reported, and stated that that the imaging-related services now bundled into CPT codes 36572, 36573, and 36584 are significantly more intense than PICC line insertion standing alone. One commenter stated that valuing a code using imaging guidance the same or less than the same code without imaging guidance is

specious and treats the use of imaging guidance as a negative work component when in fact there is additional work required in using imaging guidance. Commenters stated that the RUC-recommended values already reflect efficiencies in radiology work, and that the efficiency of radiologists should not diminish the RUC's recognition that their work is significantly more intense in these procedures.

Response: We disagree with the commenters that the addition of imaging guidance has made CPT codes 36572, 36573, and 36584 significantly more intense than the non-imaging guidance version of these procedures. While the incorporation of new technology can sometimes make services more complex and difficult to perform, it can also have the opposite effect by making services less reliant on manual skill and technique. We believe that if these procedures were significantly more intensive to perform, this would be reflected in the surveyed work times associated with these codes. However, the surveyed work times are instead decreasing in all three cases in comparison to the current non-imaging guidance version of the same services. As we stated in the proposed rule, we believe that the work times for these services are decreasing due to a combination of improving technology and greater efficiencies in practice patterns. Based on the RUC-recommended utilization crosswalk for these services, which has 90 to 95 percent of the utilization expected to be reported under the new codes that include imaging guidance, we believe that the use of imaging guidance has become typical for these services and does not represent a dramatic increase in intensity.

Comment: Many commenters disagreed with the proposed work RVU of 1.82 for CPT code 36572 and stated that CMS should finalize the RUC-recommended work RVU of 2.00. Commenters stated that the CMS use of a crosswalk to CPT code 50435 was unsupported on a clinical basis, with significant differences in work intensity and patient population. Commenters stated that CPT code 36572 involves establishing new deep venous access on a pediatric patient while ensuring maximum sterile barrier technique so as to prevent a hospital acquired infection, whereas CPT code 50435 involves the exchange of an existing catheter in an adult who understands the procedure involved and has had previous catheter exchanges to maintain patency. One commenter stated that the RUC crosswalk to CPT code 19283 (Placement of breast localization device(s) (*e.g.,* clip, metallic pellet, wire/needle, radioactive seeds)) was a more accurate choice because this service also uses imaging guidance to obtain de novo percutaneous access to a target and perform an intervention. Commenters stated that the crosswalk code would frequently be less intense than CPT code 36572.

Response: We disagree with the commenters that the work involved in CPT code 50435 would be less clinically intense than the work in CPT code 36572. We believe that the exchange of a nephrostomy catheter taking place in CPT code 50435 is more difficult than the placement of a breast localization device as in the RUC crosswalk to CPT code 19283, percutaneous; first lesion, including stereotactic guidance). We also disagree with the commenters that the crosswalk we identified lacks clinical similarity to CPT code 36572. Both the reviewed code and the crosswalk to CPT code 50435 involve the percutaneous placement of a catheter in a deep structure; we believe that this crosswalk code is more clinically similar than the RUC's choice of a crosswalk to CPT code 19283, which does not involve catheter placement at all.

Commenter: Several commenters disagreed that the RUC-recommended work RVU of 2.00 for CPT code 36572 would create a rank order anomaly within the family of codes. Commenters stated that since CPT code 36568 requires more physician time to complete than CPT code 36572 (38 versus 22 minutes intra-service time), the recommended work RVU of 2.00 for CPT code 36572 maintains the proper rank order within this family of services considering differences in patient population and differences in clinical intensity of work.

Response: The commenters did not address the concerns we expressed regarding a potential rank order anomaly within the family. We noted in the proposed rule that CPT code 36572 had a lower recommended intraservice time and total time as compared to CPT code 36569 (not CPT code 36568), yet had a higher recommended work RVU. We continue to believe that this creates the potential for a rank order anomaly within the family, and we do not believe that this discrepancy can be justified by differences in patient population and differences in clinical intensity of work.

Comment: Several commenters disagreed with the CMS statement that the reduced intraservice and total times in CPT code 36572 as compared to CPT code 36568 should result in a lower work value. Commenters stated that this was a simplistic comparison based on time, and that these were two technically different procedures, involving different patient populations and different service intensity. Commenters stated that each step in the non-image guided CPT code 36568 takes longer, though involves more periods of low intensity intraservice work as compared to CPT code 36572, where each procedural step is performed sequentially without the less intense intraservice work of the non-image guided CPT code 36568.

Response: We disagree with the commenters that the reductions in intraservice and total work time in CPT code 36572 as compared to CPT code 36568 should not result in a lower work value. Although we do not imply that the decreases in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we continue to believe that, since the two components of work are time and intensity, significant decreases in time should typically be reflected in decreases to work RVUs. We disagree that this is a simplistic comparison, and chose a crosswalk to CPT code 50435 to better fit with the recommended work RVUs for CPT codes 36568 and 36569.

We also do not agree that CPT codes 36568 and 36572 have significantly different patient populations and different service intensity. As we stated in the proposed rule, we do not believe that the revised coding of the services in this family has changed the services themselves or resulted in an increase in their intensity, only changed in the way in which they will be reported under the new coding. CPT code 36572 is a new code resulting from the bundling together of CPT code 36568 with imaging guidance. The same services that were previously reported through a combination of CPT codes 36568 and 76397 will now be reported under CPT code 36572. Given that 90 percent of the services that were formerly reported using CPT code 36568 will now be reported using CPT code 36572, we do not agree that these codes represent significantly different patient populations.

Comment: Many commenters disagreed with the proposed work RVU of 1.70 for CPT code 36573 and stated that CMS should finalize the RUC-recommended work RVU of 1.90. Commenters stated that CMS should not use a code value that is no longer in existence as the service (CPT code 36569) itself has been revised and is currently under review in this family. Commenters stated that the reference was therefore not valid to the old work RVU.

Response: We disagree with the commenters that it is somehow invalid to use a crosswalk to the current work RVU for CPT code 36569. It is not accurate to state that this code is no longer in existence, as it is being revised for CY 2019, not deleted. The RUC frequently recommends maintaining the current work RVU for reviewed codes rather than using a new work RVU from survey results when it believes that there is appropriate rationale to do so. Given that CPT code 36573 is a new code resulting from the bundling together of CPT code 36569 with imaging guidance, and that the use of imaging guidance has become typical in the performance of this service, we believe that it is appropriate to maintain the same work RVU for these services when they are reported under the new coding, especially in light of the fact that the surveyed intraservice work time for CPT code 36573 remains the same 15 minutes as the current intraservice work time for CPT code 36569.

Comment: Several commenters stated that CPT code 36573 involves a different patient population than CPT code 36569, as the patient population for CPT code 36573 does not have peripheral venous access present that can be used to obtain central venous access. Commenters stated that there is no evidence for a rank order anomaly within the codes in the family considering the differences in intensity and patient population.

Response: As we stated previously with regard to CPT codes 36568 and 36572, we also do not agree that CPT codes 36569 and 36573 have significantly different patient populations and different service intensity. As we stated in the proposed rule, we do not believe that the revised coding of the services in this family has changed the services themselves or resulted in an increase in their intensity, only changed in the way in which they will be reported under the new coding. CPT code 36573 is a new code resulting from the bundling together of CPT code 36569 with imaging guidance. The same services that were previously reported through a combination of CPT codes 36569 and 76397 will now be reported under CPT code 36573. Given that 95 percent of the services that were formerly reported using CPT code 36569 are expected to be reported using CPT code 36573, we do not agree that these codes represent noticeably different patient populations.

Comment: Several commenters disagreed with our use of CPT code 36556 as a reference code. Commenters stated that CPT code 36556 describes line placement in a larger and more central vein such as the internal jugular vein with known anatomical landmarks and a shorter distance between access and where the tip terminates centrally while CPT code 36573 describes access into a smaller vein without anatomic landmarks. Commenters stated that although imaging is inherent to CPT code 36573, the catheter is longer and there is a need to navigate the catheter through these peripheral and central veins for adequate placement, all of which would require more work.

Response: We disagree with the commenters that CPT code 36556 would not be an accurate reference code for CPT code 36573. CPT code 36556 describes the insertion of non-tunneled centrally inserted central venous catheter whereas CPT code 36573 describes the insertion of a peripherally inserted central venous catheter (PICC). We believe that these two codes, which both describe the insertion of central venous catheters, are highly similar to one another on a clinical basis and also from the perspective of work time, as they share the identical intraservice work time and total work time. Moreover, after further consideration, we are not able to identify any other more appropriate reference code for CPT code 36573 than CPT code 36556.

Comment: Many commenters disagreed with the proposed work RVU of 1.20 for CPT code 36584 and stated that CMS should finalize the RUC-recommended work RVU of 1.47. Commenters stated that CMS was completely dismissing the additional work that was bundled in with CPT code 36584 as part of the imaging guidance. Commenters stated that the RUC agreed that the recommended work RVU of 1.47 involves less time but involves a significant increase in intensity, and that the work RVU should not remain at the current work RVU of 1.20 as CPT code 36584 is now a bundled service.

Response: We disagree with the commenters that the bundling of a service or the addition of imaging guidance must necessarily increase the intensity of the service or the work RVU. As we stated above, while the incorporation of new technology can sometimes make services more complex and difficult to perform, it can also have the opposite effect by making services less reliant on manual skill and technique. We believe that if CPT code 36584 had become significantly more intensive to perform, this would be reflected in the surveyed work times associated with the code. However, the surveyed intraservice work time and total work time for CPT code 36584 are both decreasing from their current values. As we stated in the proposed rule, we believe that these work times are decreasing due to a combination of improving technology and greater efficiencies in practice patterns, and we believe that the use of imaging guidance has become now typical for CPT code 36584 and does not represent a dramatic increase in intensity.

Comment: Several commenters disagreed with the proposal to refine the clinical labor time for the ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' (CA016) activity from 4 minutes to 2 minutes for CPT codes 36572 and 36573. Commenters stated that this additional clinical labor time would be typical since it included positioning of the patient as well as positioning the two forms of imaging equipment which are being bundled into the code (fluoroscopy and ultrasound). Commenters stated that the equipment needs to be positioned in a manner that is specific to the procedure and the chosen extremity, and that it takes approximately 2 additional minutes to position the patient and the equipment for those codes which are imaging-guided as opposed to those procedures which are not. Commenters stated that this difference applies to the two new placement codes (CPT code 36572 and 36573) but not to the replacement code (CPT code 36584) as the equipment is limited to fluoroscopy and the positioning is slightly simpler as the site already contains a PICC line.

Response: After consideration of the new information provided by the commenters regarding the need for additional positioning time, we are not finalizing our proposed refinement to the CA016 clinical labor time. Due to this change in clinical labor time, we are also not finalizing any changes to the RUC-recommended equipment times.

After consideration of the public comments, we are finalizing the work RVUs for the codes in the PICC Line Procedures family as proposed. After considering public comments, we are not finalizing our proposed direct PE refinements, and we are instead finalizing the RUC-recommended direct PE inputs for all five codes.

(16) Biopsy or Excision of Inguinofemoral Node(s) (CPT Code 38531)

In September 2017, the CPT Editorial Panel created a new code to describe biopsy or excision of inguinofemoral node(s). A parenthetical was added to CPT codes 56630 (Vulvectomy, radical, partial) and 56633 (Vulvectomy, radical, complete) to instruct separate reporting of CPT code 38531 with radical

vulvectomy. This service was previously reported with unlisted codes.

CPT code 38531 (Biopsy or excision of lymph node(s); open, inguinofemoral node(s)) is a new CPT code describing a lymph node biopsy without complete lymphadenectomy. The RUC recommended a work RVU of 6.74 for CPT code 38531, with 223 minutes of total time and 65 minutes of intraservice time. We proposed the RUC-recommended work RVU of 6.74 for CPT code 38531. However, we were concerned that this CPT code is described as having a 10-day global period. The two CPT codes that are often reported together with this code, CPT codes 56630 and 56633, are both 90-day global codes. In addition, CPT code 38531 has a discharge visit and two follow up visits in the global period. This is consistent with the number of postoperative visits typically associated with 90-day global codes. Therefore, we proposed to assign a 90-day global indicator for CPT code 38531 rather than the 10-day global time period reflected in the RUC recommendation.

We did not propose any direct PE refinements for this code family.

Comment: Several commenters thanked us for proposing the RUC-recommended work RVU of 6.74 for CPT code 38531.

Response: We appreciate the support from commenters.

Comment: Several stakeholders disagreed with CMS's proposal to change the global status of this code from a 10-day global code to a 90-day global code. They maintained that there are no claims data available to assess how often CPT code 38531 will be billed together with CPT codes 56630 or 56633. Commenters also noted that there is no necessary direct correlation between the two codes (CPT code 56630 and CPT code 56633) having a 90-day global period and the new code having a 90-day global period.

Response: We agree with commenters that when two or more closely related CPT codes are billed together, there is no requirement for them to share the same global period. However, the amount of post service time and the number of visits in CPT code 38531 are consistent with other 90-day global codes. We continue to believe that CPT code 38531 should have a 90-day global period and we are finalizing that change as proposed.

Comment: A few commenters pointed out that CMS has the opportunity to review the global periods for new codes directly after CPT Editorial Panel meetings, and that CMS should have provided input regarding the code's global period at that time.

Response: While some of our staff have the opportunity to review global periods for new or modified CPT codes immediately after the CPT Editorial Panel meeting, the Agency does not systematically review or provide feedback on components of a CPT code, including global period, until we fully consider and address the code as part of the annual PFS notice-and-comment rulemaking process.

After consideration of the public comments, we are finalizing a work RVU of 6.74 for CPT code 38531 as proposed.

(17) Radioactive Tracer (CPT Code 38792)

CPT code 38792 (Injection procedure; radioactive tracer for identification of sentinel node) was identified as potentially misvalued on a screen of codes with a negative intraservice work per unit of time (IWPUT), with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes. For CY 2019, we proposed the RUC-recommended work RVU of 0.65 for CPT code 38792.

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Prepare room, equipment and supplies'' (CA013) activity to 3 minutes and to refine the clinical labor time for the ''Confirm order, protocol exam'' (CA014) activity to 0 minutes. CPT code 38792, as well as its alternate reference code, CPT code 78300 (Bone and/or joint imaging; limited area), did not previously have clinical labor time assigned for the ''Confirm order, protocol exam'' clinical labor task, and we do not have any reason to believe that the services being furnished by the clinical staff have changed, only the way in which this clinical labor time has been presented on the PE worksheets. We also note that there is no effect on the total clinical labor direct costs in these situations, since the same 3 minutes of clinical labor time is still being furnished. We also proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving CPT code 38792.

Comment: A commenter stated that they appreciated and supported our proposal to adopt the RUC-recommended work RVU of 0.65. The commenter also stated that they agreed with and supported the changes CMS proposed in clinical labor time and the standardized equipment time formulas.

Response: We appreciate the support for our proposals from the commenter.

After consideration of the public comments, we are finalizing the work RVU and direct PE inputs for CPT code 38792 as proposed.

(18) Percutaneous Change of G-Tube (CPT Code 43760)

CPT code 43760 (Change of gastrostomy tube, percutaneous, without imaging or endoscopic guidance) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. It was surveyed for the April 2017 RUC meeting and recommendations for work and direct PE inputs were submitted to CMS. However, the RUC also noted that because the data for CPT code 43760 were bimodal, it might be appropriate to consider changes in the CPT descriptors to better differentiate physician work. In September 2017, the CPT Editorial Panel deleted CPT code 43760 and will use two new CPT codes, CPT codes 43762 and 43763, which describe replacement of gastrostomy tube, with and without revision of gastrostomy tract, respectively. (See discussion of these codes below.) Therefore, we did not propose work or direct PE values for CPT code 43760.

Due to the impending deletion of CPT code 43760, we received no comments on this code.

(19) Gastrostomy Tube Replacement (CPT Codes 43762 and 43763)

In September 2017, the CPT Editorial Panel created two new codes that describe replacement of gastrostomy tube, with and without revision of gastrostomy tract, respectively. These two new codes were surveyed for the January 2018 RUC meeting and recommendations for work and direct PE inputs were submitted to CMS.

We proposed a work RVU of 0.75 for CPT code 43762 (Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; not requiring revision of gastrostomy tract.) and a work RVU of 1.41 for CPT code 43763 (Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; requiring revision of gastrostomy tract.), consistent with the RUC's recommendations for these new CPT codes.

For the direct PE inputs, we proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving the codes in the Gastrostomy Tube Replacement code family.

Comment: Several commenters stated that they appreciated CMS proposing the RUC-recommended work RVU for CPT codes 43762 and 43763.

Response: We appreciate the support for our proposals from the commenters.

Comment: One commenter stated that CMS did not indicate what amount of service period time was added to the calculation of the equipment time, and that this made it difficult to determine the accuracy of the refinements. The commenter requested more information about this change.

Response: For the four equipment items where we made time refinements, we added the clinical labor for the CA029 clinical labor activity in accordance with our standard equipment time formula for non-highly technical equipment.

After consideration of the public comments, we are finalizing the work RVU and direct PE inputs for the codes in the as Gastrostomy Tube Replacement code family as proposed.

(20) Diagnostic Proctosigmoidoscopy—Rigid (CPT Code 45300)

CPT code 45300 (Proctosigmoidoscopy, rigid; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years, with Medicare utilization greater than 20,000. For CY 2019, we proposed the RUC-recommended work RVU of 0.80 for CPT code 45300.

For the direct PE inputs, we proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving CPT code 45300.

Comment: Commenters were supportive of our proposal of the RUC-recommended work RVUs.

Response: We thank commenters for their support.

Comment: One commenter stated that CMS did not indicate what amount of service period time was removed from the calculation of the equipment time, and that this made it difficult to determine the accuracy of the refinements. The commenter requested more information about this change.

Response: For the four equipment items where we made time refinements, we removed the clinical labor for the CA035 clinical labor activity in accordance with our standard equipment time formula for non-highly technical equipment.

After consideration of the public comments, we are finalizing the work RVU and direct PE inputs for CPT code 45300 as proposed.

(21) Hemorrhoid Injection (CPT Code 46500)

CPT code 46500 (Injection of sclerosing solution, hemorrhoids) was identified as potentially misvalued on a screen of codes with a negative intraservice work per unit of time (IWPUT), with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes.

For CPT code 46500, we disagreed with the RUC-recommended work RVU of 2.00 and we proposed a work RVU of 1.74 based on a direct crosswalk to CPT code 68811 (Probing of nasolacrimal duct, with or without irrigation; requiring general anesthesia). This crosswalk code is another recently-reviewed 10-day global code with the same 10 minutes of intraservice time and slightly higher total time. When CPT code 46500 was previously reviewed as described in the CY 2016 PFS final rule with comment period (80 FR 70963), we finalized a proposal to reduce the work RVU from 1.69 to 1.42, which reduced the work RVU by the same ratio as the reduction in the total work time. In light of the additional evidence provided by this new survey, we agree that the work RVU should be increased from the current value of 1.42. However, we believe that our proposed work RVU of 1.74 based on a crosswalk to CPT code 68811 is more accurate than the RUC-recommended work RVU of 2.00.

In the most recent survey of CPT code 46500, the intraservice work time remained unchanged at 10 minutes while the total time increased by only 2 minutes, increasing from 59 minutes to 61 minutes (3 percent). However, the RUC-recommended work RVU is increasing from 1.42 to 2.00, an increase of 41 percent, and also an increase of 19 percent over the historic value of 1.69 for CPT code 46500. Although we did not imply that the increase in time as reflected in survey values must equate to a one-to-one or linear increase in the valuation of work RVUs, we believe that since the two components of work are time and intensity, minimal increases in surveyed work time typically should not be reflected in disproportionately large increases to work RVUs. In the case of CPT code 46500, we believe that our crosswalk to CPT code 68811 at a work RVU of 1.74 more accurately maintains relativity with other 10-day global codes on the PFS. We also noted that the 3 percent increase in surveyed work time for CPT code 46500 matches a 3 percent increase in the historic work RVU of the code, from 1.69 to 1.74. Therefore, we proposed a work RVU of 1.74 for CPT code 46500 based on the aforementioned crosswalk.

For the direct PE inputs, we proposed to remove 10 minutes of clinical labor time for the ''Assist physician or other qualified healthcare professional—directly related to physician work time (100%)'' (CA018) activity. This clinical labor time is listed twice in the recommendations along with a statement that although the clinical labor has not changed from prior reviews, time for both clinical staff members was inadvertently not included in the previous spreadsheets. We appreciated this notification in the recommendations, and therefore, we requested more information about why the clinical labor associated with this additional staff member was left out for previous reviews. We were particularly interested in knowing what activities the additional staff member would be undertaking during the procedure. We proposed to remove the clinical labor associated with this additional clinical staff member pending the receipt of additional information. We also proposed to remove 1 impervious staff gown (SB027), 1 surgical mask with face shield (SB034), and 1 pair of shoe covers (SB039) pending more information about the additional clinical staff member.

We proposed to remove the clinical labor time for the ''Review home care instructions, coordinate visits/prescriptions'' (CA035) activity. CPT code 46500 is typically billed with a same day E/M service, and we believe that it would be duplicative to assign clinical labor time for reviewing home care instructions given that this task would typically be done during the same day E/M service. We also proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving CPT code 46500.

Comment: Many commenters disagreed with the proposed work RVU

of 1.74 for CPT code 46500 and stated that CMS should finalize the RUC-recommended work RVU of 2.00. Commenters stated that they disagreed with CMS calculating intraservice time ratios to account for changes in work time, and that CPT code 46500 possesses a negative IWPUT, which makes the use of time ratios particularly inappropriate.

Response: We disagree with the commenters and continue to believe that the use of time ratios is one of several reasonable methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values do not account for information that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in the resource of time have been unaccounted for in a recommended RVU, then we believe we have the obligation to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. Were we to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. (As an example, CPT codes 38222, 54231, 55870, 75573, and 78814 all share identical CY 2019 work times with 15 minutes of preservice time, 30 minutes of intraservice time, and 15 minutes of postservice time; however these codes have respective CY 2019 work RVUs of 1.44, 2.04, 2.58, 2.55, and 2.20.) Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. For more details on our methodology, we direct readers to the CY 2017 PFS final rule (81 FR 80272 through 80277). We also note that in the case of CPT code 46500, we derived our proposed work RVU of 1.74 by using a direct crosswalk to CPT code 68811 and not a time ratio.

Comment: Several commenters stated that the RUC compared CPT code 46500 to the two key reference services: CPT code 46221 (Hemorrhoidectomy, internal, by rubber band ligation(s)) and CPT code 46930 (Destruction of internal hemorrhoid(s) by thermal energy (*e.g.,* infrared coagulation, cautery, radiofrequency)). Commenters stated that the RUC-recommended work RVU of 2.00 places the value correctly between the key reference services and results in similar procedure intensity, whereas the CMS crosswalk to CPT code 68811 was not well aligned with the top two key reference services due to having a lower intensity.

Response: We disagree with the commenters that our crosswalk to CPT code 68811 would be less accurate for work valuation than the two key references chosen by the survey respondents. We note, for example, that CPT code 46221 has 50 percent more intraservice time than CPT code 46500, and CPT code 46930 has 50 percent less intraservice time than CPT code 46500, whereas the CMS crosswalk to CPT code 68811 shares the same 10 minutes of intraservice time as CPT code 46500. We believe that this closer match in the work time values makes CPT code 68811 a more appropriate choice for a crosswalk code. We also note that at the RUC meeting when CPT code 46500 was under review, the specialty presenters stated that the work RVU had not changed from the historical value of 1.69 before the recommendation was changed to the final value of 2.00. As we stated in the proposed rule, the 3 percent increase in surveyed work time for CPT code 46500 matches a 3 percent increase in the historic work RVU of the code, from 1.69 to 1.74. We continue to believe that this is the most accurate value to finalize for CPT code 46500.

Comment: Several commenters compared CPT code 46500 to CPT code 68810 (Probing of nasolacrimal duct, with or without irrigation) and noted that these codes have the same intraservice work time but the comparison code includes a lower level follow-up visit and therefore correctly has a lower work RVU. Commenters stated that CPT code 46500 includes a follow-up office visit with an anoscopy to determine the effectiveness of the treatment and to monitor for infection or sepsis which adds work to the visit. Commenters stated that the proposed CMS crosswalk to CPT code 68811 includes an even lower level office visit (CPT code 99211) than the office visit in CPT code 68810, which indicated that it was an inappropriate choice for a crosswalk.

Response: We continue to disagree with the commenters that the CMS crosswalk to CPT code 68811 would provide an inappropriate work valuation for CPT code 46500 based on the differences in postoperative work and work time. We would like to clarify again that we used CPT code 68811 as our crosswalk, not CPT code 68810, and we do not understand the comparisons to CPT code 68810 suggested by the commenters. Regarding our crosswalk code, while it is true that CPT code 68811 does not contain a level three (CPT code 99213) office visit in its global period like CPT code 46500, the code does include half of a discharge visit (CPT code 99238) in its global period, which is missing from the reviewed code. Under the building block methodology, the combined work RVU and the work time of a half discharge visit (CPT code 99238) and a level 1 office visit (CPT code 99211) would equal 0.82 RVUs and 26 minutes. This is approximately equal to the level 3 office visit (CPT code 99213 with 0.97 work RVUs and 23 minutes of work time) in the global period of CPT code 46500. As a result, we do not agree with the commenters that CPT code 46500 has a significantly greater amount of postservice work and postservice work time than our crosswalk code.

Comment: Several commenters responded to our request for more information about why the clinical labor associated with the additional staff member was left out of previous reviews and what activities the additional staff member would be undertaking during the procedure. Commenters stated that two clinical staff are needed to assist the physician during the intraservice portion of the service: one staff person is handling suction and holding the retractor while the surgeon identifies and injects anesthetic and sclerosant into the poles of the hemorrhoids, and the second staff person is handing supplies (syringes, gauze) and taking soiled supplies away. The commenters stated that one staff person will assist with tasks such as irrigation, suction, etc. and one circulating staff person will hand syringes, sponges, etc. to the physician.

Response: We appreciate the additional feedback from the commenters regarding what activities the additional staff member would be undertaking during the procedure, although we note that we did not receive a response regarding why the clinical labor associated with this additional staff member was left out of previous reviews. After reviewing the

additional information supplied by the commenters, we are not finalizing our proposal to remove the clinical labor time for the ''Assist physician or other qualified healthcare professional'' (CA018) activity or the proposal to remove 1 impervious staff gown (SB027), 1 surgical mask with face shield (SB034), and 1 pair of shoe covers (SB039). We are finalizing the RUC-recommended values for these direct PE inputs.

Comment: Several commenters disagreed with the proposal to remove the clinical labor time for the ''Review home care instructions, coordinate visits/prescriptions'' (CA035) activity. Commenters stated that this clinical activity was not duplicative with the same day E/M office visit, as the home care instructions directly pertain to the procedure and would not be provided during an evaluation of the patient.

Response: We disagree with the commenters that home care instructions would not be provided during the same day E/M visit. The commenters did not provide a rationale to explain why home care instructions would not be provided during the same day E/M visit, which also directly pertains to the procedure. We continue to believe that it would be duplicative to assign clinical labor time for this task, as we believe that the home care instructions would be furnished during the same day E/M visit.

Comment: One commenter stated that CMS did not indicate what amount of service period time was removed from the calculation of the equipment time, and that this made it difficult to determine the accuracy of the refinements. The commenter requested more information about this change.

Response: For the anoscope with light source (ES002) equipment, we removed the clinical labor for the CA029 and CA035 clinical labor activities in accordance with our standard equipment time formula for scopes.

After consideration of the public comments, we are finalizing the work RVU for CPT code 46500 as proposed. We are finalizing the RUC-recommended direct PE inputs for this code, with the exception of our refinement to the CA035 clinical labor activity and standard equipment time refinements as detailed above.

(22) Removal of Intraperitoneal Catheter (CPT Code 49422)

In October 2016, CPT code 49422 (Removal of tunneled intraperitoneal catheter) was identified as a site of service anomaly because Medicare data from 2012–2014 indicated that it was performed less than 50 percent of the time in the inpatient setting, yet it included inpatient hospital E/M services within the 10-day global period. The code was resurveyed using a 0-day global period for the April 2017 RUC meeting. For CY 2019, we proposed the RUC-recommended work RVU of 4.00 for CPT code 49422.

We did not propose any direct PE refinements for this code family.

The following is a summary of the public comments we received on our proposals involving CPT code 49422.

Comment: Commenters were supportive of our proposal of the RUC-recommended work RVUs. Commenters also supported the change in global period to a 0-day global.

Response: We thank commenters for their support.

After consideration of the public comments, we are finalizing the RUC-recommended work RVU and direct PE inputs for CPT code 49422 as proposed.

(23) Dilation of Urinary Tract (CPT Codes 50436, 50437, 52334, and 74485)

In October 2014, the CPT Editorial Panel deleted 6 codes and created 12 new codes to describe genitourinary catheter procedures and bundle inherent imaging services. In January 2015, the specialty societies indicated that CPT code 50395 (Introduction of guide into renal pelvis and/or ureter with dilation to establish nephrostomy tract, percutaneous), which was identified as part of the family, would be referred to the CPT Editorial Panel to clear up any confusion with overlap in physician work with CPT code 50432 (Placement of nephrostomy catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation). In September 2017, the CPT Editorial Panel deleted CPT code 50395 and created 2 new codes to report dilation of existing tract, and establishment of new access to the collecting system, including percutaneous, for an endourologic procedure including imaging guidance (*e.g.,* ultrasound and/or fluoroscopy), all associated radiological supervision and interpretation, as well as post procedure tube placement when performed.

The specialty society surveyed the new CPT code 50436 (Dilation of existing tract, percutaneous, for an endourologic procedure including imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, as well as post procedure tube placement, when performed), and the RUC recommended a total time of 70 minutes, intraservice time of 30 minutes, and a work RVU of 3.37. The RUC indicated that its recommended work RVU for this CPT code is identical to the work RVU of the CPT code being deleted, even though imaging guidance CPT code 74485 has now been bundled into the valuation of the CPT code. The RUC provided two key reference CPT codes to support its recommendation: CPT code 50694 (Placement of ureteral stent, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (*e.g.,* ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation; new access, without separate nephrostomy catheter) with total time of 111 minutes, intraservice time of 62 minutes, and a work RVU of 5.25; and CPT code 50695 (Placement of ureteral stent, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (*e.g.,* ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation; new access, with separate nephrostomy catheter), with total time of 124 minutes and intraservice time of 75 minutes, and a work RVU of 6.80. To further support its recommendation, the RUC also referenced CPT code 52287 (Cystourethroscopy, with injection(s) for chemodenervation of the bladder) with total time of 58 minutes, intraservice time of 21 minutes, and a work RVU of 3.37.

We disagreed with the RUC that the work RVU for this CPT code should be the same as the CPT code being deleted. Survey respondents indicated that the total time for completing the service described by the new CPT code is nearly 30 minutes less than the existing CPT code, even though imaging guidance was described as part of the procedure. We also noted that the reference CPT codes both have substantially higher total and intraservice times than CPT code 50436. We considered a number of parameters to arrive at our proposed work RVU of 2.78, supported by a crosswalk to CPT code 31646 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with therapeutic aspiration of tracheobronchial tree, subsequent, same hospital stay). We examined the intraservice time ratio for the new CPT code in relation to the combination of CPT codes that the service represents and found that this would support a work RVU of 2.55. We also calculated the intraservice time ratio for the new CPT code in relation to each of the two

reference CPT codes. For the comparison with CPT code 50694, the intraservice time ratio is 2.54, while the comparison with the second reference CPT code 50695 yields an intraservice time ratio of 2.72. We took the highest of these three values, 2.72, and found a corresponding crosswalk that we believe appropriately values the service described by the new CPT code. Therefore, we proposed a work RVU of 2.78 for CPT code 50436.

The specialty society also surveyed the new CPT code 50437 (Dilation of existing tract, percutaneous, for an endourologic procedure including imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, as well as post procedure tube placement, when performed; including new access into the renal collecting system) and the RUC recommended a total time of 100 minutes, an intraservice time of 60 minutes, and a work RVU of 5.44. The recommended intraservice time of 60 minutes reflects the 75th percentile of survey results, rather than the median survey time, which is typically used for determining the intraservice time for new CPT codes. The RUC justified the use of the higher intraservice time because they believe the time better represents the additional time needed to introduce the guidewire into the renal pelvis and/or ureter, above and beyond the work involved in performing CPT code 50436. The RUC compared this CPT code to CPT code 52235 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; MEDIUM bladder tumor(s) (2.0 to 5.0 cm)), with total time of 94 minutes, intraservice time of 45 minutes, and a work RVU of 5.44. The RUC also cited as support the second key reference CPT code 50694 (Placement of ureteral stent, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (*e.g.,* ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation; new access, without separate nephrostomy catheter) with total time 111 minutes, intraservice time 62 minutes, and a work RVU of 5.25.

We did not agree with the RUC's recommended work RVU because we believed that the intraservice time for this CPT code should reflect the survey median rather than the 75th percentile. There is no indication that the additional work of imaging guidance was systematically excluded by survey respondents when estimating the time needed to furnish the service. Therefore, we proposed to reduce the intraservice time for CPT code 50437 from the RUC-recommended 60 minutes to the survey median time of 45 minutes. We noted that this is still 15 minutes more than the intraservice time for CPT code 50436, primarily for the provider to introduce the guidewire into the renal pelvis and/or ureter. We welcomed comments about the amount of time needed to furnish this procedure.

With the revised intraservice time of 45 minutes and a total time of 85 minutes, we believed that the RUC-recommended work RVU for this CPT code is overstated. When we applied the increment between the RUC-recommended values for between CPT codes 50436 and 50437 (2.07 work RVUs) in addition to our proposed work RVU for CPT code 50436, we estimated that this CPT code was more accurately represented by a work RVU of 4.83. This value is supported by a crosswalk to CPT code 36902 (Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty), which has an intraservice time of 40 minutes and a total time of 86 minutes. We believed that CPT code 36902 describes a service that is similar to the new CPT code 50437) and therefore provides a reasonable crosswalk. We proposed a work RVU of 4.83 for CPT code 50437.

We proposed the RUC-recommended work RVU of 3.37 for CPT code 52334 (Cystourethroscopy with insertion of ureteral guide wire through kidney to establish a percutaneous nephrostomy, retrograde) and the RUC-recommended work RVU of 0.83 for CPT code 74485 (Dilation of ureter(s) or urethra, radiological supervision and interpretation).

For the direct PE inputs, we proposed to remove the clinical labor time for the ''Confirm availability of prior images/studies'' (CA006) activity for CPT code 52334. This code does not currently include this clinical labor time, and unlike the two new codes in the family (CPT codes 50436 and 50437), CPT code 52334 does not include imaging guidance in its code descriptor. When CPT code 52334 is performed with imaging guidance, it would be billed together with a separate imaging code that already includes clinical labor time for confirming the availability of prior images. As a result, we believed that it would be duplicative to include this clinical labor time in CPT code 52334.

The following is a summary of the public comments we received on our proposals involving the Dilation of Urinary Tract family of codes.

Comment: Several commenters responded to our proposals regarding work RVUs for this family of codes. In general, commenters expressed support for our proposed work RVU of 3.37 for CPT code 52334 and 0.83 for CPT code 74485.

Response: We are finalizing the work RVUs for each of these codes as proposed.

Comment: Several commenters did not support our proposals regarding the work RVU for CPT codes 50436 and 50437. The RUC and other commenters stated that CMS misunderstood the RUC's summary of results (SOR) and the purpose of the reference codes and the code comparisons as part of their review process. They suggested that our rejection of the RUC recommendation for CPT code 50436 was based on a mistake about the codes that the RUC cited as reference codes.

Response: We consider a variety of documents and data during our review of the RUC's recommended work RVU for a code. The two reference codes cited in the excel summary work RVU spreadsheet for CPT code 50436 were CPT codes 50694 and 50695, while the two reference codes cited in the SOR were CPT codes 52287 52214. In other words, there was an inconsistency in the documentation. We believe that any of the four reference codes cited in the documentation and/or data are valid points of comparison for evaluating whether the RUC's recommended work RVUs are appropriate.

Comment: Some commenters did not agree with CMS's use of intraservice time ratios as a factor in determining whether a CPT code is appropriately valued. The commenters maintained that CMS's use of these parameters is inappropriate and demonstrates our prioritization of time-related factors above the intensity and complexity of the service.

Response: We routinely use intraservice time ratios to determine whether a recommended work RVU for a new CPT code adequately reflects efficiencies gained when codes are bundled and/or providers become more efficient at furnishing services and we disagree with commenters that time

ratios are an inappropriate metric. We identify a crosswalk for the purpose of establishing the work RVU by comparing the survey code to other codes in the PFS with similar intraservice and total times and also by considering the intensity among codes with similar times. We disagree that this means we are prioritizing time parameters over other factors that are relevant in considering a code's value.

Comment: Commenters disagreed with CMS's proposed work RVU of 2.78 for CPT code 50436, citing CMS's inappropriate use of time parameters in comparing this code with the deleted CPT code 50395.

Response: Even after taking into consideration the bundling of the deleted code, CPT 50395, with CPT code 74485, we believe that there are efficiencies in the work that are not adequately reflected in the RUC-recommended work RVU for this new code, CPT 50436. We examined a number of parameters in seeking an appropriate crosswalk code for CPT 50436, including the intraservice time ratio for this new code in relation to the combination of CPT codes that the service represents and the intraservice time ratio for the new code in relation to each of the RUC's two reference codes. Our crosswalk, CPT code 31646, reflects the work RVU (2.78) corresponding to the most appropriate, and the highest, work RVU (2.72) associated with these calculations. Our identification of a crosswalk code is not dictated by the time parameter calculations alone, but rather is based on a combination of the time parameters and our understanding of the intensity involved in furnishing the service. If we had been looking only at time parameters, we might have chosen a CPT code with a work RVU closest to the lowest of the time parameter calculations (2.54). We continue to believe that the most appropriate crosswalk is CPT code 31646, and we are finalizing our proposed work RVU of 2.78 for CPT code 50436.

Comment: As with CPT code 50436, commenters suggested that CMS mistook the codes included in the SOR as the codes that the RUC cited as reference codes.

Response: As we indicated in our response to this comment for CPT code 50436, we consider all documentation and data provided by the RUC in our assessment of the work RVU for a code. The reference and comparison CPT codes cited in the SOR did not match those in the summary work RVU spreadsheet.

Comment: Several commenters disagreed with our method of proposing a work RVU based on the incremental differences in the RUC-recommended work RVU between codes. Commenters stated that this erroneously considers all time components as having equal intensity.

Response: We generally apply this methodology where we agree with, and seek to maintain the relativity between two codes reflected in the RUC recommendations, but we disagree with the RUC-recommended work RVU for one or both of the codes. We also considered, as an alternative, whether it would be more appropriate to use proportional increments rather than absolute differences between two RUC-recommended work RVUs. Under that scenario, we would have proposed a work RVU of 4.49 for CPT code 50437 [(2.78 * 5.44)/3.37 = 4.49]. However, since our general approach involves applying the absolute difference in work RVUs, our proposed value for CPT code 50437 was 4.83 work RVUs. We thank the commenter for pointing out our calculation error, due to which our proposed work RVU should have been 4.85 instead of 4.83. We continue to believe that relative difference in the RUC's recommendations for work RVUs between codes is a useful and appropriate tool for determining work RVUs for CPT codes, and we are finalizing a work RVU of 4.85 for CPT code 50437 based on a comparison with CPT code 36902, which has a work RVU of 4.83.

Comment: Several commenters disagreed with the proposal to remove the clinical labor time for the ''Confirm availability of prior images/studies'' (CA006) activity for CPT code 52334. Commenters stated that the equivalent of the CA006 clinical labor activity did not exist when this service was last reviewed by the Practice Expense subcommittee in 2002, and that many surgical procedures and other types of services that do not have imaging bundled involve the physician reviewing images and studies before performing the service. Commenters stated that this review is not duplicative with image-guidance codes as it instead involves reviewing distinct previous studies.

Response: We continue to believe that this clinical labor time should be removed because it is duplicative, as CPT code 52334 would be billed together with a separate imaging code that already includes clinical labor time for confirming the availability of prior images when it is performed with imaging guidance. We believe that the commenters may be conflating the absence of the CA006 clinical labor activity when CPT code 52334 was previously reviewed with the lack of any clinical labor for reviewing images that did not exist previously in this specific code. There were hundreds of procedures that included clinical labor for reviewing images prior to the creation of the CA006 clinical labor code, and CPT code 52334 was not one of them. Similarly, while we agree that there are many services that do not have bundled imaging and nonetheless include the physician reviewing images and studies before performing the service, this does not explain why CPT code 52334 would require clinical labor time for confirming the availability of prior images and studies when the service did not include this clinical labor time previously. We continue to believe that the inclusion of this clinical labor time would be duplicative for this service.

Comment: One commenter requested that CPT code 52334 be added to the phase-in list for codes with significant PE RVU reductions.

Response: Section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2-year period. We proposed to exempt CPT code 52334 from the phase-in due to the fact that it is part of the same family of codes that included new CPT codes 50436 and 50437. We have previously finalized this policy through rulemaking, stating that significant coding revisions within a family of codes can change the relationships among codes to the extent that it changes the way that all services in the group are reported, even if some individual codes retain the same number or, in some cases, the same descriptor. Excluding codes from the phase-in when there are significant revisions to the code family also helps to maintain the appropriate rank order among codes in the family, avoiding years for which RVU changes for some codes in a family are in transition while others were fully implemented. For additional information regarding the phase-in of significant RVU reductions, we direct readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70929).

(24) Transurethral Destruction of Prostate Tissue (CPT Codes 53850, 53852, and 53854)

In September 2017, the CPT Editorial Panel created a new code (CPT code

53854) to report transurethral destruction of prostate tissue by radiofrequency-generated water vapor thermotherapy. CPT codes 53850 (Transurethral destruction of prostate tissue; by microwave thermotherapy) and 53852 (Transurethral destruction of prostate tissue; by radiofrequency thermotherapy) were also included for review as part of the same family of codes.

For CPT code 53850 (Transurethral destruction of prostate tissue; by microwave thermotherapy), the RUC recommended a work RVU of 5.42, supported by a direct crosswalk to CPT code 33272 (Removal of subcutaneous implantable defibrillator electrode) with a total time of 151 minutes, intraservice time of 45 minutes, and a work RVU of 5.42. The RUC indicated that a work RVU of 5.42 accurately reflects the lowest value of the three CPT codes in this family. We proposed the work RVU of 5.42 for CPT code 53850, as recommended by the RUC.

The RUC recommended a work RVU of 5.93 for CPT code 53852 (Transurethral destruction of prostate tissue; by radiofrequency thermotherapy) and for CPT code 53854 (Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy). We proposed the RUC-recommended work RVU of 5.93 for CPT code 53852.

CPT code 53854 is a service reflecting the use of a new technology, ''radiofrequency generated water vapor thermotherapy,'' as distinct from CPT code 53852, which describes destruction of tissue by ''radiofrequency thermotherapy.'' The RUC indicated that this CPT code is the most intense of the three CPT codes in this family, thereby justifying a work RVU identical to that of CPT code 53852, despite lower intraservice and total times. The RUC stated that 15 minutes of post service time is appropriate due to greater occurrence of post-procedure hematuria necessitating a longer monitoring time. However, the post-service monitoring time for this CPT code, 15 minutes, is identical to that for CPT code 53852. We did not agree with the explanation provided by the RUC for recommending a work RVU identical to that of CPT code 53852, given that the total time is 5 minutes lower, and the post service times are identical. Both the intraservice time ratio between this new CPT code and CPT code 53852 (4.94) and the total time ratio between the two CPT codes (5.72) suggest that the RUC-recommended work RVU of 5.93 overestimates the work involved in furnishing this service. We reviewed other 90-day global CPT codes with similar times and identified CPT code 24071 (Excision, tumor, soft tissue of upper arm or elbow area, subcutaneous; 3 cm or greater) with a total time of 183 minutes, intraservice time of 45 minutes, and a work RVU of 5.70 as an appropriate crosswalk. We believed that this would be a better reflection of the work involved in furnishing CPT code 53854, and therefore, we proposed a work RVU of 5.70 for this CPT code. We welcomed comments about the time and intensity required to furnish this new service. Since this CPT code reflects the use of a new technology, it will be reviewed again in 3 years.

For the direct PE inputs, we proposed to add a new supply (SA128: ''kit, Rezum delivery device''), a new equipment item (EQ389: ''generator, water thermotherapy procedure''), and proposed to update the price of two supplies (SA036: ''kit, transurethral microwave thermotherapy'' and SA037: ''kit, transurethral needle ablation (TUNA)'') after reviewing invoices that we received. We noted that these invoices were submitted along with additional information listing the vendor discount for these supplies and equipment. We appreciated the inclusion of the discounted prices on these invoices, and we encouraged other invoice submissions to provide the discounted price as well, where available. Based on market research on supply and equipment pricing carried out by our contractors, we believe that a vendor discount of 10–15 percent is common on many supplies and equipment. Since we are obligated by statute to establish RVUs for each service as required based on the resource inputs required to furnish the typical case of a service, we have concerns that relying on invoices for supply and equipment pricing absent these vendor discounts may overestimate the resource cost of some services. We encouraged the submission of additional invoices that include the discounted price of supplies and equipment to more accurately assess the market cost of these resources.

The following is a summary of the public comments we received on our proposals involving the Transurethral Destruction of Prostate Tissue family of codes.

Comment: Several commenters expressed support for our proposed work RVU of 5.42 for CPT code 53850 and 5.93 for CPT code 53852, which reflect the RUC's recommendations for these two codes.

Response: We appreciate the commenters' support and we are finalizing a work RVU of 5.42 for CPT code 53850 and a work RVU of 5.93 for CPT code 53852.

Comment: A commenter pointed out that there is an error in our description of the RUC's time components for this code. We stated that there was less post service time for CPT code 53854 than for CPT code 53852 when, in fact, both codes have a post service time of 15 minutes. The intraservice time between the two codes differs by 5 minutes, with CPT code 53854 having 5 fewer minutes than CPT code 53852.

Response: We thank the commenter for informing us of the error. We note, however, that this does not affect our proposal which is based on a comparison of both intraservice and total time ratios.

Comment: Several commenters, ranging from device manufacturers and professional associations, disagreed with our proposed value of 5.70 for CPT code 53854 instead of the RUC-recommended work RVU of 5.93. Commenters stated that the work involved in furnishing the service described by CPT code 53854 is the most intense of the three CPT codes in this family because of the added risk of bleeding, urinary retention and damage to the external urinary sphincter with resultant incontinence of urine if not performed properly. Commenters also urged CMS to approach the time results from the survey for this code with caution, as few practitioners are likely to have had much experience with the new technology described by this service.

Response: In our proposal, we requested additional information from stakeholders about the time and intensity required to furnish this service because we were not convinced that the work involved in furnishing the service described by CPT code 53854 is more intense than the work involved in furnishing CPT code 53852, which the RUC used as a reference code in developing their recommendation. We were convinced by commenters, however, that the additional risk in furnishing this service supports a higher work RVU than what we proposed. Therefore, we are finalizing a work RVU of 5.93 for this CPT code, as recommended by the RUC.

Comment: One commenter stated that both CPT codes should be subject to the phase-in for CY 2019 because they will decrease more than 20 percent and are not new or revised codes. The commenter urged CMS to add CPT codes 52380 and 52382 to the list of codes subject to the phase-in.

Response: Section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, specifies that for services that

are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2-year period. We proposed to exempt CPT codes 52380 and 52382 from the phase-in of significant RVU reductions required by section 1848(b)(11) of the Act because these codes are part of the same family of codes that included new CPT code 53854. We have previously finalized this policy through rulemaking, stating that significant coding revisions within a family of codes can change the relationships among codes to the extent that it changes the way that all services in the group are reported, even if some individual codes retain the same number or, in some cases, the same descriptor. Excluding codes from the phase-in when there are significant revisions to the code family also helps to maintain the appropriate rank order among codes in the family, avoiding years for which RVU changes for some codes in a family are in transition while others were fully implemented. For additional information regarding the phase-in of significant RVU reductions, we direct readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70929).

Comment: One commenter stated that they were concerned about substantial reductions in billable staff time and supply costs associated with CPT codes 53850 and 53852. The commenter stated that reductions in billable staff time will require treating physicians to minimize non-procedural time which may include: Comfort control protocols; patient expectation management; patient post-procedure instructions; and recommended best practices for follow-up care. The commenter stated that they were concerned that the proposed supply costs are not in line with actual pricing or with actual cost increases for manufacturing of the product, and indicated that significant reductions in reimbursement will limit patient access to a therapy with demonstrated safety, effectiveness, and cost efficacy.

Response: We appreciate the feedback from the commenter, and we are sensitive to the need for accurate payment under the PFS to ensure that beneficiaries maintain access to care. However, we note that we proposed the RUC-recommended direct PE inputs for this family of codes without refinement, and the decreases in clinical staff time for these procedures were almost entirely due to shorter surveyed intraservice work times and the removal of office visits in the postoperative portion of the global period as identified by the RUC. We agree with the RUC that fewer follow-up office visits and shorter intraservice times are now typical for these procedures, and we do not believe that the resulting decreases in clinical labor time will create barriers to accessing care. With regard to changes in the proposed supply costs, we direct readers to our discussion of the market-based supply and equipment pricing update in section II.B. of this final rule. We encourage stakeholders to continue to provide feedback concerning accurate supply and equipment pricing.

After consideration of the comments, we are finalizing the RUC-recommended work RVUs and direct PE inputs for the three codes in the Transurethral Destruction of Prostate Tissue family of codes.

(25) Vaginal Treatments (CPT Codes 57150 and 57160)

CPT codes 57150 (Irrigation of vagina and/or application of medicament for treatment of bacterial, parasitic, or fungoid disease) and 57160 (Fitting and insertion of pessary or other intravaginal support device) were identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. For CY 2019, we proposed the RUC-recommended work RVU of 0.50 for CPT code 57150 and the RUC-recommended work RVU of 0.89 for CPT code 57160.

We did not propose any direct PE refinements for this code family.

The following is a summary of the public comments we received on our proposals involving the Vaginal Treatments family of codes.

Comment: Commenters were supportive of our proposal of the RUC-recommended work RVUs.

Response: We thank commenters for their support.

After consideration of the public comments, we are finalizing the RUC-recommended work RVUs and direct PE inputs for CPT codes 57150 and 57160 as proposed.

(26) Biopsy of Uterus Lining (CPT Codes 58100 and 58110)

CPT code 58100 (Endometrial sampling (biopsy) with or without endocervical sampling (biopsy), without cervical dilation, any method) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. CPT code 58110 (Endometrial sampling (biopsy) performed in conjunction with colposcopy) was also included for review as part of the same family of codes. For CY 2019, we proposed the RUC-recommended work RVU of 1.21 for CPT code 58100 and the RUC-recommended work RVU of 0.77 for CPT code 58110.

For the direct PE inputs, we proposed to remove the clinical labor time for the ''Review/read post-procedure x-ray, lab and pathology reports'' (CA028) activity for CPT code 58100. This code is typically billed with a same day E/M service, and we believe that it would be duplicative to assign clinical labor time for reviewing reports given that this task would typically be done during the same day E/M service. We also proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving the Biopsy of Uterus Lining family of codes.

Comment: Several commenters stated that they appreciated that CMS proposed the RUC-recommended work RVU of 1.21 for CPT code 58100 and the RUC-recommended work RVU of 0.77 for CPT code 58110.

Response: We appreciate the support for our proposals from the commenters.

Comment: Several commenters disagreed with the CMS proposal to remove the clinical labor time for the ''Review/read post-procedure x-ray, lab and pathology reports'' (CA028) activity for CPT code 58100. Commenters stated that this clinical labor activity was not duplicative, as CA028 is designed specifically for post-procedure activity during the postservice of the service period which would not overlap with activities in the E/M office visit, which typically occur prior to the procedure and are listed as a preservice clinical labor activity. Commenters stated that the clinical description of the service for CPT code 58100 clearly notes that the E/M service is done the day before the service and that the patient returns for the biopsy.

Response: We disagree with the commenters' statements about the timing of the E/M office visit. The same day billing data indicates that CPT code 58100 is typically billed with an E/M office visit on the same day (59 percent of the time), and it therefore seems clear that the E/M office visit typically takes place during the day of the procedure,

not the day before. We do not understand how the claims analysis fits with the statement from the commenters that the E/M service happens the day before the procedure, especially since CPT code 58100 has a 0-day global period that does not include preoperative care that takes place the day before the procedure. We continue to believe that it would be duplicative to assign clinical labor time for reviewing reports given that this task would typically be done during the same day E/M service. We believe that this clinical labor would be carried out during the same day E/M visit.

After consideration of the public comments, we are finalizing the work RVUs and the direct PE inputs for the codes in the Biopsy of Uterus Lining family of codes as proposed.

(27) Injection Greater Occipital Nerve (CPT Code 64405)

CPT code 64405 (Injection, anesthetic agent; greater occipital nerve) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. For CY 2019, we proposed the RUC-recommended work RVU of 0.94 for CPT code 64405.

For the direct PE inputs, we proposed to refine the equipment time for the exam table (EF023) in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving CPT code 64405.

Comment: Some commenters expressed support for our proposal to accept the RUC-recommended work RVU for this code.

Response: We appreciate the support from the commenters for our proposals.

After consideration of the public comments, we are finalizing the work RVU and the direct PE inputs for CPT code 64405 as proposed.

(28) Injection Digital Nerves (CPT Code 64455)

CPT code 64455 (Injection(s), anesthetic agent and/or steroid, plantar common digital nerve(s) (*e.g.,* Morton's neuroma)) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. For CY 2019, we proposed the RUC-recommended work RVU of 0.75 for CPT code 64455.

For the direct PE inputs, we proposed to refine the equipment time for the exam table (EF023) in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving CPT code 64455.

Comment: Several commenters supported the CMS proposal of the RUC-recommended work RVU of 0.75.

Response: We appreciate the support for our proposals from the commenters.

After consideration of the public comments, we are finalizing the work RVU and the direct PE inputs for CPT code 64455 as proposed.

(29) Removal of Foreign Body—Eye (CPT Codes 65205 and 65210)

CPT codes 65205 (Removal of foreign body, external eye; conjunctival superficial) and 65210 (Removal of foreign body, external eye; conjunctival embedded (includes concretions), subconjunctival, or scleral nonperforating) were identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000.

For CY 2019, we proposed the RUC-recommended work RVU of 0.49 for CPT code 65205. We noted that the recommendations for this code included a statement that the work required to perform CPT code 65205 and the procedure itself had not fundamentally changed since the time of the last review. However, due to the fact that the surveyed intraservice time had decreased from 5 minutes to 3 minutes, the work RVU was lowered from the current value of 0.71 to the recommended work RVU of 0.49, based on a direct crosswalk to CPT code 68200 (Subconjunctival injection). We noted that this recommendation appears to have been developed under a methodology similar to our ongoing use of time ratios as one of several methods used to evaluate work. We used time ratios to identify potential work RVUs and considered these work RVUs as potential options relative to the values developed through other options. As we have stated in past rulemaking (such as 82 FR 53032–53033), we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in newly valued work RVUs, as indeed it does not in the case of CPT code 65205 here. Instead, we believed that, since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. We appreciate that the RUC-recommended work RVU for CPT code 65205 has taken these changes in work time into account, and we support the use of similar methodologies, where appropriate, in future work valuations.

For CPT code 65210, we disagreed with the RUC-recommended work RVU of 0.75 and we proposed a work RVU of 0.61 based on a direct crosswalk to CPT code 92511 (Nasopharyngoscopy with endoscope). This crosswalk code has the same intraservice time of 5 minutes and 4 additional minutes of total time as compared to CPT code 65210. We noted that the recommended intraservice time for CPT code 65210 is decreasing from 13 minutes to 5 minutes (62 percent reduction), and the recommended total time for CPT code 65210 is decreasing from 25 minutes to 13 minutes (48 percent reduction); however, the RUC-recommended work RVU is only decreasing from 0.84 to 0.75, which is a reduction of about 11 percent. As we noted earlier, we do not believe that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, and we did not propose a linear decrease in the work valuation based on these time ratios. However, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs, and we do not believe that the recommended work RVU of 0.75 appropriately reflects these decreases in surveyed work time.

Our proposed work RVU of 0.61 is also based on a crosswalk to CPT code 51700 (Bladder irrigation, simple, lavage and/or instillation), another recently reviewed code with higher time values and a work RVU of 0.60. We also noted that two injection codes (CPT codes 20551 and 64455) were reviewed at the same RUC meeting as CPT code 65210, each of which shared the same intraservice time of 5 minutes and had a higher total time of 21 minutes. Both of these codes had a RUC-recommended work RVU of 0.75, which we proposed without refinement for CY 2019. Due to the fact that CPT code 65210 has a lower total time and a lower intensity than both of these injection procedures, we did not agree that CPT code 65210 should be valued at the same work RVU of 0.75. We believe that our proposed work RVU of 0.61 based on a crosswalk to CPT code 92511 is a more accurate value for this code.

For the direct PE inputs, we noted that the RUC-recommended equipment time for the screening lane (EL006)

equipment in CPT codes 65205 and 65210 was equal to the total work time in addition to the clinical labor time needed to set up and clean the equipment. We disagreed that the screening lane would typically be in use for the total work time, given that this includes the preservice evaluation time and the immediate postservice time. Although we did not currently propose to refine the equipment time for the screening lane in these two codes, we solicited comments on whether the use of the intraservice work time would be more typical than the total work time for CPT codes 65205 and 65210.

The following is a summary of the public comments we received on our proposals involving the Removal of Foreign Body—Eye family of codes.

Comment: Commenters agreed with the CMS proposal of the RUC-recommended work RVU for CPT code 65205.

Response: We appreciate the support for our proposal from the commenters.

Comment: Several commenters disagreed with our statement that the RUC-recommended work RVU for CPT code 65205 appeared to have been developed under a methodology similar to the use of time ratios. Commenters stated that time ratios were not used in arriving at the value of 0.49 for CPT code 65205, and that the recommended work RVU was based instead on a crosswalk to the second key reference code from the survey, CPT code 68200, which requires the same total time to perform and shares identical intensity and complexity.

Response: We appreciate the additional information provided by the commenters regarding the methodology behind the recommended work RVU for CPT code 65205. As we noted in the proposed rule, this recommendation appeared to have been developed under a methodology similar to our ongoing use of time ratios; we did not state that the recommendation was explicitly based on the use of a time ratio.

Comment: Many commenters disagreed with the proposed work RVU of 0.61 for CPT code 65210 and stated that CMS should finalize the RUC-recommended work RVU of 0.75. Commenters stated that CMS should not use intraservice time ratios for work valuation as this methodology ignored the work estimates present in the survey data and the RUC review of those work estimates. Commenters stated that the RUC-recommended work values consider intensity and complexity of the work, while CMS substituted an arbitrary determination of work values based on time and a subjective estimate of intensity and complexity based on an unknown and clinically uninformed opinion.

Response: We disagree with the commenters and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in the resource of time have been unaccounted for in a recommended RVU, then we believe we have the obligation to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. Were we to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. (As an example, CPT codes 38222, 54231, 55870, 75573, and 78814 all share identical CY 2019 work times with 15 minutes of preservice time, 30 minutes of intraservice time, and 15 minutes of postservice time; however these codes have respective CY 2019 work RVUs of 1.44, 2.04, 2.58, 2.55, and 2.20.) Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion in the CY 2017 PFS final rule (81 FR 80272 through 80277). We also note that in the case of CPT code 65210, we derived our proposed work RVU of 0.61 by using a direct crosswalk to CPT code 92511 and not a time ratio.

Comment: Several commenters noted that CPT code 65210 had never been surveyed and was based on Harvard time which contributed to the median survey intraservice time of 5 minutes being less than half of the current value of 13 minutes. Commenters stated that Harvard times should be not be used for any sort of time comparison, especially when the code was not originally surveyed by Harvard, and any comparisons with these work times were inappropriate.

Response: We agree that it is important to use the most recent data available regarding time, and we note that when many years have passed between when time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The times currently associated with codes play a very important role in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had routinely been overestimated, this would undermine the relativity of the work RVUs on the PFS in general, given the process under which codes are often valued by comparisons to codes with similar times, and it also would undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS. Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times used in the PFS ratesetting processes are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we want to reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of current work time values in our methodology, we refer readers to our discussion of the subject in the CY 2017 final rule (81 FR 80273 through 80274).

Comment: Several commenters stated that the procedure described by CPT code 65210 has not fundamentally changed, and therefore the RUC had recommended a work RVU at the 25th percentile in accordance with the recent survey. One commenter stated that the

intensity of the procedure was also unchanged. Commenters stated that the crosswalk and reference codes chosen by CMS were clearly not as intense as the removal of an embedded foreign body described by CPT code 65210, in which an incision into ocular tissue is required.

Response: We disagree with the commenters that CPT code 65210 has not fundamentally changed. We note for example that the surveyed work times have decreased drastically from the prior valuation, and similarly, the intensity of the service as measured by the survey more than doubled. These factors do not comport with the statement from the commenters that intensity of this service is unchanged. We also note that the RUC-recommended work RVU of 0.75 was a decrease from the current work RVU of 0.84, which also does not appear to reflect the idea that the intensity of the service has not changed. We similarly disagree with the commenters that our crosswalk and reference codes are not as intense as CPT code 65210. CPT code 92511 in particular describes a nasopharyngoscopy with endoscope that requires removing secretions and dried mucus blocking passage to the nasopharynx with suction and/or forceps. We disagree with the commenters that this procedure would be less intensive than the removal of a foreign body as described in CPT code 65210.

Comment: Several commenters disagreed with the CMS comparison of CPT code 65210 to two injection codes (CPT codes 20551 and 64455) which were reviewed at the same RUC meeting as CPT code 65210. Commenters stated that the two referenced codes both have a lower intensity than CPT code 65210 and therefore they were not appropriate references for work valuation. Commenters stated that CPT code 65210 has a lower total time and a higher intensity than both of these injection procedures, justifying the recommended work RVU of 0.75.

Response: We disagree with the commenters that CPT code 65210 would typically have a higher intensity than CPT codes 20551 and 64455. These codes both describe injection procedures, with CPT code 20551 describing an injection into the tendon and CPT code 64455 describing an injection into the plantar common digital nerve. We do not agree that the removal of a foreign body from the eye as described in CPT code 65210 would have such greater intensity that it warrants a work RVU of 0.75 (to match CPT codes 20551 and 64455) despite having approximately 40 percent less total work time.

Comment: Several commenters stated in response to the CMS comment solicitation that the screening lane (EL006) equipment would typically be in use for the total work time of CPT codes 65205 and 65210. Commenters stated that the screening lane is the ophthalmic equivalent of an exam room in the non-facility setting which would be needed for the total time of the procedure. Commenters stated that this equipment time represented the total time taken by the physician to perform the service in the screening lane (which would be not be available for use by another patient during the time of the procedure), plus the time inputs for the technician work as listed above.

Response: We appreciate the additional information provided by the commenters regarding the use of the screening lane (EL006) equipment.

After consideration of the public comments, we are finalizing the work RVUs and the direct PE inputs for the codes in the Removal of Foreign Body—Eye family of codes as proposed.

(30) Injection—Eye (CPT Codes 67500, 67505, and 67515)

CPT code 67515 (Injection of medication or other substance into Tenon's capsule) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. CPT codes 67500 (Retrobulbar injection; medication (separate procedure, does not include supply of medication)) and 67505 (Retrobulbar injection; alcohol) were also included for review as part of the same family of codes. For CY 2019, we proposed the RUC-recommended work RVU of 1.18 for CPT code 67500.

For CPT code 67505, we disagreed with the RUC-recommended work RVU of 1.18 and we proposed a work RVU of 0.94 based on a direct crosswalk to CPT code 31575 (Laryngoscopy, flexible; diagnostic). This is a recently reviewed code with the same intraservice time of 5 minutes and 2 fewer minutes of total time as compared to CPT code 67505. We disagreed with the recommendation to propose the same work RVU of 1.18 for both CPT code 67500 and 67505 for several reasons. We noted that the current work RVU of 1.44 for CPT code 67500 is higher than the current work RVU of 1.27 for CPT code 67505, while the current work time of CPT code 67500 is less than the current work time for CPT code 67505. This supported the view that CPT code 67500 should be valued higher than CPT code 67505 due to its greater intensity, which we also found to be supportable on clinical grounds. The typical patient for CPT code 67505 has already lost their sight, and there is less of a concern about accidental blindness as compared to CPT code 67500. At the recommended identical work RVUs, CPT code 67500 has almost triple the intensity of CPT code 67505. Similarly, the intensity does not match our clinical understanding of the complexity and difficulty of the two procedures.

We also noted that the surveyed total time for CPT code 67505 was 7 minutes less than the surveyed time for CPT code 67500, approximately 21 percent lower. If we were to take the total time ratio between the two codes, it would produce a suggested work RVU of 0.93 (26 minutes divided by 33 minutes times a work RVU of 1.18). This time ratio suggested a work RVU almost identical to the 0.94 value that we determined via a crosswalk to CPT code 31575. Based on the preceding rationale, we proposed a work RVU of 0.94 for CPT code 67505.

For CPT code 67515, we disagreed with the RUC-recommended work RVU of 0.84 and we proposed a work RVU of 0.75 based on a crosswalk to CPT code 64450 (Injection, anesthetic agent; other peripheral nerve or branch). The recommended work RVU is based on a direct crosswalk to CPT code 65222 (Removal of foreign body, external eye; corneal, with slit lamp) at a work RVU of 0.84. However, the recommended crosswalk code has more than double the intraservice time of CPT code 67515 at 7 minutes, and we believe that it would be more accurate to use a crosswalk to a code with a more similar intraservice time such as CPT code 64450, which is another type of injection procedure. The proposed work RVU of 0.75 is also based on the use of the intraservice time ratio with the first code in the family, CPT code 67500. The intraservice time ratio between these codes is 0.60 (3 minutes divided by 5 minutes), which yields a suggested work RVU of 0.71 when multiplied by the recommended work RVU of 1.18 for CPT code 67500. We believe that this provides further rationale for our proposed work RVU of 0.75 for CPT code 67515.

We did not propose any direct PE refinements for this code family.

The following is a summary of the public comments we received on our proposals involving the Injection—Eye family of codes.

Comment: Commenters were supportive of the CMS proposal of the RUC-recommended work RVU of 1.18 for CPT code 67500.

Response: We appreciate the support for our proposal from the commenters.

Comment: Many commenters disagreed with the proposed work RVU of 0.94 for CPT code 67505 and stated that CMS should finalize the RUC-recommended work RVU of 1.18. Commenters were confused by the CMS statement that, at the recommended identical work RVUs, CPT code 67500 has almost triple the intensity of CPT code 67505. Commenters stated that the RUC recommendation for CPT code 67505 has less total time and slightly higher intensity than CPT code 67500.

Response: We agree with the commenters that this was an inaccurate statement; we intended to state that the current intensity of CPT code 67500 prior to review is almost triple the current intensity of CPT code 67505. We regret any resulting confusion on this subject.

Comment: Several commenters disagreed with the use of a time ratio analysis to support the CMS proposed work value. Commenters stated that time ratios do not adequately account for intensity and complexity of work, which can only be addressed through the survey and the RUC process.

Response: We disagree with the commenters and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in the resource of time have been unaccounted for in a recommended RVU, then we believe we have the obligation to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. Were we to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. (As an example, CPT codes 38222, 54231, 55870, 75573, and 78814 all share identical CY 2019 work times with 15 minutes of preservice time, 30 minutes of intraservice time, and 15 minutes of postservice time; however these codes have respective CY 2019 work RVUs of 1.44, 2.04, 2.58, 2.55, and 2.20.) Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion CY 2017 PFS final rule (81 FR 80272 through 80277). We also note that in the case of CPT code 65210, we derived our proposed work RVU of 0.61 by using a direct crosswalk to CPT code 31575 and not a time ratio.

Comment: Several commenters stated that while it was true that the current work value for CPT code 67500 is higher than that of CPT code 67505, the survey 25th percentiles indicated that the physician work of CPT code 67505 (work RVU = 1.30) is higher than that of CPT code 67500 (work RVU = 1.18). Commenters stated that the reason for performing surveys is to adjust for changes in physician work that have occurred since the prior survey, and that it was inappropriate to put more weight on old data than on the most recent data. Commenters also disagreed with the proposed work RVU on clinical grounds, stating that CPT code 67505 has a higher intensity than CPT code 67500, not because of potential vision loss, but because of the risk of death if the absolute alcohol is injected accidentally into the optic nerve sheath. Commenters stated that the alcohol injection involved in CPT code 67505 is typically very painful, even after a local anesthetic injection, and carries with it the risk of death which therefore makes it a high-intensity procedure for both patient and physician.

Response: We appreciate the additional clinical details involving CPT code 67505 from the commenters. After reviewing the information provided by the commenters, we are not finalizing our proposed work RVU of 0.94 for CPT code 67505, and we are finalizing the RUC-recommended work RVU of 1.18 instead due to the additional risks carried by the procedure.

Comment: Many commenters disagreed with the proposed work RVU of 0.75 for CPT code 67515 and stated that CMS should finalize the RUC-recommended work RVU of 0.84. Commenters disagreed with the CMS crosswalk to CPT code 64450 and stated that the intensity of an injection adjacent to the eye in which the physician is unable to see the needle tip is clearly greater than that of an injection into a peripheral nerve as in the code for the CMS proposed crosswalk. Commenters stated that the use of a time ratio methodology for CPT code 67515 was particularly inappropriate due to changes in the RUC survey methodology since the last survey for this service was performed, and that increases in the intensity of CPT code 67515 should not be of concern due to the 0-day global period and short intraservice work time.

Response: We continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs, as described in more detail in our response to the comments for CPT code 67505 above. We also disagree with the commenters on their objections on clinical grounds concerning our crosswalk to CPT code 64450. CPT code 64450 describes the injection of an anesthetic agent into a peripheral nerve or branch, and the practitioner performing this service also cannot see a needle tip when injecting into a peripheral nerve. In other words, this is the same situation as that described in CPT code 67515: The practitioner performing the service is unable to see the needle tip in both cases. We continue to note that the RUC-recommended crosswalk code (CPT code 65222) has more than double the intraservice time of CPT code 67515 at 7 minutes, and we continue to believe that it would be more accurate to use a crosswalk to a code with a similar intraservice time such as CPT code 64450.

After consideration of the public comments, we are finalizing the work RVUs for CPT codes 67500 and 67515 as proposed. We are finalizing the RUC-recommended work RVU of 1.18 for CPT code 67505. We are also finalizing the direct PE inputs for all three codes as proposed.

(31) X-Ray Spine (CPT Codes 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120)

CPT codes 72020 (Radiologic examination, spine, single view, specify level) and 72072 (Radiologic examination, spine; thoracic, 3 views) were identified on a screen of CMS or

Other source codes with Medicare utilization greater than 100,000 services annually. The code family was expanded to include ten additional CPT codes to be reviewed together as a group: CPT codes 72040 (Radiologic examination, spine, cervical; 2 or 3 views), 72050 (Radiologic examination, spine, cervical; 4 or 5 views), 72052 (Radiologic examination, spine, cervical; 6 or more views), 72070 (Radiologic examination, spine; thoracic, 2 views), 72074 (Radiologic examination, spine; thoracic, minimum of 4 views), 72080 (Radiologic examination, spine; thoracolumbar junction, minimum of 2 views), 72100 (Radiologic examination, spine, lumbosacral; 2 or 3 views), 72110 (Radiologic examination, spine, lumbosacral; minimum of 4 views), 72114 (Radiologic examination, spine, lumbosacral; complete, including bending views, minimum of 6 views), and 72120 (Radiologic examination, spine, lumbosacral; bending views only, 2 or 3 views).

The radiologic examination procedures described by CPT codes 72020 (Radiologic examination, spine, single view, specify level), 72040 (Radiologic examination, spine, cervical; 2 or 3 views), 72050 (Radiologic examination, spine, cervical; 4 or 5 views), 72052 (Radiologic examination, spine, cervical; 6 or more views), 72070 (Radiologic examination, spine; thoracic, 2 views), 72072 (Radiologic examination, spine; thoracic, 3 views), 72074 (Radiologic examination, spine; thoracic, minimum of 4 views), 72080 (Radiologic examination, spine; thoracolumbar junction, minimum of 2 views), 72100 (Radiologic examination, spine, lumbosacral; 2 or 3 views), 72110 (Radiologic examination, spine, lumbosacral; minimum of 4 views), 72114 (Radiologic examination, spine, lumbosacral; complete, including bending views, minimum of 6 views), 72120 (Radiologic examination, spine, lumbosacral; bending views only, 2 or 3 views), 72200 (Radiologic examination, sacroiliac joints; less than 3 views), 72202 (Radiologic examination, sacroiliac joints; 3 or more views), 72220 (Radiologic examination, sacrum and coccyx, minimum of 2 views), 73070 (Radiologic examination, elbow; 2 views), 73080 (Radiologic examination, elbow; complete, minimum of 3 views), 73090 (Radiologic examination; forearm, 2 views), 73650 (Radiologic examination; calcaneus, minimum of 2 views), and 73660 (Radiologic examination; toe(s), minimum of 2 views) were all identified as potentially misvalued through a screen for CPT codes with high utilization.

With approval from the RUC Research Subcommittee, the specialty societies responsible for reviewing these CPT codes did not conduct surveys, but instead employed a ''crosswalk methodology,'' in which they derived physician work and time components for CPT codes by comparing them to similar CPT codes. We recognize that a substantial amount of time and effort is involved in conducting surveys of potentially misvalued CPT codes; however, we had concerns about the quality of the underlying data used to value these CPT codes. The descriptors and other information on which the recommendations are based have themselves not been surveyed, in several instances, since 1995. Without the benefit of a survey or other external source of data about these CPT codes, there is no information that would allow us to detect any potential improvements in efficiency of furnishing the service or evaluate whether changes in practice patterns have affected time and intensity. We are not categorically opposed to changes in the RUC process or methodology that might reduce the burden of conducting surveys, but without the benefit of any additional data, through surveys or otherwise, we were not convinced that there was a basis for evaluating the RUC's recommendations for work RVUs for each of these CPT codes.

Since all 20 of the CPT codes in this group have very similar intraservice (from 3–5 minutes) and total (ranging from 5–8 minutes) times, we proposed to use an alternative approach to the valuation of work RVUs for these CPT codes. We calculated the utilization-weighted average RUC-recommended work RVU for the 20 CPT codes. The result of this calculation was a work RVU of 0.23, which we proposed to apply uniformly to each CPT code: 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, 72120, 72200, 72202, 72220, 73070, 73080, 73090, 73650, and 73660. We recognized that the proposed work RVU for some of these CPT codes might be somewhat lower at the code level than the RUC's recommendation, while the proposed work RVU for other CPT codes might be slightly higher than the RUC's recommended value. We nevertheless believe that the alternative, accepting the RUC's recommendation for each separate CPT code implied a level of precision about the time and intensity of the CPT codes that we had no way to validate.

For the direct PE inputs, we proposed to add a patient gown (SB026) supply to CPT code 72120. We noted that all of the other codes in the family that included clinical labor time for the ''Greet patient, provide gowning, ensure appropriate medical records are available'' (CA009) task included a patient gown, and we proposed to add the patient gown to match the other codes in the family. We believed that the exclusion of the patient gown for CPT code 72120 was most likely due to a clerical error in the recommendations. We also proposed to refine the equipment time for the basic radiology room (EL012) in accordance with our standard equipment time formulas.

In our review of the clinical labor time recommended for the ''Perform procedure/service—NOT directly related to physician work time'' (CA021) task, we noted that the standard convention for this family of codes seemed to be 3 minutes of clinical labor time per view being conducted. For example, CPT code 72020 with a single view had 3 minutes of recommended clinical labor time for this activity, while CPT code 72070 with two views had 6 minutes. However, we also noted that for the codes with 2–3 views such as CPT codes 72040 and 72100, the recommended clinical labor time of 9 minutes appears to assume that 3 views would always be typical for the procedure. The same pattern occurred for codes with 4–5 views, which have a recommended clinical labor time of 15 minutes (assuming 5 views is typical), and for codes with 6 or more views, which have a recommended clinical labor time of 21 minutes (assuming 7 views is typical).

We did not propose to refine the clinical labor times for this task as we did not have data available to know how many views would be typical for these CPT codes. However, we noted that the intraservice clinical labor time has not changed in roughly 2 decades for these X-ray services, including during this most recent review, and we believed that improving technology during this span of time may have resulted in greater efficiencies in the procedures. We continue to be interested in data sources regarding the intraservice clinical labor times for services such as these that do not match the physician intraservice time, and we welcomed any comments that may be able to provide additional details for the 12 codes under review in this family.

The following is a summary of the public comments we received on our proposals involving the X-Ray Spine family of codes.

Comment: A number of commenters disagreed with our proposal to apply an identical work RVU, calculated as the utilization-weighted average RUC-recommended work RVU for each of the 20 CPT codes, to each of the CPT codes in this group. Commenters defended the crosswalk methodology, stating that it is the best approach for valuing work RVUs for codes in which the service times are very low and therefore difficult to survey. The commenters noted that the specialty societies have tried to survey codes such as this in the past with results that yielded substantial inconsistencies.

Response: We share the commenters' concerns about the validity of surveying services with very low intraservice and total time, but we have even more substantial concerns about a methodology that introduces no new information about the work involved in furnishing these CPT codes and then states their accuracy to the hundredth of a work RVU. Survey data from the specialty societies is often the only data source available to us that reflects the experiences of a cross-section of providers. We remind stakeholders that we welcome additional information or data from all sources to assist us in making proposals and finalizing values.

Comment: In response to our proposal, the RUC offered to survey each code in the expanded family of X-ray codes to which CMS applied the weighted average methodology and provide survey based recommendations for CY 2020.

Response: We appreciate the recognition on the part of the RUC of our serious concerns about the crosswalk methodology and the integrity of the resulting RUC recommended work RVUs. We welcome the submission of any additional data or information that would allow us to consider these codes for review at a future time. Commenters raised concerns that assigning a single weighted average work RVU across this broad family of x-ray codes inadequately reflects meaningful differences among the codes, including the number of views and the complexity of positioning for some x-ray services. In response to commenters' concerns, we are instead maintaining the CY 2018 work RVUs for each CPT code as follows: Work RVU of 0.15 for CPT code 72020, 0.22 for CPT 72040, 0.31 for CPT code 72050, 0.36 for CPT code 72052, 0.22 for CPT code 72070, 0.22 for CPT code 72072, 0.22 for CPT code 72074, 0.22 for CPT code 72080, 0.22 for CPT code 72100, 0.31 for CPT code 72110, 0.32 for CPT code 72114, and 0.22 for CPT code 72120.

Comment: Several commenters indicated that it was inappropriate for CMS to value the practice expense portion of the 20 CPT codes identically because the resources required to furnish each of the services differ in accordance with the number of X-rays or views and other factors.

Response: We did not propose to value the practice expense portion of these codes identically. The proposal regarding the weighted average for these codes refers to the work component of RVUs only.

Comment: One commenter stated that they appreciated and agreed with adding a patient gown (SB026) supply to CPT code 72120.

Response: We appreciate the support for our proposal from the commenter.

Comment: Several commenters stated that they would like to provide clarity on the typical number of films obtained for the X-ray spine codes and the rationale for the number of minutes and assumed number of views that would be typical. Commenters stated that a minimum of 3 views would be needed in order to adequately assess the cervical spine as described by CPT code 72040. Commenters stated that the open mouth odontoid view helps in the assessment of the atlanto-occipital joint, and that the AP and lateral views of the vertebral bodies are required to assess the alignment of the vertebral bodies in two planes, the disc spaces, the spinal canal, fractures, and widening of different joints. Commenters provided a similar level of clinical detail regarding the typical number of views required for CPT codes 72050 and 72052.

Response: We appreciate the detailed information provided by the commenters in response to our request for data sources regarding the intraservice clinical labor times in those services that do not match the physician intraservice time.

After consideration of the public comments, we are maintaining the CY 2018 work RVUs for the codes in the X-Ray Spine family of codes. We are finalizing the direct PE inputs for these codes as proposed.

(32) X-Ray Sacrum (CPT Codes 72200, 72202, and 72220)

CPT code 72220 (Radiologic examination, sacrum and coccyx, minimum of 2 views) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. CPT codes 72200 (Radiologic examination, sacroiliac joints; less than 3 views) and 72202 (Radiologic examination, sacroiliac joints; 3 or more views) were also included for review as part of the same family of codes. See (31) X-Ray Spine (CPT codes 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120) for a discussion of proposed work RVUs for these codes.

For the direct PE inputs, we proposed to refine the equipment time for the basic radiology room (EL012) in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving the X-Ray Sacrum family of codes.

Comment: Comments regarding our proposed work RVU for this family of codes were similar to those discussed in (31) X-Ray Spine (CPT codes 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120).

Response: As discussed above, we are maintaining the CY 2018 work RVUs for each code in this family as follows: Work RVU of 0.17 for CPT code 72200, 0.19 for CPT Code 72202, and 0.17 for CPT code 72220.

Comment: One commenter stated that CMS did not indicate what amount of service period time was removed from the calculation of the equipment time, and that this made it difficult to determine the accuracy of the refinements. The commenter requested more information about this change.

Response: For the basic radiology room (EQ137) equipment, we removed the clinical labor for the CA030 clinical labor activity in accordance with our standard equipment time formula for highly technical equipment.

After consideration of the public comments, we are maintaining the CY 2018 work RVUs for the codes in the X-Ray Sacrum family of codes. We are finalizing the direct PE inputs for these codes as proposed.

(33) X-Ray Elbow-Forearm (CPT Codes 73070, 73080, and 73090)

CPT codes 73070 (Radiologic examination, elbow; 2 views) and 73090 (Radiologic examination; forearm, 2 views) were identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. CPT code 73080 (Radiologic examination, elbow; complete, minimum of 3 views) was also included for review as part of the same family of codes. See (31) X-Ray Spine (CPT codes 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120) above for a discussion of proposed work RVUs for these codes.

For the direct PE inputs, we proposed to refine the equipment time for the

basic radiology room (EL012) in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving the X-Ray Elbow-Forearm family of codes.

Comment: Comments regarding our proposed work RVU for this family of codes were similar to those discussed in (31) X-Ray Spine (CPT codes 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120).

Response: As discussed above, we are maintaining the CY 2018 work RVUs for each code in this family as follows: Work RVU of 0.15 for CPT code 73070, 0.17 for CPT code 73080, 0.17 for CPT code 73090.

Comment: One commenter stated that CMS did not indicate what amount of service period time was removed from the calculation of the equipment time, and that this made it difficult to determine the accuracy of the refinements. The commenter requested more information about this change.

Response: For the basic radiology room (EQ137) equipment, we removed the clinical labor for the CA030 clinical labor activity in accordance with our standard equipment time formula for highly technical equipment.

After consideration of the public comments, we are maintaining the CY 2018 work RVUs for the codes in the X-Ray Elbow-Forearm family of codes. We are finalizing the direct PE inputs for these codes as proposed.

(34) X-Ray Heel (CPT Code 73650)

CPT code 73650 (Radiologic examination; calcaneus, minimum of 2 views) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. See (31) X-Ray Spine above for a discussion of proposed work RVUs for these codes.

For the direct PE inputs, we proposed to refine the equipment time for the basic radiology room (EL012) in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving CPT code 73650.

Comment: Comments regarding our proposed work RVU for this code were similar to those discussed in (31) X-Ray Spine (CPT codes 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120).

Response: As discussed above, we are maintaining the CY 2018 work RVU of 0.16 for CPT code 73650.

Comment: One commenter stated that CMS did not indicate what amount of service period time was removed from the calculation of the equipment time, and that this made it difficult to determine the accuracy of the refinements. The commenter requested more information about this change.

Response: For the basic radiology room (EQ137) equipment, we removed the clinical labor for the CA030 clinical labor activity in accordance with our standard equipment time formula for highly technical equipment.

After consideration of the public comments, we are maintaining the CY 2018 work RVUs for the codes in the X-Ray Heel family of codes. We are finalizing the direct PE inputs for these codes as proposed.

(35) X-Ray Toe (CPT Code 73660)

CPT code 73660 (Radiologic examination; toe(s), minimum of 2 views) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. See (31) X-Ray Spine above for a discussion of proposed work RVUs for these codes.

For the direct PE inputs, we proposed to add a patient gown (SB026) supply to CPT code 73660. We noted that the other codes in related X-ray code families that included clinical labor time for the ''Greet patient, provide gowning, ensure appropriate medical records are available'' (CA009) task included a patient gown, and we proposed to add the patient gown to match the other codes in these families. We also proposed to refine the equipment time for the basic radiology room (EL012) in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving CPT code 73660.

Comment: Comments regarding our proposed work RVU for this code were similar to those discussed in (31) X-Ray Spine (CPT codes 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120).

Response: As discussed above, we are maintaining the CY 2018 work RVU of 0.13 for CPT code 73660.

Comment: Several commenters stated that the typical patient for this service would not require a patient gown. Commenters stated that this was different than other codes in the family where the patient may need to be rotated lateral and prone for different views.

Response: We appreciate the feedback from the commenters. In light of the information supplied by commenters, we will not finalize our proposal to add a patient gown (SB026) supply to CPT code 73660.

Comment: One commenter stated that CMS did not indicate what amount of service period time was removed from the calculation of the equipment time, and that this made it difficult to determine the accuracy of the refinements. The commenter requested more information about this change.

Response: For the basic radiology room (EQ137) equipment, we removed the clinical labor for the CA030 clinical labor activity in accordance with our standard equipment time formula for highly technical equipment.

After consideration of the public comments, we are maintaining the CY 2018 work RVUs for the codes in the X-Ray Toe family of codes. We are finalizing the direct PE inputs as proposed with the exception of the patient gown (SB026) supply as detailed above.

(36) X-Ray Esophagus (CPT Codes 74210, 74220, and 74230)

CPT code 74220 (Radiologic examination; esophagus) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. CPT codes 74210 (Radiologic examination; pharynx and/or cervical esophagus) and 74230 (Swallowing function, with cineradiography/videoradiography) were also included for review as part of the same family of codes.

We proposed the work RVUs recommended by the RUC for the CPT codes in this family as follows: A work RVU 0.59 for CPT code 74210 (Radiologic examination; pharynx and/or cervical esophagus), a work RVU of 0.67 for CPT code 74220 (Radiologic examination; esophagus), and a work RVU of 0.53 for CPT code 74230 (Swallowing function, with cineradiography/videoradiography).

For the direct PE inputs, we noted that the recommended quantity of the Polibar barium suspension (SH016) supply is increasing from 1 ml to 150 ml for CPT code 74210 and 100 ml are being added to CPT code 74220, which did not previously include this supply. The RUC recommendation states that this supply quantity increase is due to clinical necessity, but does not go into further details about the typical use of the supply. Although we did not propose to refine the quantity of the Polibar barium suspension at this time, we solicited additional comment about the typical use of the supply in these procedures. We also proposed to refine the equipment times for all three codes in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our

proposals involving the X-Ray Esophagus family of codes.

Comment: We received no specific comments regarding our proposals for work RVUs in this family.

Response: As a result, we are finalizing a work RVU of 0.59 for CPT code 74210, a work RVU of 0.67 for CPT code 74220, and a work RVU of 0.53 for CPT code 74230 as proposed.

Comment: Several commenters responded to the comment solicitation about the typical use of the Polibar barium suspension (SH016) supply in these procedures. Commenters stated that the barium suspension quantity listed for CPT code 74210 prior to review was only 1 ml which appeared to be a technical error in mistaking number of milliliters for number of items, as this was an insufficient quantity of barium for the procedure. Commenters stated that CPT code 74220 did not have barium suspension listed as a supply item, which appeared to be an oversight. The commenters described how the patient swallows a small quantity of high density barium to outline the esophagus, followed by multiple subsequent swallows of normal density barium that are assessed under fluoroscopy from different angles to evaluate the esophageal anatomy and mucosa.

Response: We appreciate the additional details provided by the commenters regarding the use of the Polibar barium suspension (SH016) supply, and the clarification that the previous supply quantities in these procedures appear to have been in error.

After consideration of the public comments, we are finalizing the work RVU and the direct PE inputs for the codes in the X-Ray Esophagus family of codes as proposed.

(37) X-Ray Urinary Tract (CPT Code 74420)

CPT code 74420 (Urography, retrograde, with or without KUB) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. We proposed the RUC-recommended work RVU of 0.52 for CPT code 74420 (Urography, retrograde, with or without KUB).

For the direct PE inputs, we proposed to remove the 1 minute of clinical labor time for the ''Confirm order, protocol exam'' (CA014) activity. The clinical labor time recommended for this activity is not included in the reference code, nor is it included in any of the two dozen other X-ray codes that were reviewed at the same RUC meeting. There is also no explanation in the recommended materials as to why this clinical labor time would need to be added. We do not believe that this clinical labor would be typical for CPT code 74420, and we proposed to remove it to match the rest of the X-ray codes. We also proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving CPT code 74420.

Comment: We received no specific comments regarding our proposal for the work RVU for CPT code 74420.

Response: We are finalizing a work RVU of 0.52 for CPT code 74420.

Comment: Several commenters disagreed with the proposal to remove the 1 minute of clinical labor time for the ''Confirm order, protocol exam'' (CA014) activity. The commenters stated that this service was distinct from the other X-ray services reviewed during this cycle and encouraged CMS to modify this proposal by finalizing the RUC-recommended direct PE inputs for clinical labor.

Response: We addressed this subject in detail in the PE section of this final rule under the Changes to Direct PE Inputs for Specific Services heading (section II.B.3. of this final rule). For CPT code 74420, we are finalizing these clinical labor refinements as proposed as there is no clinical labor assigned to the ''Review patient clinical extant information and questionnaire'' (CA007) activity. We also note that commenters did not provide a rationale as to what made CPT code 74420 distinct from the other X-ray services reviewed during this cycle and would justify this additional clinical labor time.

After consideration of the public comments, we are finalizing the work RVU and the direct PE inputs for CPT code 74420 as proposed.

(38) Fluoroscopy (CPT Code 76000)

CPT code 76000 (Fluoroscopy (separate procedure), up to 1 hour physician or other qualified health care professional time) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. CPT code 76001 (Fluoroscopy, physician or other qualified health care professional time more than 1 hour, assisting a nonradiologic physician or other qualified health care professional) was also included for review as part of the same family of codes. However, due to the fact that supervision and interpretation services have been increasingly bundled into the underlying procedure codes, the RUC concluded that this practice is rare, if not obsolete, and CPT code 76001 was recommended for deletion by the CPT Editorial Panel for CY 2019.

We proposed the RUC-recommended work RVU of 0.30 for CPT code 76000 (Fluoroscopy (separate procedure), up to 1 hour physician or other qualified health care professional time, other than 71023 or 71034 (*e.g.,* cardiac fluoroscopy)). For the direct PE inputs, we proposed to refine the equipment times in accordance with our standard equipment time formulas.

We did not receive specific comments regarding our proposals for CPT code 76000. We are finalizing a work RVU of 0.30 and the direct PE inputs for CPT code 76000 as proposed.

(39) Echo Exam of Eye Thickness (CPT Code 76514)

CPT code 76514 (Ophthalmic ultrasound, diagnostic; corneal pachymetry, unilateral or bilateral (determination of corneal thickness)) was identified as potentially misvalued on a screen of codes with a negative intraservice work per unit of time (IWPUT), with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard-valued and CMS/Other source codes.

For CPT code 76514, we disagreed with the RUC-recommended work RVU of 0.17 and we proposed a work RVU of 0.14. We noted that the recommended intraservice time for CPT code 76514 is decreasing from 5 minutes to 3 minutes (40 percent reduction), and the recommended total time for CPT code 76514 is decreasing from 15 minutes to 5 minutes (67 percent reduction); however, the RUC-recommended work RVU is not decreasing at all and remains at 0.17. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs.

We also noted that the RUC recommendations for CPT code 76514 stated that, although the steps in the procedure are unchanged since it was first valued, the workflow has changed. With the advent of smaller and easier to use pachymeters, the technician now typically takes the measurements that used to be taken by the practitioner for CPT code 76514, and the intraservice time was reduced by two minutes to account for the technician performing this service. We believe that this change in workflow indicates that the work RVU for the code should be reduced in some fashion, since some of the work

that was previously done by the practitioner is now typically performed by the technician. We have no reason to believe that there is more intensive cognitive work being performed by the practitioner after these measurements are taken since the recommendations indicated that the steps in the procedure are unchanged since this code was first valued.

Therefore, we proposed a work RVU of 0.14 for CPT code 76514, which is based on taking half of the intraservice time ratio. We considered applying the intraservice time ratio to CPT code 76514, which would reduce the work RVU to 0.10 based on taking the change in intraservice time (from 5 minutes to 3 minutes) and multiplying this ratio of 0.60 times the current work RVU of 0.17. However, we recognized that the minutes shifted to the clinical staff were less intense than the minutes that remained in CPT code 76514, and therefore, we applied half of the intraservice time ratio for a reduction of 0.03 RVUs to arrive at a proposed work RVU of 0.14. We believe that this proposed value more accurately takes into account the changes in workflow that have caused substantial reductions in the surveyed work time for the procedure.

We did not propose any direct PE refinements for this code family.

The following is a summary of the public comments we received on our proposals involving CPT code 76514.

Comment: Many commenters disagreed with the proposed work RVU of 0.14 for CPT code 76514 and stated that CMS should finalize the RUC-recommended work RVU of 0.17. Commenters stated that using an approach that takes a fraction of the intraservice time ratio in lieu of strong crosswalks and input from the RUC and physicians providing these services is unfounded. Commenters restated the key reference codes chosen by the survey participants and urged CMS to use survey data and supportive relative reference services when valuing services.

Response: We disagree with the commenters and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in the resource of time have been unaccounted for in a recommended RVU, then we believe we have the obligation to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. Were we to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. (As an example, CPT codes 38222, 54231, 55870, 75573, and 78814 all share identical CY 2019 work times with 15 minutes of preservice time, 30 minutes of intraservice time, and 15 minutes of postservice time; however these codes have respective CY 2019 work RVUs of 1.44, 2.04, 2.58, 2.55, and 2.20.) Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion CY 2017 PFS final rule (81 FR 80272 through 80277). We also note that in the case of CPT code 76514, we recognized that the minutes shifted to the clinical staff were less intense than the minutes that remained in CPT code 76514, and therefore, we applied only half of the intraservice time ratio instead of the full ratio.

Comment: Several commenters stated that while it is true that changes in workflow as a result of smaller, portable, easier to use pachymeters now mean that the technician typically takes the measurements that used to be taken by the physician, the remaining 3 minutes of intraservice work time reflect the more intense cognitive work performed by the physician after the measurements are taken. Commenters agreed that the procedure has not fundamentally changed and that maintaining a work RVU of 0.17 was warranted.

Response: We disagree with the commenters and continue to believe that CPT code 76514 does not require more intensive cognitive work being performed by the practitioner after these measurements are taken, since the recommendations indicated that the steps in the procedure are unchanged since this code was first valued. While the incorporation of new technology can sometimes make services more complex and difficult to perform, it can also have the opposite effect by making services less reliant on manual skill and technique, and we believe that for CPT code 76514 the latter case is true since the same work previously carried out by the practitioner is now being carried out by the technician.

After consideration of the public comments, we are finalizing the work RVU and the direct PE inputs for CPT code 76514 as proposed.

(40) Ultrasound Elastography (CPT Codes 76981, 76982, and 76983)

In September 2017, the CPT Editorial Panel created three new codes describing the use of ultrasound elastography to assess organ parenchyma and focal lesions: CPT codes 76981 (Ultrasound, elastography; parenchyma), 76982 (Ultrasound, elastography; first target lesion) and 76983 (Ultrasound, elastography; each additional target lesion). The most common use of this code set will be for preparing patients with disease of solid organs, like the liver, or lesions within solid organs.

The RUC recommended a work RVU of 0.59 for CPT code 76981 (Ultrasound, elastography; parenchyma (*e.g.,* organ)), a work RVU of 0.59 for CPT code 76982 (Ultrasound, elastography; first target lesion), and a work RVU of 0.50 for add-on CPT code 76983 (Ultrasound, elastography; each additional target lesion). We are proposing the RUC-recommended work RVUs for each of these new CPT codes.

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Prepare room, equipment and supplies'' (CA013) activity to 3 minutes and to refine the clinical labor time for the ''Confirm order, protocol exam'' (CA014) activity to 0 minutes for CPT codes 76981 and 76982. CPT code 76700 (Ultrasound, abdominal, real time with image documentation; complete), the reference code for these two new codes, did not previously have clinical labor time assigned for the ''Confirm order, protocol exam'' clinical labor task, and we do not have any reason to believe that these particular services being furnished by the clinical staff have changed in the new codes, only the way in which this clinical labor time has been presented on the PE

worksheets. We also noted that there is no effect on the total clinical labor direct costs in these situations, since the same 3 minutes of clinical labor time is still being furnished in CPT codes 76981 and 76982. We also proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving the Ultrasound Elastography family of codes.

Comment: Several commenters expressed support for our proposed work RVUs for each of the three CPT codes in this family.

Response: We appreciate the support of commenters.

Comment: A commenter stated that in the CMS refinements to the direct PE inputs for CPT codes 76981 and 76982, CMS proposed to remove 1 minute from the CA014 activity code and proposed to add 1 minute to the CA013 activity code. The commenter stated that this refinement was inaccurate and encouraged CMS to modify this proposal by finalizing the RUC-recommended direct PE inputs for clinical labor.

Response: We addressed this subject in detail in the PE section of this final rule under the Changes to Direct PE Inputs for Specific Services heading (section II.B.3. of this final rule). For CPT codes 76981 and 76982, we are not finalizing these clinical labor refinements as proposed, as these codes have the ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'' task in predecessor CPT code 76700 on the old PE worksheet as well as 1 minutes of CA007 clinical labor time. We are instead finalizing the RUC-recommended clinical labor times for CA013 and CA014 for CPT codes 76981 and 76982. We are also not finalizing our refinements to the corresponding equipment times as a result.

After consideration of the public comments, we are finalizing the work RVUs for the codes in the Ultrasound Elastography family of codes as proposed: 0.59 work RVUs for CPT code 76981, 0.59 work RVUs for CPT code 76982, and 0.50 work RVUs for CPT code 76983. We are not finalizing our proposed direct PE inputs and are instead finalizing the RUC-recommended direct PE inputs for these three codes.

(41) Ultrasound Exam—Scrotum (CPT Code 76870)

CPT code 76870 (Ultrasound, scrotum and contents) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. We proposed a work RVU of 0.64 for CPT code 76870 (Ultrasound, scrotum and contents), as recommended by the RUC.

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Prepare room, equipment and supplies'' (CA013) activity to 3 minutes and to refine the clinical labor time for the ''Confirm order, protocol exam'' (CA014) activity to 0 minutes. CPT code 76870 did not previously have clinical labor time assigned for the ''Confirm order, protocol exam'' clinical labor task, and we did not have any reason to believe that the services being furnished by the clinical staff have changed, only the way in which this clinical labor time has been presented on the PE worksheets. We also noted that there was no effect on the total clinical labor direct costs in these situations since the same 3 minutes of clinical labor time is still being furnished under the CA013 room preparation activity. We also proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving CPT code 76870.

Comment: We received general support from commenters for our proposed work RVU of 0.64 for CPT code 76870, as recommended by the RUC.

Response: We thank commenters for their support.

Comment: A commenter stated that in the CMS refinements to the direct PE inputs for CPT code 76870, CMS proposed to remove 1 minute from the CA014 activity code and proposed to add 1 minute to the CA013 activity code. The commenter stated that this refinement was inaccurate and encouraged CMS to modify this proposal by finalizing the RUC-recommended direct PE inputs for clinical labor.

Response: We addressed this subject in detail in the PE section of this final rule under the Changes to Direct PE Inputs for Specific Services heading (section II.B.3. of this final rule). For CPT code 76870, we are finalizing these clinical labor refinements as proposed.

After consideration of the public comments, we are finalizing the work RVU of 0.64 and direct PE inputs for CPT code 76870 as proposed.

(42) Contrast-Enhanced Ultrasound (CPT Codes 76978 and 76979)

In September 2017, the CPT Editorial Panel created two new CPT codes describing the use of intravenous microbubble agents to evaluate suspicious lesions by ultrasound. CPT code 76978 (Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); initial lesion) is a stand-alone procedure for the evaluation of a single target lesion. CPT code 76979 (Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); each additional lesion with separate injection) is an add-on code for the evaluation of each additional lesion.

The two new CPT codes in this family represent a new technology that involves the use of intravenous microbubble agents to evaluate suspicious lesions by ultrasound. The first new CPT code 76978 (Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); initial lesion), is the base code for the new add-on CPT code 76979 (Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); each additional lesion with separate injection). The RUC reviewed the survey results for CPT code 76978 and recommended total time of 30 minutes and intraservice time of 20 minutes. Their recommendation for a work RVU of 1.62 is based neither on the median of the survey results (1.82) nor the 25th percentile of the survey results (1.27). Instead, the RUC-recommended work RVU is based on a crosswalk to CPT code 73719 (Magnetic resonance (*e.g.,* proton) imaging, lower extremity other than joint; with contrast material(s)), which has identical intraservice and total times as the survey CPT code. The RUC also identified a comparison CPT code (CPT code 73222 (Magnetic resonance (*e.g.,* proton) imaging, any joint of upper extremity; with contrast material(s)) with work RVU 1.62 and similar times. For add-on CPT code 76979, the RUC recommended a work RVU of 0.85, which is the 25th percentile of survey results, with total and intraservice times of 15 minutes.

Although we generally agree that, particularly in instances where a CPT code represents a new technology or procedure, there may be reason to deviate from survey metrics, we are confused by the logic behind the RUC's recommendation of a work RVU of 1.62 for CPT code 76978. When we considered the range of existing CPT codes with 30 minutes total time and 20 minutes intraservice time, we noted that a work RVU of 1.62 is among the highest potential crosswalks. We also noted that the RUC agreed with the 25th percentile of survey results for the new add-on CPT code, 76979, and we did not see

why the 25th percentile would not also be appropriate for the base CPT code, 76978. Therefore, we proposed a work RVU of 1.27 for CPT code 76978. We identified two CPT codes with total time of 30 minutes and intraservice time of 20 minutes that bracket the proposed work RVU of 1.27: CPT code 93975 (Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study) has a work RVU of 1.16, and CPT code 72270 (Myelography, 2 or more regions (*e.g.,* lumbar/thoracic, cervical/thoracic, lumbar/cervical, lumbar/thoracic/cervical), radiological supervision and interpretation) has a work RVU of 1.33. We proposed the RUC-recommended work RVU of 0.85 for add-on CPT code 76979.

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Prepare room, equipment and supplies'' (CA013) activity to 3 minutes and to refine the clinical labor time for the ''Confirm order, protocol exam'' (CA014) activity to 0 minutes for CPT code 76978. CPT codes 76700 (Ultrasound, abdominal, real time with image documentation; complete) and 76705 (Ultrasound, abdominal, real time with image documentation; limited), the reference codes for this new code, did not previously have clinical labor time assigned for the ''Confirm order, protocol exam'' clinical labor task, and we did not have any reason to believe that these particular services being furnished by the clinical staff have changed in the new code, only the way in which this clinical labor time has been presented on the PE worksheets. We also noted that there is no effect on the total clinical labor direct costs in these situations, since the same 3 minutes of clinical labor time is still being furnished in CPT code 76978.

We proposed to remove the 50 ml of the phosphate buffered saline (SL180) for CPT codes 76978 and 76979. When these codes were reviewed by the RUC, the conclusion that was reached was to remove this supply and replace it with normal saline. Since the phosphate buffered saline remained in the recommended direct PE inputs, we believe its inclusion may have been a clerical error. We proposed to remove the supply and solicited comments on the phosphate buffered saline or a replacement saline solution. We also proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving the Contrast-Enhanced Ultrasound family of codes.

Comment: Commenters were supportive of our proposed work RVU of 0.85 for CPT code 76979, as recommended by the RUC.

Response: We thank the commenters for their support of our proposal regarding the work RVU for this CPT code.

Comment: A few commenters expressed opposition to our proposed work RVU of 1.27 for new CPT code 76978. Commenters acknowledged that the code is valued at the high end of the range of values for a given intraservice time. However, they stated, being on the high end of a range of comparison codes is not necessarily in itself a reason to reduce the work RVU. They cite this as an illustration of CMS's discounting the importance of intensity in valuing physician services in favor of considering only time. The same commenters also noted that the new technology used in furnishing the service, Contrast Enhanced Ultrasound (CEUS), requires more technical skill and time than other established ultrasound services.

Response: Our observation that a survey code is on the high end of codes on the PFS with similar intraservice and total times is only one among several factors we consider when we perceive that the code is not properly valued in relation to other similar codes. We agree that there are instances in which valuing a code at the high range of work RVUs for codes with similar times is appropriate. However, on the whole, if a recommended work RVU places the code on the very high end of work RVUs with similar time parameters, we expect that the code would be of notably higher intensity than most other codes with those time parameters. We were not convinced that this was the case with CPT code 76978.

We were, however, persuaded by commenters that the higher technical skill and time involved in using the new technology, CEUS, compared with other established ultrasound services, is better reflected by the RUC's recommended work RVU than our proposed value. Consequently we are finalizing the RUC-recommended work RVU of 1.62 for CPT code 76978.

Comment: A commenter stated that in the CMS refinements to the direct PE inputs for CPT code 76978, CMS proposed to remove 1 minute from the CA014 activity code and proposed to add 1 minute to the CA013 activity code. The commenter stated that this refinement was inaccurate and encouraged CMS to modify this proposal by finalizing the RUC-recommended direct PE inputs for clinical labor.

Response: We addressed this subject in detail in the PE section of this final rule under the Changes to Direct PE Inputs for Specific Services heading (section II.B.3. of this final rule). For CPT code 76978, we are not finalizing these clinical labor refinements as proposed, as this code has the ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'' task in predecessor CPT code 76700 on the old PE worksheet as well as 1 minutes of CA007 clinical labor time. We are therefore finalizing the RUC-recommended clinical labor times for CA013 and CA014 for CPT code 76978. We are also not finalizing our refinements to the corresponding equipment times as a result.

Comment: Several commenters disagreed with the proposal to remove the 50 ml of the phosphate buffered saline (SL180) for CPT codes 76978 and 76979. Commenters stated that the SL180 supply can be replaced with ''normal saline'', however the change was not made because an appropriate replacement could not be identified. Commenters stated that the SL180 phosphate buffered saline (PBS) had been removed but ''normal saline'' has not replaced it. Commenters agreed that this change was appropriate and urged CMS to add the correct supply item for the appropriate type of saline.

Response: We disagree with the commenters that the ''normal saline'' was not added to these procedures. Both of these CPT codes include the ''sodium chloride 0.9% inj bacteriostatic (30ml uou)'' (SH068) supply which would function as a form of normal saline. We do not believe that it would be typical for these procedures to contain 50 ml of the phosphate buffered saline (SL180) in addition to the ''normal saline'' described by the SH068 supply.

After consideration of the public comments, we are finalizing the RUC-recommended work RVUs for both codes in this family as follows: Work RVU of 0.85 for CPT code 76979 and a work RVU of 1.62 for CPT code 76978. We are also finalizing the RUC-recommended direct PE inputs for these codes, with the exception of the refinement to the phosphate buffered saline (SL180) supply as detailed above.

(43) Magnetic Resonance Elastography (CPT Code 76391)

The CPT Editorial Panel created new stand-alone CPT code 76391 describing the use of magnetic resonance elastography for the evaluation of organ parenchymal pathology. This code will most often be used to evaluate patients

with disease of solid organs (for example, cirrhosis of the liver) or pathology within solid organs that manifest with increasing fibrosis or scarring. The goal with magnetic resonance elastography is to evaluate the degree of fibrosis/scarring (that is, stiffness) without having to perform more invasive procedures (for example, biopsy). This technique can be used to characterize the severity of parenchymal disease, follow disease progression, or response to therapy.

The RUC recommended a work RVU for new CPT code 76391 (Magnetic resonance (*e.g.,* vibration) elastography) of 1.29, with 15 minutes of intraservice time and 25 minutes of total time. The recommendation is based on a comparison with two reference CPT codes, CPT code 74183 (Magnetic resonance (*e.g.,* proton) imaging, abdomen; without contrast material(s), followed by with contrast material(s) and further sequences) with total time of 40 minutes, intraservice time of 30 minutes, and a work RVU of 2.20; and CPT code 74181 (Magnetic resonance (*e.g.,* proton) imaging, abdomen; without contrast material(s)), which has a total time of 30 minutes, intraservice time of 20 minutes, and a work RVU of 1.46. The RUC stated that both reference CPT codes have higher work values than the new CPT code, which is justified in both cases by higher intra-service times. They noted that, despite shorter intraservice and total time, CPT code 76391 is slightly more intense to perform due to the evaluation of wave propagation images and quantitative stiffness measures. We did not agree with the RUC's recommended work RVU for this CPT code. Using the RUC's two top reference CPT codes as a point of comparison, the intraservice time ratio in both instances suggests that a work RVU closer to 1.10 would be more appropriate. We recognize that the RUC believes the new CPT code is slightly more intense to furnish, but we are concerned about the relativity of this code in comparison with other imaging procedures that have similar intraservice and total times. Instead of the RUC-recommended work RVU of 1.29 for CPT code 76391, we proposed a work RVU of 1.10, which is based on a direct crosswalk to CPT code 71250 (Computed tomography, thorax; without contrast material). CPT code 71250 has identical intraservice time (15 minutes) and total time (25 minutes) compared to CPT code 76391, and we believe that the work involved in furnishing both services is similar. We note that CPT code 76391 describes a new technology and will be reviewed again by the RUC in 3 years.

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Prepare room, equipment and supplies'' (CA013) activity from 6 minutes to 5 minutes, and for the ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' (CA016) activity from 4 minutes to 3 minutes. We disagreed that this additional clinical labor time would be typical for these activities, which are already above the standard times for these tasks. In both cases, we proposed to maintain the current time from the reference CPT code 72195 (Magnetic resonance (*e.g.,* proton) imaging, pelvis; without contrast material(s)) for these clinical labor activities. We also proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving CPT code 76391.

Comment: A commenter stated that CMS misunderstood the role of reference CPT codes in the RUC's valuation process, and therefore our proposed work RVU for CPT code 76391 is premised on a false time comparison and a methodology that is invalid.

Response: In the materials provided to us, the RUC explicitly compared the two key reference services to CPT 76391 and stated that the higher work values for these codes are justified by higher intraservice times. The RUC did not provide a crosswalk code for CPT 76391. Because of the RUC's justification of the higher work RVUs in the reference services in relation to the higher intraservice times for these codes, and because the RUC did not provide a crosswalk CPT code for us to review, we believe it is an entirely appropriate methodology to calculate the intraservice time ratios using those reference codes. We acknowledged that the survey code is slightly more intense to perform than the reference codes, according to the RUC's SOR, which is why our calculation of intraservice time ratios is only a starting point in our review of the code's recommended work RVU. We considered the intraservice time ratios for both reference codes, which were not identical, and compared these values to other CPT codes in the PFS with similar intraservice and total times. For this particular CPT code 76391, we identified a crosswalk to CPT code 71250, which, as we stated, achieved an overall balance of similar times and similar intensity as the survey code and has a work RVU of 1.10.

Comment: Some commenters stated that our proposed value of 1.10 work RVUs for CPT code 76391 creates a rank order anomaly between an MRI code and CPT code, CPT code 74160.

Response: We do not agree that our proposed work RVU of 1.10 for this code creates a rank order anomaly between an MRI code and CT code because this service is described as being unlike a routine magnetic resonance imaging. This service also involves use of a new technology, which makes it difficult to compare directly to services involving magnetic resonance imaging. We are finalizing a work RVU of 1.10 for CPT code 76391.

Comment: One commenter agreed with the refinements to the direct PE inputs.

Response: We appreciate the support for our proposals from the commenter.

After consideration of the public comments, we are finalizing the work RVU of 1.10 and the direct PE inputs for CPT code 76391 as proposed.

(44) Computed Tomography (CT) Scan for Needle Biopsy (CPT Code 77012)

CPT code 77012 (Computed tomography guidance for needle placement (*e.g.,* biopsy, aspiration, injection, localization device), radiological supervision and interpretation) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually.

We proposed the RUC-recommended work RVU of 1.50 for CPT code 77012 (Computed tomography guidance for needle placement (*e.g.,* biopsy, aspiration, injection, localization device), radiological supervision and interpretation).

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Prepare room, equipment and supplies'' (CA013) activity to 3 minutes and to refine the clinical labor time for the ''Confirm order, protocol exam'' (CA014) activity to 0 minutes. CPT code 77012 did not previously have clinical labor time assigned for the ''Confirm order, protocol exam'' clinical labor task, and we did not have any reason to believe that the services being furnished by the clinical staff have changed, only the way in which this clinical labor time has been presented on the PE worksheets. We also noted that there is no effect on the total clinical labor direct costs in these situations since the same 3 minutes of clinical labor time is still being furnished under the CA013 room preparation activity.

We proposed to refine the equipment time for the CT room (EL007) to maintain the current time of 9 minutes. CPT code 77012 is a radiological supervision and interpretation

procedure and there has been a longstanding convention in the direct PE inputs, shared by 38 other codes, to assign an equipment time of 9 minutes for the equipment room in these procedures. We do not believe that it would serve the interests of relativity to increase the equipment time for the CT room in CPT code 77012 without also addressing the equipment room time for the other radiological supervision and interpretation procedures. Therefore, we proposed to maintain the current equipment room time of 9 minutes until this group of procedures can be subject to a more comprehensive review. We also proposed to refine the equipment time for the Technologist PACS workstation (ED050) in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving CPT code 77012.

Comment: We received support from a few commenters for our proposed work RVU for CPT code 77012, as recommended by the RUC.

Response: We appreciate commenters' support. We are finalizing a work RVU of 1.50 for CPT code 77012.

Comment: A commenter stated that in the CMS refinements to the direct PE inputs for CPT code 77012 CMS proposed to remove 1 minute from the CA014 activity code and proposed to add 1 minute to the CA013 activity code. The commenter stated that this refinement was inaccurate and encouraged CMS to modify this proposal by finalizing the RUC-recommended direct PE inputs for clinical labor.

Response: We addressed this subject in detail in the PE section of this final rule under the Changes to Direct PE Inputs for Specific Services heading (section II.B.3. of this final rule). For CPT code 77012, we are finalizing these clinical labor refinements as proposed.

Comment: Several commenters disagreed with the proposal to refine the equipment time for the CT room (EL007) to maintain the current time of 9 minutes. Commenters stated that the room time is included in CT guidance, as it is in US guidance (such as in CPT code 76942) because that is the room the procedure is performed in. Commenters stated that they agreed with CMS that other RS&I codes use the 9 minutes for room time as a precedent, but this was specific to angiographic rooms and referred to language from 2013 regarding angiographic rooms.

Response: We disagree with the commenters regarding the equipment time for the CT room (EL007) due to the longstanding convention in the direct PE inputs, shared by 38 other codes, to assign an equipment time of 9 minutes for the equipment room in radiological supervision and interpretation procedure. We agree with the commenters that at least some portion of the procedure is performed in the CT room, but we continue to believe that it would not serve the interests of relativity to increase the equipment time for the CT room in CPT code 77012 without also addressing the equipment room time for the other radiological supervision and interpretation procedures in a more comprehensive fashion. We also disagree with the commenters that this policy is specific to angiography rooms, as CPT codes 75989 and 77012 both employ CT rooms and currently utilize the standardized 9 minutes of equipment time for radiological supervision and interpretation procedures.

After consideration of the public comments, we are finalizing the work RVU and direct PE inputs for CPT code 77012 as proposed.

(45) Dual-Energy X-Ray Absorptiometry (CPT Code 77081)

CPT code 77081 (Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; appendicular skeleton (peripheral) (*e.g.,* radius, wrist, heel)) was identified as potentially misvalued on a screen of codes with a negative intraservice work per unit of time (IWPUT), with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes. For CY 2019, we proposed the RUC-recommended work RVU of 0.20 for CPT code 77081.

We did not propose any direct PE refinements for this code family.

The following is a summary of the public comments we received on our proposals involving CPT code 77081.

Comment: Commenters were supportive of our proposal regarding the work RVU for CPT code 77081.

Response: We appreciate the support for our proposals from the commenters.

After consideration of the public comments, we are finalizing the work RVU of 0.20 and direct PE inputs for CPT code 77081 as proposed.

(46) Breast MRI With Computer-Aided Detection (CPT Codes 77046, 77047, 77048, and 77049)

CPT codes 77058 (Magnetic resonance imaging, breast, without and/or with contrast material(s); unilateral) and 77059 (Magnetic resonance imaging, breast, without and/or with contrast material(s); bilateral) were identified in 2016 on a high expenditure services screen across specialties with Medicare allowed charges of $10 million or more. When preparing to survey these codes, the specialties noted that the clinical indications had changed for these exams. The technology had advanced to make computer-aided detection (CAD) typical and these codes did not parallel the structure of other magnetic resonance imaging (MRI) codes. In June 2017 the CPT Editorial Panel deleted CPT codes 0159T, 77058, and 77059 and created four new CPT codes to report breast MRI with and without contrast (including computer-aided detection).

The RUC recommended a work RVU of 1.45 for CPT code 77046 (Magnetic resonance imaging, breast, without contrast material; unilateral). This recommendation was based on a comparison with CPT codes 74176 (Computed tomography, abdomen and pelvis; without contrast material) and 74177 (Computed tomography, abdomen and pelvis; with contrast material(s)), which both have similar intraservice and total times in relation to CPT code 77046. We disagreed with the RUC's recommended work RVU because we did not believe that the reduction in total time of 15 minutes between the new CPT code 77046 and the deleted CPT code 77058 was adequately reflected in its recommendation. Although total time has decreased by 15 minutes, the only other difference between the two CPT codes is the change in the descriptor from the phrase 'without and/or with contrast material(s)' to 'without contrast material,' suggesting that there is less work involved in the new CPT code than in the deleted CPT code. Instead, we proposed a work RVU of 1.15 for CPT code 77046, which is similar to the total time ratio between the new CPT code and the deleted CPT code. It is also supported by a crosswalk to CPT code 77334 (Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts)). CPT code 77334 has total time of 35 minutes, intraservice time of 30 minutes, and a work RVU of 1.15.

CPT code 77047 (Magnetic resonance imaging, breast, without contrast material; bilateral) describes the same work as CPT code 77046, but reflects a bilateral rather than the unilateral procedure. The RUC recommended a work RVU of 1.60 for CPT code 77047. Since we proposed a different work RVU for the unilateral procedure than the value proposed by the RUC, we believe it is appropriate to recalibrate the work RVU for CPT code 77047 relative to the RUC's recommended difference in work between the two CPT codes. The RUC's recommendation for

the bilateral procedure is 0.15 work RVUs larger than for the unilateral procedure. Therefore, we proposed a work RVU of 1.30 for CPT code 77047.

The RUC recommended a work RVU of 2.10 for CPT code 77048 (Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD-real time lesion detection, characterization and pharmacokinetic analysis) when performed; unilateral). CPT code 77048 is a new CPT code that bundles the deleted CPT code for unilateral breast MRI without and/or with contrast material(s) with CAD, which was previously reported, in addition to the primary procedure CPT code, as CPT code 0159T (computer aided detection, including computer algorithm analysis of MRI image data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation, breast MRI). Consistent with our belief that the proposed value for the base CPT code in this series of new CPT codes (CPT code 77046) should be a work RVU of 1.15, we are proposing a work RVU for CPT code 77048 that adds the RUC-recommended difference in RUC-recommended work RVUs between CPT codes 77046 and 77048 (0.65 work RVUs) to the proposed work RVU for CPT code 77046. Therefore, we proposed a work RVU of 1.80 for CPT code 77048.

The last new CPT code in this series, CPT code 77049 (Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD-real time lesion detection, characterization and pharmoacokinetic analysis) when performed; bilateral) describes the same work as CPT code 77048, but reflects a bilateral rather than a unilateral procedure. The RUC recommended a work RVU of 2.30 for this CPT code. Similar to the process for valuing work RVUs for CPT code 77047 and CPT code 77048, we believe that a more appropriate work RVU is calculated by adding the difference in the RUC recommended work RVU for CPT codes 77046 and 77049, to the proposed value for CPT code 77046. Therefore, we proposed a work RVU of 2.00 for CPT code 77049.

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' (CA016) activity from 7 minutes to 3 minutes for CPT codes 77046 and 77047, and from 9 minutes to 5 minutes for CPT codes 77048 and 77049. We noted that when the MRI of Lower Extremity codes were reviewed during the previous rule cycle (CPT codes 73718–73720), these codes contained either 3 minutes or 5 minutes of recommended time for this same clinical labor activity. We also noted that the current Breast MRI codes that are being deleted and replaced with these four new codes, CPT codes 77058 and 77059, contain 5 minutes of clinical labor time for this same activity. We had no reason to believe that the new codes would require additional clinical labor time for patient positioning, especially given that the recommended clinical labor times are decreasing in comparison to the reference codes for obtaining patient consent (CA011) and preparing the room (CA013). Therefore, we refined the clinical labor time for the CA016 activity as detailed earlier to maintain relativity with the current clinical labor times in the reference codes, as well as with other recently reviewed MRI procedures.

Included in the recommendations for this code family were five new equipment items: CAD Server (ED057), CAD Software (ED058), CAD Software—Additional User License (ED059), Breast coil (EQ388), and CAD Workstation (CPU + Color Monitor) (ED056). We did not receive any invoices for these five equipment items, and as such we do not have any direct pricing information to use in their valuation. We proposed to use crosswalks to similar equipment items as proxies for three of these new types of equipment until we do have pricing information:

- CAD software (ED058) is crosswalked to flow cytometry analytics software (EQ380).
- Breast coil (EQ388) is crosswalked to Breast biopsy device (coil) (EQ371).
- CAD Workstation (CPU + Color Monitor) (ED056) is crosswalked to Professional PACS workstation (ED053).

We welcomed the submission of invoices with pricing information for these three new equipment items for our consideration to replace the use of these proxies. For the other two equipment items (CAD Server (ED057) and CAD Software—Additional User License (ED059)), we did not propose to establish a price at this time as we believe both of them would constitute forms of indirect PE under our methodology. We do not believe that the CAD Server or Additional User License would be allocated to the use of an individual patient for an individual service, and can be better understood as forms of indirect costs similar to office rent or administrative expenses. We understand that as the PE data age, these issues involving the use of software and other forms of digital tools become more complex. However, the use of new technology does not change the statutory requirement under which indirect PE is assigned on the basis of direct costs that must be individually allocable to a particular patient for a particular service. We look forward to continuing to seek out new data sources to help in updating the PE methodology.

We also proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving the Breast MRI with Computer-Aided Detection (CAD) family of codes.

Comment: A commenter disagreed with our use of deleted CPT code 77058 as a point of reference for considering whether the reduction in work RVU in the new code, CPT code 77046, is commensurate with the reduction in work time between the two codes. The commenter stated that CMS should not compare these new services with the old deleted services, as indicated by the specialty society having demonstrated compelling evidence that the work involved in the breast MRI code family has fundamentally changed.

Response: We disagree that it is inappropriate to use time comparisons with a code that is being deleted as a guide for assessing whether the reduction in work RVU recommended by the RUC is commensurate with the reduction in time based on survey results. The description of the work involved in furnishing CPT code 77046 has not changed substantively from the code being deleted. The compelling evidence that the commenter cites is related to the two new codes, CPT code 77048 and 77049, which are newly bundled with CAD. The main distinction in the description of physician work for this CPT code is that the new code specifies 'without contrast', while the deleted code described the service 'without and/or with contrast.' The change in patient population, also cited by the commenter, actually suggests that the more complex patients will be screened using the advanced technologies, such as is described by CPT code 77048. We recognize that changes in technology and work flow for the work described by CPT code 77046 have affected the work involved in furnishing these services. This is why we use the time ratios as a starting point for code comparisons rather than the end point.

Comment: One commenter stated that our proposed crosswalk code for CPT 77046, CPT code 77334, is inappropriate because of different preservice and intraservice times between the two codes, and because there is more low-

intensity time in CPT code 77334 compared with CPT code 77046. The commenter also indicated that our proposed work RVU for CPT code 77046 would create a rank order anomaly with other MRI codes.

Response: As a matter of principle, we do not agree that a chosen crosswalk for a CPT code is required to be clinically similar or to have identical intraservice and/or total time as the code being valued. However, in this instance, after further consideration, we agree with the commenter that our crosswalk code, CPT 77334, is not a particularly good comparison, in terms of intensity, to CPT 77046. We also agree with the commenter that our proposed work RVU for CPT code 77046 would create an anomaly among other CPT codes involving MRI. We are finalizing a work RVU for CPT code 77046 of 1.45, as recommended by the RUC.

Comment: A commenter disagreed with our use of increments in recalibrating work RVUs for codes that precede or follow a new or revalued CPT code, as was the process underlying our proposed work RVUs for CPT codes 77047, 77048, and 77049.

Response: The recalibration of CPT codes based on incremental difference in the work RVUs recommended by the RUC is an established methodology used by CMS to value the work involved in furnishing a service. There are certain types of code groups, particularly those with clear stepwise changes in intensity, as described by the RUC, for which we believe this is entirely appropriate. We continue to believe that this is an appropriate approach. However, having agreed with the commenter that our proposed work RVU for CPT code 77046 should be finalized at the RUC recommended work RVU of 1.45, we also believe that it is unnecessary to recalibrate the RUC's recommended work RVUs for the remainder of the three codes in the series. Therefore, we are finalizing a work RVU of 1.60 for CPT code 77047, 2.10 for CPT code 77048, and 2.30 for CPT code 77049.

Comment: Several commenters disagreed with the CMS proposal to refine the clinical labor time for the ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' (CA016) activity from 7 minutes to 3 minutes for CPT codes 77046 and 77047, and from 9 minutes to 5 minutes for CPT codes 77048 and 77049. Commenters stated that the rationale for this change was likely derived from reference to the lower clinical labor times for this activity associated with lower extremity MRI codes, and that it was an error to treat the clinical labor time for this activity as akin to that for lower extremity MRI. Commenters requested that CMS consider the experience of an 80-year-old patient who needs assistance on and off the table, along with reassurance, added explanation, IV insertion into delicate skin, and other anxiety needs. Commenters stated that another major distinction between breast MRI and extremity MRI is that the patient lies prone on the coil, which requires an awkward process of positioning and causes the need for additional clinical labor time.

Response: We continue to disagree with the commenters that the RUC-recommended clinical labor time would be typical for these procedures. As part of our review, we compared the clinical labor times for the CA016 activity not only to the codes in the MRI of Lower Extremity family, but also to the current Breast MRI codes that are being deleted and replaced with these four new codes. CPT codes 77058 and 77059 contain 5 minutes of clinical labor time for this same activity, and we do not agree that the clinical labor times would be increasing to 7 and 9 minutes in the newly created CPT codes, especially given that commenters did not provide a rationale as to why time would be increasing. We also note that while some patients will have conditions that are more difficult than the typical case, such as the 80-year-old patient described by the commenters, other patients would have conditions that are less difficult than the typical case. We remind the reader that valuation of services under the PFS is based on the typical case and not the most difficult cases that may arise. We further note that the clinical vignette for CPT code 77047 describes a 53-year old female patient, not an 80-year old patient, and was stated to be typical by 96 percent of the survey respondents.

Comment: A commenter stated that in the CMS refinements to the direct PE inputs for these four CPT codes, CMS proposed to remove 1 minute from the CA014 activity code and proposed to add 1 minute to the CA013 activity code. The commenter stated that this refinement was inaccurate and encouraged CMS to modify this proposal by finalizing the RUC-recommended direct PE inputs for clinical labor.

Response: We believe that the commenter may have been confused with several of the other code families that included these clinical labor refinements, which we described in the PE section of this final rule under the Changes to Direct PE Inputs for Specific Services heading (section II.B.3. of this final rule). We did not propose any refinements to the CA014 clinical labor for the codes in this family.

Comment: Several commenters requested that CMS add 5 minutes to CPT codes 77048 and 77049 to account for the time required to obtain vital signs. Commenters stated that to maintain consistency within the codes for MRI with contrast, they requested that new codes for breast MRI with contrast receive an additional two minutes of time for MRI technologist (L047A) bringing the total time for obtain vital signs to 5 minutes.

Response: We proposed in CY 2018 to assign 5 minutes of clinical labor time for all codes that include the ''Obtain vital signs'' task, that included at least 1 minute previously assigned to this task regardless of the date of last review. After considering the comments, we did not finalize our proposal to establish 5 minutes as the new standard for the ''Obtain vital signs'' clinical labor task. As a result, we do not agree with the commenters that the clinical labor time for the CA010 activity should be increased to 5 minutes for CPT codes 77048 and 77049, especially given that we did not make a proposal to do so. We refer readers to the CY 2018 PFS final rule (82 FR 52990–52991) for additional details about last year's proposal on this issue.

Comment: One commenter requested that CMS assign additional clinical labor time for MRI procedures with contrast in order to account for time spent counseling patients. Commenters stated that because of the increased public awareness of the risk relating to gadolinium, additional time is required to explain the benefits and risks of the procedure.

Response: We note that the MRI procedures in this family that are done with contrast (CPT codes 77048 and 77049) already contain more clinical labor than the MRI procedures that are done without contrast (CPT codes 77046 and 77047). Specifically, these procedures already contain two additional minutes for ''Provide education/obtain consent'' (CA011) clinical labor than the non-contrast versions of the procedures, which we believe indicates that the concerns of the commenters have been taken into account.

Comment: Several commenters stated that the lack of invoices for the new equipment items may have been an oversight and enclosed new invoices with their comment letter. Commenters also stated that the CAD Software equipment (ED058) is actually synonymous with the ''breast biopsy software'' (EQ370) equipment, and recognized that in hindsight they should

have been consistent in identifying the equipment item between the breast biopsy codes and the MR breast codes. One commenter disagreed that the CAD Server or Additional User License equipment constituted forms of direct PE, and requested that CMS consider the cost of CAD service contracts and ''C-view'' costs in order to accurately access the calculation of indirect practice expenses.

Response: We appreciate the submission of additional invoices from the commenters to assist in pricing these new equipment items. As we detailed in the Practice Expense portion of this final rule (section II.B. of this final rule), we are finalizing an update in the price of the CAD Software (ED058) equipment to $43,308.12 based on the new invoice submission and additional review by the StrategyGen contractor. We are also finalizing a price of $83,200 for the Breast coil (EQ388) equipment and a price of $12,031.52 for the CAD Workstation (CPU + Color Monitor) (ED056) based on the invoices submitted by the commenters. For the other two equipment items (CAD Server (ED057) and CAD Software—Additional User License (ED059)), we continue to believe that both of them would constitute forms of indirect PE under our methodology. The submitted invoices indicated that the CAD Server was a server type used in a data center while the user license was for a third license above and beyond the two licenses included in the price of the CAD software. As we stated in the proposed rule, we do not believe that these types of equipment would be allocated to the use of an individual patient for an individual service, and can be better understood as forms of indirect costs similar to office rent or administrative expenses.

Comment: Several commenters stated that CMS had overstated the useful life of a breast coil. The commenters stated that a coil will start to display signs of wear, such as cracking of its case, flex spots, exposed wiring, or a degradation of its attenuated field causing a loss in image quality after about three to four years. Commenters stated that a useful life of 5 years would be more appropriate and consistent with the experience of their members.

Response: We appreciate the additional information regarding the useful life of the breast coil equipment from the commenters. Our proposal to use 10 years as the useful life for this new equipment was based on our use of the breast biopsy device (EQ371) equipment as a proxy. We agree with the commenters that it would be more accurate to update the useful life to 5 years in light of this new information.

After consideration of the public comments, we are finalizing the RUC-recommended work RVUs for the codes in the Breast MRI with Computer-Aided Detection family of codes. We are finalizing the direct PE inputs as proposed, with the updates to the pricing of the new equipment as detailed above.

(47) Blood Smear Interpretation (CPT Code 85060)

CPT code 85060 (Blood smear, peripheral, interpretation by physician with written report) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. For CY 2019, the RUC recommended a work RVU of 0.45 based on maintaining the current work RVU.

We disagreed with the recommended value and proposed a work RVU of 0.36 for CPT code 85060 based on the total time ratio between the current time of 15 minutes and the recommended time established by the survey of 12 minutes. This ratio equals 80 percent, and 80 percent of the current work RVU of 0.45 equals a work RVU of 0.36. When we reviewed CPT code 85060, we found that the recommended work RVU was higher than nearly all of the other global XXX codes with similar time values, and we do not believe that this blood smear interpretation procedure would have an anomalously high intensity. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 85060, we believe that it would be more accurate to propose the total time ratio at a work RVU of 0.36 to account for these decreases in the surveyed work time.

The proposed work RVU was also based on the use of three crosswalk codes. We directly supported the proposed valuation through a crosswalk to CPT code 95930 (Visual evoked potential (VEP) checkerboard or flash testing, central nervous system except glaucoma, with interpretation and report), which has a work RVU of 0.35 along with 10 minutes of intraservice time and 14 minutes of total time. We also explained the proposed valuation by bracketing it between two other crosswalks, with CPT code 99152 (Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 minutes of intraservice time, patient age 5 years or older) on the lower end at a work RVU of 0.25 and CPT code 93923 (Complete bilateral noninvasive physiologic studies of upper or lower extremity arteries, 3 or more levels, or single level study with provocative functional maneuvers) on the higher end at a work RVU of 0.45.

The RUC recommended no direct PE inputs for CPT code 85060 and we proposed none.

The following is a summary of the public comments we received on our proposals involving CPT code 85060.

Comment: Many commenters disagreed with the proposed work RVU of 0.36 for CPT code 85060 and stated that CMS should finalize the RUC-recommended work RVU of 0.45. Commenters stated that a time ratio should not be used because any decrease will result in a large ratio and a corresponding but inappropriate decrease to the physician work RVU. Commenters stated that rather than using time ratios CMS should examine the magnitude estimation between the physician work, time, and intensity. Commenters also stated that the current time was not based on a survey and it was unclear how the time was determined.

Response: We disagree with the commenters and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in the resource of time have been unaccounted for in a recommended RVU, then we believe we have the obligation to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual

procedures. Were we to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. (As an example, CPT codes 38222, 54231, 55870, 75573, and 78814 all share identical CY 2019 work times with 15 minutes of preservice time, 30 minutes of intraservice time, and 15 minutes of postservice time; however these codes have respective CY 2019 work RVUs of 1.44, 2.04, 2.58, 2.55, and 2.20.) Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion CY 2017 PFS final rule (81 FR 80272 through 80277).

Comment: Several commenters disagreed with our statement that the recommended work value of 0.45 is higher than nearly all of the other global XXX codes with similar time values. Commenters stated that a search of the RUC database contradicted this finding, showing that eleven XXX codes with 12 minutes of intraservice time have values lower than 0.45 and thirteen XXX codes with 12 minutes of intraservice time have values the same or higher than 0.45 RVUs. Commenters stated that none of these services are pathology services and were not comparable, except for CPT code 88388 (Macroscopic examination, dissection, and preparation of tissue for non-microscopic analytical studies (*e.g.,* nucleic acid-based molecular studies)) which has identical work value and intra-service time and was the reference code cited in the RUC recommendation. Commenters also disagreed with the CMS crosswalk to CPT code 95930 due to the fact that it is not a pathology service.

Response: We disagree with the commenters' statement that pathology services are only comparable to other pathology services. Although we agree that the unique nature of pathology and laboratory services can make comparisons across codes more difficult than in other services, we believe the comparison of codes with similar work RVUs across different specialties is important to maintaining the relativity of the PFS. We disagree with the commenters that the crosswalk to CPT code 95930 would be methodologically inappropriate solely on the grounds that it is not a pathology service.

Comment: Several commenters stated that there are a number of variables that must be considered in the evaluation of a blood smear when compared to others, including red blood cell count, size and morphology, platelet morphology and number, white blood cell morphology and the presence of white blood cell precursors. Commenters stated that other services with identical physician work include CPT code 88314 (Special stain including interpretation and report; histochemical stain on frozen tissue block) and CPT code 93923 (Complete bilateral noninvasive physiologic studies of upper or lower extremity arteries, 3 or more levels). Commenters stated the proposed work value would create significant rank order anomalies within the array of pathology services, as CPT code 85060 has nearly identical work time to CPT code 88314 but would be valued lower at the proposed work RVU.

Response: We appreciate the detailed information about CPT code 85060 provided by the commenters regarding the clinical comparisons to CPT codes 88314 and 93923.

After consideration of the public comments, we are not finalizing our proposed work RVU of 0.36 for CPT code 85060. We are finalizing the RUC-recommended work RVU of 0.45 instead.

(48) Bone Marrow Interpretation (CPT Code 85097)

CPT code 85097 (Bone marrow, smear interpretation) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. For CY 2019, the RUC recommended a work RVU of 1.00 based on a direct crosswalk to CPT code 88121 (Cytopathology, in situ hybridization (*e.g.,* FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes, each specimen; using computer-assisted technology).

We disagreed with the RUC-recommended value and we proposed a work RVU of 0.94 for CPT code 85097 based on maintaining the current work valuation. We noted that the survey indicated that CPT code 85097 typically takes 25 minutes of work time to perform, down from a previous work time of 30 minutes, and, generally speaking, since the two components of work are time and intensity, we believe that significant decreases in time should be reflected in decreases to work RVUs. For the specific case of CPT code 85097, we supported our proposed work RVU of 0.94 through a crosswalk to CPT code 88361 (Morphometric analysis, tumor immunohistochemistry (*e.g.,* Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure; using computer-assisted technology), a recently reviewed code from CY 2018 with the identical time values and a work RVU of 0.95.

We also considered a work RVU of 0.90 based on double the recommended work RVU of 0.45 for CPT code 85060 (Blood smear, peripheral, interpretation by physician with written report). When both of these CPT codes were under review, the explanation was offered that in a peripheral blood smear, typically, the practitioner does not have the approximately 12 precursor cells to review, whereas in an aspirate from the bone marrow, the practitioner is examining all the precursor cells. Additionally, for CPT code 85097, there are more cell types to look at as well as more slides, usually four, whereas with CPT code 85060 the practitioner would typically only look at one slide. Although we did not propose to value CPT code 85097 at twice the work RVU of CPT code 85060, we believe this analysis also supports maintaining the current work RVU of 0.94 as opposed to raising it to 1.00.

For the direct PE inputs, we proposed to remove the clinical labor time for the ''Accession and enter information'' (PA001) and ''File specimen, supplies, and other materials'' (PA008) activities. As we stated previously, information entry and specimen filing tasks are not individually allocable to a particular patient for a particular service and are considered to be forms of indirect PE. Although we agree that these are necessary tasks, under our established methodology we believe that they are more appropriately classified as indirect PE.

The following is a summary of the public comments we received on our proposals involving CPT code 85097.

Comment: Many commenters disagreed with the proposed work RVU of 0.94 for CPT code 85097 and stated that CMS should finalize the RUC-recommended work RVU of 1.00. Commenters stated that the CMS rationale about changes in work time was out of place in this context because the survey respondents indicate that the service requires 25 minutes to perform rather than the current time of 30 minutes, yet CMS proposed to maintain the current work value. The commenters suggested that maintaining the current work RVU of 0.94 was therefore inappropriate. Commenters also stated that the current work time for CPT code 85097 was not based on a survey and that it was unknown how this time was

determined and what it actually represents.

Response: We agree that it is important to use the most recent data available regarding time, and we note that when many years have passed between when time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The times currently associated with codes play a very important role in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had routinely been overestimated, this would undermine the relativity of the work RVUs on the PFS in general, given the process under which codes are often valued by comparisons to codes with similar times, and it also would undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS. Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times used in the PFS ratesetting processes are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we want to reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values in our methodology, we refer readers to our discussion of the subject in the CY 2017 final rule (81 FR 80273 through 80274). With regard to the specific case of CPT code 85097, we proposed to maintain the current work RVU rather than decreasing the work RVU due to some of the same concerns about the historical work times for this code raised by the commenters. We believe that the logic provided by the commenters suggests that the decreases in the work time of CPT code 85097 should have been reflected in decreases to the work RVU (as opposed to maintaining the current value), which we do not believe was their intention.

Comment: Several commenters stated that given the total work, time, intensity, and complexity of the patient case, the current work RVU of 0.94 was too low for CPT code 85097. Commenters stated that the RUC chose a crosswalk to CPT code 88121 (Cytopathology, in situ hybridization (*e.g.,* FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes, each specimen; using computer-assisted technology) specifically because it is a similar pathology code with a value between the current work value of 0.94 and the survey 25th percentile of 1.15. Commenters stated that the CMS reference code (CPT code 88361) was less intense and complex to perform as it involves evaluating a single antibody and determining the percentage of tumor cells that are positive for that antibody, as opposed to the work of CPT code 85097 which involves evaluating all blood cell precursors for quantitative and morphologic abnormalities, as well as evaluating for metastatic tumor cells, evidence of infection, or evidence of lymphoid neoplasms.

Response: We disagree with the commenters that the current work RVU of 0.94 or the work RVU of our reference code of 88361 are too low in comparison to CPT code 85097. All three of the codes under discussion (CPT codes 85097, 88121, and 88361) are clinically similar procedures that involve the practitioner using their eyes to look at staining patterns. We do not agree with the commenters that the RUC's use of CPT code 88121 as a crosswalk would be any more accurate on clinical grounds that the reference code of 88361 that we chose in the proposed rule. Overall, we do not believe that there is a significant difference between these three procedures given their nearly identical work RVUs, intensities, and work times. However, given the decrease in surveyed work time, we continue to believe that it is more appropriate to maintain the current work RVU of 0.94 than to increase it to 1.00 due to our longstanding belief that decreases in work time should typically be not be reflected in increases to the work RVU. We note that we are not proposing to decrease the work RVU for CPT code 85097 despite this decrease in the surveyed work time, only to maintain the current valuation.

Comment: Several commenters responded to the CMS consideration of a work RVU of 0.90 based on double the recommended work RVU of 0.45 for CPT code 85060. Commenters stated that they wished to clarify that this explanation was put forward to a RUC member whom was simply questioning why this service requires twice the time of CPT code 85060. Commenters stated that simply doubling the RUC-recommended work RVU of 0.45 for CPT code 85060 based on the amount of time does not account for the considerably greater intensity and complexity of CPT code 85097 over CPT code 85060 as described elsewhere in their comments.

Response: We appreciate the clarification on this issue from the commenters.

Comment: Several commenters disagreed with the CMS proposal remove the clinical labor time for the ''Accession and enter information'' (PA001) and ''File specimen, supplies, and other materials'' (PA008) activities. Commenters stated that although the descriptions for the PA001 and PA008 clinical labor activities appeared to describe data entry and filing activities, these tasks are very different in the pathology lab. Commenters stated that it is crucial for the performance of these tasks be executed accurately according to rigid patient laboratory protocols, standards, and legal processes associated with specimen/patient care and they should not be considered a form of indirect expense.

Response: Although we agree that the unique nature of pathology and laboratory services can make comparisons across codes more difficult than for other services, we believe the comparison of similar clinical labor activities across different services is important to maintaining the relativity of the direct PE inputs. As we stated in the CY 2017 PFS final rule (81 FR 80324), we agree with the commenters that entering patient data into information systems and filing specimens are important tasks, and we agree that these would take more than zero minutes to perform. However, we continue to believe that these activities are correctly categorized as indirect PE as administrative functions, and therefore, we do not recognize the entry of patient data or the filing of specimens as direct PE inputs, and we do not consider this task as typically performed by clinical labor on a per-service basis.

After consideration of the public comments, we are finalizing the work RVU and direct PE inputs for CPT code 85097 as proposed.

(49) Fibrinolysins Screen (CPT Code 85390)

CPT code 85390 (Fibrinolysins or coagulopathy screen, interpretation and report) was identified as potentially misvalued on a screen of codes with a negative IWPUT, with 2016 estimated Medicare utilization over 10,000 for

RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes. For CY 2019, we are proposing the RUC-recommended work RVU of 0.75 for CPT code 85390. Because this is a work only code, the RUC did not recommend, and we did not propose any direct PE inputs for CPT code 85390.

The following is a summary of the public comments we received on our proposals involving CPT code 85390.

Comment: A commenter expressed support for our proposal to accept the RUC-recommended work RVU for this code.

Response: We appreciate the support for our proposals from the commenter.

After consideration of the public comments, we are finalizing our proposal to accept the RUC-recommended work RVU for this code.

(50) Electroretinography (CPT Codes 92273, 92274, and 0509T)

CPT code 92275 (Electroretinography with interpretation and report) was identified in 2016 on a high expenditure services screen across specialties with Medicare allowed charges of $10 million or more. In January 2016, the specialty society noted that they became aware of inappropriate use of CPT code 92275 for a less intensive version of this test for diagnosis and indications that are not clinically proven and for which less expensive and less intensive tests already exist. CPT changes were necessary to ensure that the service for which CPT code 92275 was intended was clearly described, as well as an accurate vignette and work descriptor were developed. In September 2017, the CPT Editorial Panel deleted CPT code 92275 and replaced it with two new codes to describe electroretinography full field and multi focal. A category III code was retained for pattern electroretinography.

For CPT code 92273 (Electroretinography (ERG) with interpretation and report; full field (*e.g.,* ffERG, flash ERG, Ganzfeld ERG)), we disagreed with the recommended work RVU of 0.80 and we instead proposed a work RVU of 0.69 based on a direct crosswalk to CPT code 88172 (Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, first evaluation episode, each site). CPT code 88172 is another interpretation procedure with the same 20 minutes of intraservice time, which we believe is a more accurate comparison for CPT code 92273 than the two reference codes chosen by the survey participants due to their significantly higher and lower intraservice times. We noted that the recommended intraservice time for CPT code 92273 as compared to its predecessor CPT code 92275 is decreasing from 45 minutes to 20 minutes (56 percent reduction), and the recommended total time is decreasing from 71 minutes to 22 minutes (69 percent reduction); however, the work RVU is only decreasing from 1.01 to 0.80, which is a reduction of just over 20 percent. Although we did not imply that the decreases in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 92273, we have reason to believe that the significant drops in surveyed work time as compared to CPT code 92275 are a result of improvements in technology since the predecessor code was reviewed. The older machines used for electroretinography were slower and more cumbersome, and now the same work for the service can be performed in significantly less time. Therefore, we proposed a work RVU of 0.69 based on the direct crosswalk to CPT code 88172, which we believe more accurately accounts for these decreases in surveyed work time.

For CPT code 92274 (Electroretinography (ERG) with interpretation and report; multifocal (mfERG)), we disagreed with the RUC-recommended work RVU of 0.72 and proposed a work RVU of 0.61. We concurred that the relative difference in work between CPT code 92273 and 92274 is equivalent to the recommended interval of 0.08 RVUs. Therefore, we proposed a work RVU of 0.61 for CPT code 92274, based on the recommended interval of 0.08 fewer RVUs below our proposed work RVU of 0.69 for CPT code 92273. The proposed work RVU is also based on the use of two crosswalk codes: CPT code 88387 (Macroscopic examination, dissection, and preparation of tissue for non-microscopic analytical studies; each tissue preparation); and CPT code 92100 (Serial tonometry (separate procedure) with multiple measurements of intraocular pressure over an extended time period with interpretation and report, same day). Both codes share the same 20 minutes of intraservice and 20 minutes of total time, with a work RVU of 0.62 for CPT code 88387 and a work RVU of 0.61 for CPT code 92100.

The recommendations for this code family also include CPT Category III code 0509T (Electroretinography (ERG) with interpretation and report, pattern (PERG)). We typically assign contractor pricing for Category III codes since they are temporary codes assigned to emerging technology and services. However, in cases where there is an unusually high volume of services that will be performed under a Category III code, we have sometimes assigned an active status to the procedure and developed RVUs before a formal CPT code is created. In the case of CPT code 0509T, the recommendations indicate that approximately 80 percent of the services currently reported under CPT code 92275 will be reported under the new Category III code. Since this will involve an estimated 100,000 services for CY 2019, we believe that the interests of relativity would be better served by assigning an active status to CPT code 0509T and creating RVUs through the use of a proxy crosswalk to a similar existing service. Therefore, we proposed to assign an active status to CPT Category III code 0509T for CY 2019, with a work RVU and work time values crosswalked from CPT code 92250 (Fundus photography with interpretation and report). CPT code 92250 is a clinically similar procedure that was recently reviewed during the CY 2017 rule cycle. We proposed a work RVU of 0.40 and work times of 10 minutes of intraservice and 12 minutes of total time for CPT code 0509T based on this crosswalk to CPT code 92250.

For the direct PE inputs, we proposed to remove the preservice clinical labor in the facility setting for CPT codes 92273 and 92274. Both of these codes are diagnostic tests under which the professional (26 modifier) and technical (TC modifier) components will be separately billable, and codes that have these professional and technical components typically will not have direct PE inputs in the facility setting since the technical component is only valued in the nonfacility setting. We also noted on this subject that the predecessor code, CPT code 92275, does not currently include any preservice clinical labor, nor any facility direct PE inputs.

We proposed to remove the clinical labor time for the ''Greet patient, provide gowning, ensure appropriate medical records are available'' (CA009) and the ''Provide education/obtain consent'' (CA011) activities for CPT codes 92273 and 92274. Both of these CPT codes will typically be reported with a same day E/M service, and we believe that these clinical labor tasks will be carried out during the E/M service. We believe that their inclusion in CPT codes 92273 and 92274 would be duplicative. We also proposed to refine the clinical labor time for the

''Prepare room, equipment and supplies'' (CA013) activity to 3 minutes and to refine the clinical labor time for the ''Confirm order, protocol exam'' (CA014) activity to 0 minutes for both codes. The predecessor CPT code 92275 did not previously have clinical labor time assigned for the ''Confirm order, protocol exam'' clinical labor task, and we did not have any reason to believe that the services being furnished by the clinical staff had changed in the new codes, only the way in which this clinical labor time has been presented on the PE worksheets. We also noted that there is no effect on the total clinical labor direct costs in these situations since the same 3 minutes of clinical labor time is still being furnished.

We proposed to refine the clinical labor time for the ''Clean room/equipment by clinical staff'' (CA024) activity from 12 minutes to 8 minutes for CPT codes 92273 and 92274. The recommendations for these codes stated that cleaning is carried out in several steps: The patient is first cleaned for 2 minutes, followed by wires and electrodes being scrubbed carefully with detergent, soaked, and then rinsed with sterile water. We agree with the need for 2 minutes of patient cleaning time and for the cleaning of the wires and electrodes to take place in two different steps. However, our standard clinical labor time for room/equipment cleaning is 3 minutes, and therefore, we proposed a total time of 8 minutes for these codes, based on 2 minutes for patient cleaning and then 3 minutes for each of the two steps of wire and electrode cleaning.

We proposed to refine the clinical labor time for the ''Technologist QC's images in PACS, checking for all images, reformats, and dose page'' (CA030) activity from 10 minutes to 3 minutes for CPT codes 92273 and 92274. We finalized in the CY 2017 PFS final rule (81 FR 80184–80186) a range of appropriate standard minutes for this clinical labor activity, ranging from 2 minutes for simple services up to 5 minutes for highly complex services. We believe that the complexity of the imaging in CPT codes 92273 and 92274 is comparable to the CT and magnetic resonance (MR) codes that have been recently reviewed, such as CPT code 76391 (Magnetic resonance (*e.g.,* vibration) elastography). Therefore, in order to maintain relativity, we proposed the same clinical labor time of 3 minutes for CPT codes 92273 and 92274 that has been recommended for these CT and MR codes. We also proposed to refine the clinical labor time for the ''Review examination with interpreting MD/DO'' (CA031) activity from 5 minutes to 2 minutes for CPT codes 92273 and 92274. We also finalized in the CY 2017 PFS final rule a standard time of 2 minutes for reviewing examinations with the interpreting MD, and we have no reason to believe that these codes would typically require additional clinical labor at more than double the standard time.

We noted that the new equipment item ''Contact lens electrode for mfERG and ffERG'' (EQ391) was listed twice for CPT code 92273 but only a single time for CPT code 92274. We solicited additional information about whether the recommendations intended this equipment item to be listed twice, with one contact intended for each eye, or whether this was a clerical mistake. We are also interested in additional information as to why the contact lens electrode was listed twice for CPT code 92273 but only a single time for CPT code 92274. Finally, we also proposed to refine the equipment times in accordance with our standard equipment time formulas.

We proposed to use the direct PE inputs for CPT code 92274, including the refinements detailed above, as a proxy for CPT Category III code 0509T until it can be separately reviewed by the RUC.

The following is a summary of the public comments we received on our proposals involving the Electroretinography family of codes.

Comment: Many commenters disagreed with the proposed work RVU of 0.69 for CPT code 92273 and stated that CMS should finalize the RUC-recommended work RVU of 0.80. Commenters stated that the RUC-recommended work RVU was based on the survey 25th percentile and CMS should use survey data in establishing the work RVU. Commenters stated that the decrease in intraservice work time of deleted CPT code 92275 from when it was last surveyed in 1995 was due to the fact that the physician no longer participates in the acquisition of the data or performing the test on the patient, which has become the technician's work. Commenters stated that the RUC determined that the physician work is not the same as it was with CPT code 92275 and the recommended decrease in work RVUs appropriately addresses the decrease in physician time to perform this service.

Response: We disagree with the commenters that the RUC-recommended decrease in work RVUs appropriately addresses the decrease in physician time to perform this service. As we stated in the proposed rule, the recommended intraservice time for CPT code 92273 as compared to its predecessor CPT code 92275 is decreasing from 45 minutes to 20 minutes (56 percent reduction), and the recommended total time is decreasing from 71 minutes to 22 minutes (69 percent reduction); however, the RUC-recommended work RVU is only decreasing from 1.01 to 0.80, which is a reduction of just over 20 percent. Although we did not imply that the decreases in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. As a result, we believe that our proposed work RVU of 0.69 more accurately captures the changes in work that have taken place since the previous survey.

Comment: Several commenters stated that while the time required for CPT code 92273 is less than the time required for CPT code 92275, the code it replaced, the intensity and complexity of the work involved in interpreting the test has increased significantly. Commenters stated that the newer machines are easily programmed to produce more images and numbers for interpretation (double or more) than the machines in use in 1995 when the procedure was last valued and that advances in medical knowledge have identified more specific retinal dystrophy diagnoses with specific genotypes that the clinician must consider when interpreting the test. Commenters emphasized that while the machine may be more efficient as stated by CMS, the cognitive work required by the physician interpreting the test has increased significantly.

Response: We disagree with the commenters that all of the efficiencies gained in work time via improved technology would be offset via higher intensity (that is, greater cognitive work on the part of the practitioner). While the incorporation of new technology can sometimes make services more complex and difficult to perform, it can also have the opposite effect by making services less reliant on manual skill and technique. At the RUC-recommended work RVU of 0.80, the intensity of CPT code 92273 would increase by nearly 300 percent, and we do not agree that the cognitive intensity of the procedure would have increased by this amount. We continue to believe that our proposed work RVU of 0.69 more accurately captures the changes in work taking place as a result of greater technological efficiencies in the service.

Comment: Many commenters disagreed with the proposed work RVU of 0.61 for CPT code 92274 and stated that CMS should finalize the RUC-recommended work RVU of 0.72. Commenters stated that CMS should use valid methods of evaluating services, such as survey data and magnitude estimation, instead of relying on an incremental difference in work RVUs between codes 92273 and 92274.

Response: We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. We note that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service. We further note that we did not rely solely on an increment for our proposed work RVU for CPT code 92274, as the proposed work RVU was also based on the use of a reference code (CPT code 88387) and a crosswalk code (CPT code 92100). Both codes share the same 20 minutes of intraservice and 20 minutes of total time, with a work RVU of 0.62 for CPT code 88387 and a work RVU of 0.61 for CPT code 92100.

Comment: Several commenters stated that while there was no predecessor code for direct comparison, the intensity and complexity of the work involved in interpreting the test has increased significantly compared to 1995, when CPT code 92275 was last valued. Commenters restated the same arguments they expressed for CPT code 92273: The new machines used in CPT code 92274 have become more efficient but the cognitive work required by the physician interpreting the test has increased significantly.

Response: As we stated with regard to CPT code 92273, we continue to disagree with the commenters that all of the efficiencies gained in work time via improved technology would be offset via higher intensity (that is, greater cognitive work on the part of the practitioner). At the RUC-recommended work RVU of 0.72, the intensity of CPT code 92274 would also increase by nearly 300 percent, and we do not agree that the cognitive intensity of the procedure would have increased by this amount. We continue to believe that our proposed work RVU of 0.61 more accurately captures the changes in work taking place as a result of greater technological efficiencies in the service.

Comment: Several commenters stated that CPT code 92274 requires more physician work than the crosswalks we identified. Commenters stated that CPT code 88387 is a straightforward manual dissection that does not require interpretation of multiple images and numeric values to arrive at a diagnosis. Commenters stated that CPT code 92100 also requires less physician work, as CPT code 92274 requires interpretation of significantly more data and consideration of many more diagnostic possibilities.

Response: We disagree with the commenters that our reference and crosswalk codes require less work than CPT code 92274. While it is true that CPT code 88387 does not require interpretation of multiple images and numeric values, this is because it is not an imaging service, and it is inappropriate to state that the work of CPT code 88387 is lower than CPT code 92274 based on this criteria. We do not agree that the macroscopic examination, dissection, and preparation of tissue taking place in CPT code 88387 would inherently constitute less work than CPT code 92274. Similarly, we do not agree that the serial tonometry with multiple measurements of intraocular pressure taking place in CPT code 92100 would involve less work than CPT code 92274, especially due to the nearly identical intraservice and total work times shared by these procedures.

Comment: One commenter disagreed with our proposal to assign active pricing to Category III code 0509T. The commenter stated that this code should go through the regular vetting process that other new technology typically follows, including development of appropriate clinical literature that would qualify it for elevation to a full Category I CPT code, and then a RUC survey in order to develop accurate valuation for work and practice expense. The commenter was concerned that CMS would single out and put forward a value for a technology that has not gone through the same scrutiny as other new technologies.

Response: We understand the concerns expressed by the commenter. As we stated in the proposed rule, we typically assign contractor pricing for Category III codes since they are temporary codes assigned to emerging technology and services. However, in cases where there is an unusually high volume of services that will be performed under a Category III code, we have sometimes assigned an active status to the procedure, and in the case of Category III code 0509T the recommendations indicated that approximately 80 percent of the services currently reported under CPT code 92275 will be reported under the new Category III code. Since this will involve an estimated 100,000 services for CY 2019, we continue to believe that the interests of relativity would be better served by assigning an active status to Category III code 0509T and creating RVUs through the use of a proxy crosswalk to a similar existing service. We agree with the commenter that this code should still go through the regular vetting process that other new technology typically follows, and we look forward to receiving recommendations for work and practice expense inputs in the future.

Comment: One commenter stated that many of the proposed changes to the direct PE inputs were made with the intent to standardize inputs. The commenter stated that although the RUC has created many standards, they have always acknowledged that there are and will be exceptions to those standards. The commenter stated that these important diagnostic tests are unusual services that require significant amounts of preservice clinical labor time in whichever setting they are performed, and that the recommended direct PE inputs were carefully prepared based upon documented personal observation and time motion studies. The commenter stated that the predecessor CPT code 92275 had an over-simplified PE spreadsheet with very few data inputs, each comprising substantial amounts of time that are now broken out into separate inputs, and as a result the work required had not changed substantially but there had been additional granularity in the direct PE inputs.

Response: As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640 through 67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and postservice periods for each code. We have stated that we believe this additional level of detail helps to facilitate transparency, allows us to more easily compare clinical labor times across the PFS to maintain relativity, and helps in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years. However, we have always recognized that standards for clinical labor cannot be applied universally due to the differences between individual services, and we have frequently finalized

clinical labor times above the standard values where we believed that there was sufficient reason to establish these values as the typical case. In the case of CPT code 92273 and 92274, we detailed our rationale in the proposed rule for why we believed that some of the RUC-recommended direct PE inputs should be refined to a standard clinical labor time. We also note that we did not propose the standard clinical labor time for all activities, such as the ''Clean room/equipment by clinical staff'' (CA024) activity.

Comment: Several commenters disagreed with the proposal to remove the preservice clinical labor in the facility setting for CPT codes 92273 and 92274. Commenters stated that these procedures, when done in a facility, must be scheduled in the operating room. Commenters stated that these procedures would typically be done in the facility only when it is not clinically appropriate for them to be performed in the clinic, such as for children or the cognitively impaired; and it takes substantial amounts of time for the staff to accomplish this coordination of care for these higher-needs patients.

Response: We recognize that these procedures are rarely performed in the facility setting, with approximately 1 percent of the utilization of predecessor CPT code 92275 taking place in this setting. However, we disagree that these procedures would typically be performed in the operating room when furnished in the facility, and therefore, we do not agree that these procedures would typically require preservice clinical labor for coordination of care. We also noted on this subject that the predecessor code, CPT code 92275, does not currently include any preservice clinical labor, nor any facility direct PE inputs, and we did not receive an explanation from the commenters as to why this was the case. Furthermore, both of these codes are diagnostic tests under which the professional (26 modifier) and technical (TC modifier) components will be separately billable, and codes that have these professional and technical components typically will not have direct PE inputs in the facility setting since the technical component is only valued in the nonfacility setting.

Comment: Several commenters disagreed with the proposal to remove the clinical labor time for the ''Greet patient, provide gowning, ensure appropriate medical records are available'' (CA009) and the ''Provide education/obtain consent'' (CA011) activities for CPT codes 92273 and 92274. Commenters stated that although slightly more than 50 percent of these services are done on the same day as an office visit, the clinical staff time involved is completely divorced from the office visit and the staff performing the test are different from the staff assisting in the office visit. Commenters stated that the machine used for these procedures is housed in a different room, the patient needs to be transported from the ophthalmic exam lane to the ERG room and back, additional instructions are required that are never done during a typical office visit, and the nature of this test requires extra supplies and work in addition to those used for the office visit. Commenters emphasized that these clinical tasks are not duplicative with an E/M, as they represent separate actions by a different technician in a different room.

Response: We disagree with the commenters and continue to believe that this clinical labor would be duplicative with the same day E/M office visit. While it is true that there is a different clinical labor staff type used by CPT codes 92273 and 92274, we are not suggesting that all clinical labor is duplicative with the same day E/M visit, only that clinical labor activities such as greeting and gowning the patient would only be done a single time. We also note that we do not include patient transportation as a form of direct PE, as it is not individually allocable to a single service and would instead be classified as an administrative task under indirect PE. However, we do agree with the commenters that additional instructions would be required for these electroretinography services, and as a result we will restore the 1 minute of clinical labor time for the ''Provide education/obtain consent'' (CA011) activity. We agree that this would not be duplicative with the same day E/M office visit.

Comment: Several commenters stated that in our refinements to the direct PE inputs for CPT codes 92273 and 92274, CMS proposed to remove 1 minute from the CA014 activity code and proposed to add 1 minute to the CA013 activity code. The commenter stated that this refinement was inaccurate and encouraged CMS to modify this proposal by finalizing the RUC-recommended direct PE inputs for clinical labor. One commenter stated that this work is done by a different technician in a different room typically in a busy clinical setting and this work was separate from that being done during the office visit.

Response: We addressed this subject in detail in the PE section of this final rule under the Changes to Direct PE Inputs for Specific Services heading (section II.B.3. of this final rule). For CPT codes 92273 and 92274, we are finalizing these clinical labor refinements as proposed. We also note in response to the one commenter that our refinements to the CA013 and CA014 clinical labor activities were not based on the premise on being duplicative with the same day E/M visit.

Comment: Several commenters disagreed with the proposal to refine the clinical labor time for the ''Clean room/equipment by clinical staff'' (CA024) activity from 12 minutes to 8 minutes for CPT codes 92273 and 92274. Commenters stated that this was the time that the specialty society found when directly shadowing the process to clean the patient and the equipment. Commenters stated that the technician needs to clean the patient's skin, rinse their eyes, and clean around the patient and escort them out. Commenters stated that the expensive and delicate eye electrodes require a significant amount of time to remove and clean the conductive paste and Goniosol without damaging the electrodes, which needs to be performed after each procedure so that the electrodes can be re-used for the next procedure. Commenters emphasized that the equipment cleaning process requires meticulous care and a significant amount of technician time.

Response: We agree with the commenters that these procedures require more time for cleaning the room and equipment than the standard for the CA024 activity. This is the reason we proposed 8 minutes of clinical labor time instead of 3 minutes, almost triple the standard value for this activity code. As we stated in the proposed rule, we agreed with the need for 2 minutes of patient cleaning time and for the cleaning of the wires and electrodes to take place in two different steps. Since our standard clinical labor time for room/equipment cleaning is 3 minutes, we therefore proposed a total time of 8 minutes for these codes, based on 2 minutes for patient cleaning and then 3 minutes for each of the two steps of wire and electrode cleaning. We continue to believe that 8 minutes would be the typical amount of clinical labor used for these procedures.

Comment: Several commenters disagreed with the proposal to refine the clinical labor time for the ''Technologist QC's images in PACS, checking for all images, reformats, and dose page'' (CA030) activity from 10 minutes to 3 minutes for CPT codes 92273 and 92274. Commenters stated that the machine used for the ERG codes is not typically integrated into the clinic's electronic medical record. Commenters stated that this machine requires printing all images created by the testing

machine and uploading them into the EMR for subsequent review by the physician and that it is not unusual for re-printing using a different scale or limits to be necessary. Commenters stated that this clinical labor differed from a typical radiology scenario because the procedure is in fact different from a typical imaging study.

Response: We disagree with the commenters that the full recommended time of 10 minutes would be typical for this clinical labor activity. We do not agree that it would be typical to physically print out all of the images produced by the machine, and note that we do not include additional direct PE inputs for inefficiencies in practice operations. We continue to believe that the complexity of the imaging in CPT codes 92273 and 92274 is comparable to the CT and magnetic resonance (MR) codes, and that in order to maintain relativity, we proposed the same clinical labor time of 3 minutes.

Comment: Several commenters disagreed with the proposal to refine the clinical labor time for the ''Review examination with interpreting MD/DO'' (CA031) activity from 5 minutes to 2 minutes for CPT codes 92273 and 92274. Commenters stated that this input was calculated by direct observation of typical procedures with a stopwatch. Commenters stated that this test is performed in a different room than the office visit, and the technician needs to take time to find the ordering/interpreting physician and review the quality of the gain and results.

Response: We disagree with the commenters that the full recommended time of 5 minutes would be typical for this clinical labor activity. We note again that we do not include additional direct PE inputs for inefficiencies in practice operations, and that we would not increase the clinical labor to include time that the technician needs to find the ordering/interpreting physician. We finalized in the CY 2017 PFS final rule a standard time of 2 minutes for reviewing examinations with the interpreting MD, and we have no reason to believe that these codes would typically require additional clinical labor at more than double the standard time.

Comment: Several commenters responded to the comment solicitation regarding additional information about whether the recommendations for the ''Contact lens electrode for mfERG and ffERG'' (EQ391) equipment intended this equipment item to be listed twice, with one contact intended for each eye, or whether this was a clerical mistake. Commenters stated that this was not an error but was intentional and reflects typical practice. Commenters stated that the test carried out in CPT code 92273 is performed with two contact lenses in place (one in each eye at the same time) in a simultaneous testing fashion. Commenters stated that the test carried out in CPT code 92274 is typically performed sequentially one eye at a time, re-using the same contact lens for each eye. Commenters stated that this discrepancy is primarily due to the dark and light-adaptation needs for the ffERG, which if done sequentially would double the amount of clinical time.

Response: We appreciate the additional information supplied by the commenters in response to our comment solicitation.

Comment: One commenter stated that the highly technical equipment formula should be used for the mfERG and ffERG electrodiagnostic unit (EQ390) equipment item.

Response: We did not propose to classify the EQ390 equipment as highly technical. We note that if we were to use the highly technical equipment formula for the EQ390 equipment, the total equipment time for this item would decrease, and we do not believe that this was what the commenter intended.

After consideration of the public comments, we are finalizing the work RVUs for the codes in the Electroretinography family of codes as proposed. We are also finalizing the direct PE inputs as proposed, with the exception of the CA011 clinical labor activity as described above.

(51) Cardiac Output Measurement (CPT Codes 93561 and 93562)

CPT codes 93561 (Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; with cardiac output measurement) and 93562 (Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; subsequent measurement of cardiac output) were identified as potentially misvalued on a screen of codes with a negative IWPUT, with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes. The specialty societies noted that CPT codes 93561 and 93562 are primarily performed in the pediatric population, thus the Medicare utilization for these Harvard-source services is not over 1,000. However, the specialty societies requested and the RUC agreed that these services should be reviewed under this negative IWPUT screen.

For CPT code 93561, we disagreed with the RUC-recommended work RVU of 0.95 and we proposed a work RVU of 0.60 based on a crosswalk to CPT code 77003 (Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid)). CPT Code 77003 is another recently-reviewed add-on global code with the same 15 minutes of intraservice time and 2 additional minutes of preservice evaluation time. In our review of CPT code 93561, we found that there was a particularly unusual relationship between the surveyed work times and the RUC-recommended work RVU. We noted that the recommended intraservice time for CPT code 93561 was decreasing from 29 minutes to 15 minutes (48 percent reduction), and the recommended total time for CPT code 93561 was decreasing from 78 minutes to 15 minutes (81 percent reduction); however, the recommended work RVU was instead increasing from 0.25 to 0.95, which is an increase of nearly 300 percent. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should typically be reflected in decreases to work RVUs, not increases in valuation. We recognized that CPT code 93561 is an unusual case, as it is shifting from 0-day global status to add-on code status. However, when the work time for a code is going down and the unit of service is being reduced, we would not expect to see an increased work RVU under these circumstances, and especially not such a large work RVU increase. Therefore, we proposed instead to crosswalk CPT code 93561 to CPT code 77003 at a work RVU of 0.60, which we believe is a more accurate valuation in relation to other recently-reviewed add-on codes on the PFS. We believe that this proposed work RVU of 0.60 better preserves relativity with other clinically similar codes with similar surveyed work times.

For CPT code 93562, we disagreed with the recommended work RVU of 0.77 and proposed a work RVU of 0.48 based on the intraservice time ratio with CPT code 93561. We observed a similar pattern taking place with CPT code 93562 as with the first code in the family, noting that the recommended intraservice time was decreasing from 16 minutes to 12 minutes (25 percent reduction), and the recommended total time was decreasing from 44 minutes to

12 minutes (73 percent reduction); however, the RUC-recommended work RVU was instead increasing from 0.01 to 0.77. We recognized that CPT code 93562 is another unusual case, as it is also shifting from 0-day global status to add-on code status, and the current work RVU of 0.01 is a decrease from the code's former valuation of 0.16 following the removal of moderate sedation in the CY 2017 rule cycle. However, when the work time for a code is going down and the unit of service is being reduced, we typically would not expect to see a work RVU increase under these circumstances, and especially not such a large work RVU increase. Therefore, we proposed instead to apply the intraservice time ratio from CPT code 93561, for a ratio of 0.80 (12 minutes divided by 15 minutes) multiplied by the proposed work RVU of 0.60 for CPT code 93561, which results in the proposed work RVU of 0.48 for CPT code 93562. We noted that the RUC-recommended work values also line up according to the same intraservice time ratio, with the recommended work RVU of 0.77 for CPT code 93562 existing in a ratio of 0.81 with the recommended work RVU of 0.95 for CPT code 93561. We believe that this provides further rationale for our proposal to value the work RVU of CPT code 93562 at 80 percent of the work RVU of CPT code 93561.

There are no recommended direct PE inputs for the codes in this family and we did not propose any direct PE inputs.

The following is a summary of the public comments we received on our proposals involving the Cardiac Output Measurement family of codes.

Comment: Commenters stated that there were three intertwined flawed assumptions that CMS considered when proposing values for CPT codes 93561 and 93562, which if finalized would lead to continued misvaluation of these services. Commenters stated that the first of these flawed assumptions was a comparison of the survey data to Harvard data: The current time data for these codes came from the Harvard studies, has zero validity and should not be used to compare to current valid survey data. Commenters stated that the second of these flawed assumptions was a comparison of the recommended physician work RVUs to old work RVUs: The negative intensity of these codes confirmed that this previous methodology in which the current work RVU was derived from is flawed. Commenters stated that the third of these flawed assumptions was the use of an intraservice time ratio: This inaccurately treated all components of the physician time as having identical intensity and is incorrect. Other commenters identified changes in the global period from 0-day to add-on status and changes in the patient population from adult patients to pediatric patients as a rationale for why the increases in valuation were appropriate.

Many commenters disagreed with the proposed work RVU of 0.60 for CPT code 93561 and stated that CMS should finalize the RUC-recommended work RVU of 0.95. Commenters disagreed with the CMS crosswalk to CPT code 77003, stating that it was not a good crosswalk despite having the same intraservice work time. Commenters stated that CPT code 77003 is the imaging guidance code for needle placement for the epidural injection, and that placing a catheter in the heart and lungs of a child is not merely an imaging procedure. Commenters stated that a more appropriate injection procedure comparison would be the actual epidural injection procedure code, CPT code 62320 (Injection(s), of diagnostic or therapeutic substance(s) (*e.g.,* anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance) at a work RVU of 1.80 or to the top key reference CPT code 93567 (Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for supravalvular aortography) at a work RVU of 0.97.

Many commenters also disagreed with the proposed work RVU of 0.48 for CPT code 93562 and stated that CMS should finalize the RUC-recommended work RVU of 0.77. Commenters stated that using an incremental approach in lieu of strong crosswalks and input from the RUC and physicians providing these services was an unfounded methodology. Commenters stated that CMS should rely on the survey data instead of the use of an increment, and commenters listed the reference codes chosen by the RUC which they stated were more appropriate for valuation.

Response: We appreciate the detailed feedback from the commenters regarding CPT Codes 93561 and 93562. We agree with the commenters that the proposed crosswalk to CPT code 77003 would result in an inappropriately low intensity for CPT code 93561.

After consideration of the public comments, we are finalizing the RUC-recommended work RVU of 0.95 for CPT code 93561 and the RUC-recommended work RVU of 0.77 for CPT code 93562. We are also finalizing our proposal to have no direct PE inputs for these codes.

(52) Coronary Flow Reserve Measurement (CPT Codes 93571 and 93572)

CPT code 93571 (Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel) was identified on a list of all services with total Medicare utilization of 10,000 or more that have increased by at least 100 percent from 2009 through 2014. CPT code 93572 (Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; each additional vessel) was also included for review as part of the same family of CPT codes. The RUC recommended a work RVU of 1.50 for CPT code 93571, which is lower than the current work RVU of 1.80. The total time for this service decreased by 5 minutes from 20 minutes to 15 minutes. The RUC's recommendation is based on a crosswalk to CPT code 15136 (Dermal autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof), which has an identical intraservice and total time as CPT code 93571 of 15 minutes.

We disagreed with the recommended work RVU of 1.50 for this CPT code because we did not believe that a reduction in work RVU from 1.80 to 1.50 was commensurate with the reduction in time for this service of 5 minutes. Using the building block methodology, we believed the work RVU for CPT code 93571 should be 1.35. We believe that a crosswalk to CPT code 61517 (Implantation of brain intracavitary chemotherapy agent (List separately in addition to CPT code for primary procedure)) with a work RVU of 1.38 was more appropriate because it has an identical intraservice and total time (15 minutes) as CPT code 93571, described work that is similar, and was closer to the calculations for intraservice time ratio, total time ratio, and the building block method. Therefore, we proposed a work RVU of 1.38 for CPT code 93571.

We proposed the RUC-recommended work RVU for CPT code 93572 (Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft)

during coronary angiography including pharmacologically induced stress; each additional vessel) of 1.00.

Both of these codes are facility-only procedures with no recommended direct PE inputs.

The following is a summary of the public comments we received on our proposals involving the Coronary Flow Reserve Measurement family of codes.

Comment: We received several comments regarding our proposed work RVU of 1.38 for CPT 93571. Commenters generally did not agree with the use of time based metrics in our assessment of the work RVU for this code. In particular, they opposed CMS's reduction of work RVUs in proportion to the total reduction in time for furnishing this service. This methodology, they maintain, ignores the fact that the time reduction of 5 minutes in furnishing this service is associated with the low intensity portion of the work.

Response: We do not agree that a reduction in work RVU proportional to the total time decrease for this code, which has essentially only one time parameter since the intraservice time and total time are the same, is not appropriate. We continue to believe that this calculated value of 1.35 (a 75 percent reduction in both time and work RVU) accounts more appropriately for the reduction in time for a service in which the work to perform the service has not changed. We therefore continue to believe that our crosswalk to CPT code 61517 is similar in both work and time to CPT code 93571, and we are finalizing our proposed work RVU for CPT code 93571 of 1.38.

Comment: We received support from commenters regarding our proposed work RVU of 1.00 for CPT code 93572.

Response: We appreciate the support and are finalizing a work RVU of 1.00 for CPT code 93572 as proposed.

After consideration of the public comments, we are finalizing the work RVUs for the codes in the Coronary Flow Reserve Measurement family of codes as proposed.

(53) Peripheral Artery Disease (PAD) Rehabilitation (CPT Code 93668)

During 2017, we issued a national coverage determination (NCD) for Medicare coverage of supervised exercise therapy (SET) for the treatment of peripheral artery disease (PAD). Previously, the service had been assigned noncovered status under the PFS. CPT code 93668 (Peripheral arterial disease (PAD) rehabilitation, per session) was payable before the end of CY 2017, retroactive to the effective date of the NCD (May 25, 2017), and for CY 2018, CMS made payment for Medicare-covered SET for the treatment of PAD, consistent with the NCD, reported with CPT code 93668. We used the most recent RUC-recommended work and direct PE inputs and requested that the RUC review the service, which had not been reviewed since 2001, for direct PE inputs. The RUC did not recommend a work RVU for CPT code 93668 due to the belief that there is no physician work involved in this service. After reviewing this code, we proposed a work RVU of 0.00 for CPT code 93668 and proposed to continue valuing the code for PE only.

The following is a summary of the public comments we received on our proposals involving CPT code 93688.

Comment: Commenters were supportive of our proposal of the RUC-recommended work RVUs and PE inputs.

Response: We thank commenters for their support.

Comment: Several commenters noted that the proposed reductions in payment would impact their ability to perform the service in an office setting and that this would force them to perform the service in a hospital setting. They further noted that this would ultimately increase costs and impact patient satisfaction as well as impact their ability to provide the service to rural and under insured patients.

Response: We appreciate the feedback these commenters provided. We note that we accepted the RUC-recommended work RVU of 0.00 and the RUC-recommended direct PE inputs without refinements for CPT code 93668. We further note that the RUC has generally provided recommendations on work, work time, and direct PE inputs. We do not believe that the work or direct PE inputs assigned to these services are inaccurate. We further note that if commenters believe an additional RUC review would serve to address the issues they identified in our proposal, we would consider this information or recommendations from other interested stakeholders for future rulemaking.

After consideration of the public comments received, we are finalizing the RUC-recommended work RVUs and direct PE inputs for CPT code 93668 as proposed.

(54) Home Sleep Apnea Testing (CPT Codes 95800, 95801, and 95806)

CPT codes 95800 (Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (*e.g.,* by airflow or peripheral arterial tone), and sleep time), 95801 (Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (*e.g.,* by airflow or peripheral arterial tone)), and 95806 (Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (*e.g.,* thoracoabdominal movement)) were flagged by the CPT Editorial Panel and reviewed at the October 2014 Relativity Assessment Workgroup meeting. Due to rapid growth in service volume, the RUC recommended that these services be reviewed after 2 more years of Medicare utilization data (2014 and 2015 data). These three codes were surveyed for the April 2017 RUC meeting and new recommendations for work and direct PE inputs were submitted to CMS.

For CPT code 95800, the RUC recommended a work RVU of 1.00 based on the survey 25th percentile value. We disagreed with the recommended value and proposed a work RVU of 0.85 based on a pair of crosswalk codes: CPT code 93281 (Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead pacemaker system) and CPT code 93260 (Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; implantable subcutaneous lead defibrillator system). Both of these codes have a work RVU of 0.85, as well as having the same intraservice time of 15 minutes, similar total times to CPT code 95800, and recent review dates within the last few years.

In reviewing CPT code 95800, we noted that the recommended intraservice time is decreasing from 20 minutes to 15 minutes (25 percent reduction), and the recommended total time is decreasing from 50 minutes to 31 minutes (38 percent reduction); however, the RUC-recommended work RVU is only decreasing from 1.05 to 1.00, which is a reduction of less than 5 percent. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 95800, we believe that it would be more accurate to propose a work RVU of 0.85

based on the aforementioned crosswalk codes to account for these decreases in the surveyed work time. We also noted that in this case where the surveyed times are decreasing and the utilization of CPT code 95800 is increasingly significantly (quadrupling in the last 5 years), we had reason to believe that practitioners are becoming more efficient at performing the procedure, which, under the resource-based nature of the RVU system, lends further support for a reduction in the work RVU.

For CPT code 95801, the RUC proposed a work RVU of 1.00 again based on the survey 25th percentile. We disagreed with the recommended value and we proposed a work RVU of 0.85 based on the same pair of crosswalk codes, CPT codes 93281 and 93260. We noted that CPT codes 95800 and 95801 had identical recommended work RVUs and identical recommended survey work times. Given that these two codes also have extremely similar work descriptors, we interpreted this to mean that the two codes could have the same work RVU, and therefore, we proposed the same work RVU of 0.85 for both codes.

For CPT code 95806, the RUC recommended a work RVU of 1.08 based on a crosswalk to CPT code 95819 (Electroencephalogram (EEG); including recording awake and asleep). Although we disagreed with the RUC-recommended work RVU of 1.08, we concurred that the relative difference in work between CPT codes 95800 and 95801 and CPT code 95806 was equivalent to the recommended interval of 0.08 RVUs. Therefore, we proposed a work RVU of 0.93 for CPT code 95806, based on the recommended interval of 0.08 additional RVUs above our proposed work RVU of 0.85 for CPT codes 95800 and 95801. We also noted that CPT code 95806 is experiencing a similar change in the recommended work and time values comparable to CPT code 95800. The recommended intraservice time for CPT code 95806 is decreasing from 25 minutes to 15 minutes (40 percent), and the recommended total time is decreasing from 50 minutes to 31 minutes (38 percent); however, the recommended work RVU is only decreasing from 1.25 to 1.08, which is a reduction of only 14 percent. As we stated for CPT code 95800, we do not believe that decreases in work time must equate to a one-to-one or linear decrease in the valuation of work RVUs, but we do believe that these changes in surveyed work time suggest that practitioners are becoming more efficient at performing the procedure, and that it would be more accurate to maintain the recommended work interval with CPT codes 95800 and 95801 by proposing a work RVU of 0.93 for CPT code 95806.

We did not propose any direct PE refinements for this code family.

The following is a summary of the public comments we received on our proposals involving the Home Sleep Apnea Testing family of codes.

Comment: One commenter stated that the obesity epidemic has contributed to the rising prevalence of obstructive sleep apnea, and sleep centers have already worked to reduce costs in diagnosis of obstructive sleep apnea by utilizing out-of-center, or home, sleep apnea testing. The commenter stated that further reduction in work RVUs, and hence payments for home sleep apnea testing services, may endanger the sustainability of sleep centers to provide this service to Medicare beneficiaries and may thus deny beneficiaries access to testing for obstructive sleep apnea. A different commenter stated that a reduction in work RVUs for home sleep apnea testing services will discourage vendors from producing technically better home sleep apnea testing devices and software.

Response: We agree with the commenter regarding the importance of sleep centers in helping to diagnose and treat the occurrence of obstructive sleep apnea. However, we remind the commenter that we are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2017 PFS final rule (81 FR 80272 through 80277), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes. When the recommended work RVUs do not appear to account for significant changes in time, we have employed the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. For the codes in the Home Sleep Apnea Testing family, we believe that the decreases in the surveyed work times should be reflected in decreases to the work RVUs.

Comment: Many commenters disagreed with the proposed work RVU of 0.85 for CPT codes 95800 and 95801, and stated that CMS should finalize the RUC-recommended work RVU of 1.00 for these services. Commenters stated that it was unclear why CMS chose to employ the crosswalk to CPT codes 93281 and 93260, which the commenters stated were not at all similar to the home sleep apnea test codes and are cardiovascular implantable recording device codes, not diagnostic studies.

Response: We continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes with clinically similar services are sometimes stronger comparator codes, we do not agree that codes must both constitute diagnostic studies to be used as a crosswalk. In the case of our specific crosswalk to CPT codes 93281 and 93260, we noted in the proposed rule that both of these codes have a work RVU of 0.85, as well as having the same intraservice time of 15 minutes and similar total times to CPT codes 95800 and 95801, and recent review dates within the last few years.

Comment: Several commenters stated that the existing times for CPT codes 95800 and 95801 were likely an overestimate due to the lack of experience providing these services when they were first valued as new codes in April 2010. Commenters stated that physicians are now more familiar with home sleep apnea testing and the new survey times were more reflective of this family of services.

Response: This information from the commenters appears to suggest that the current work RVUs for CPT codes 95800 and 95801 are also overestimates. If practitioners have become more familiar and efficient in the practice of home sleep apnea testing, we believe that the work RVUs should also be decreased to reflect the fact that the procedures can now be performed faster. We remind the commenters that we are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services, and we have no reason to believe that the intensity of these procedures has increased to the point of offsetting these gains in time efficiency.

Comment: Several commenters stated that, despite the fact that we indicated we did not intend to imply that the decrease in time should equate to a linear decrease in the valuation of work RVUs, this seems to be the approach taken in the proposed rule. Commenters stated that modifications to work RVUs should be based on empirical evidence, gathered through the survey process, which takes into consideration the amount of time required to provide a service as well as the complexity and intensity of each service.

Response: We disagree with the commenters, and we note that the proposed work RVUs for both CPT codes 95800 and 95801 were not based on pure time ratios on a one-to-one or linear basis. For CPT code 95800, use of

the intraservice time ratio alone would have yielded a work RVU of 0.79 and the total time ratio would have yielded a work RVU of 0.65. For CPT code 95801, use of the intraservice time ratio would have yielded a work RVU of 1.00 and the total time ratio would have yielded a work RVU of 0.78. We did not propose these values and instead proposed a work RVU of 0.85 for both codes specifically because the consideration of time ratios is only one component of our review process. We believe that our proposed work RVU of 0.85 for these services based on a pair of crosswalk codes, CPT codes 93281 and 93260 is appropriate, and note that we recognized that the use of pure time ratios at a one-to-one or linear basis would not accurately capture the changes in work taking place in these codes since their last valuation.

Comment: Many commenters disagreed with the proposed work RVU of 0.93 for CPT code 95806, and stated that CMS should finalize the RUC-recommended work RVU of 1.08. Commenters stated that the survey process values a service compared to other similar services, and that using an incremental approach in lieu of strong crosswalks and input from the RUC and physicians providing these services was unfounded.

Response: We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. We note that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service. We continue to believe that the proposed work RVU of 0.93 would be the most accurate valuation for CPT code 95806.

Comment: Several commenters stated that CPT code 95806 has become a more complex study and requires more time as well as greater levels of skill and training to perform the interpretation for this study. Commenters stated that more complex patients with a wider variety of sleep problems and more severe conditions are being studied with this modality, which means that the skills and continuing updates to education required to interpret these studies have dramatically increased.

Response: We agree with the commenters that due to the decreasing surveyed work times and rapidly increasing utilization for these codes, we had reason to believe that practitioners are becoming more efficient at performing the procedure. While the incorporation of new technology can sometimes make services more complex and difficult to perform, it can also have the opposite effect by making services less reliant on manual skill and technique. We do not agree with the commenter that the need for additional training to use the equipment would necessarily be grounds for an increase in the work RVU, as improvements in technology are commonplace across many different services and are not specific to this procedure. As detailed above, we also have reason to believe that the improved technology has led to greater efficiencies in the procedure which, under the resource-based nature of the RVU system, lends further support for a reduction in the work RVU.

After consideration of the public comments, we are finalizing the work RVUs and the direct PE inputs for the codes in the Home Sleep Apnea Testing family of codes as proposed.

(55) Neurostimulator Services (CPT Codes 95970, 95976, 95977, 95983, and 95984)

In October 2013, CPT code 95971 (Electronic analysis of implanted neurostimulator pulse generator system; simple spinal cord, or peripheral (*i.e.,* peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming) was identified in the second iteration of the High Volume Growth screen. In January 2014, the RUC recommended that CPT codes 95971, 95972 (Electronic analysis of implanted neurostimulator pulse generator system; complex spinal cord, or peripheral (*i.e.,* peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming) and 95974 (Electronic analysis of implanted neurostimulator pulse generator system; complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour) be referred to the CPT Editorial Panel to address the entire family regarding the time referenced in the CPT code descriptors. In June 2017, the CPT Editorial Panel revised CPT codes 95970, 95971, and 95972, deleted CPT codes 95974, 95975 (Electronic analysis of implanted neurostimulator pulse generator system; complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour), 95978 (Electronic analysis of implanted neurostimulator pulse generator system, complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming; first hour), and 95979 (Electronic analysis of implanted neurostimulator pulse generator system, complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming; each additional 30 minutes after first hour) and created four new CPT codes for analysis and programming of implanted cranial nerve neurostimulator pulse generator, analysis, and programming of brain neurostimulator pulse generator systems and analysis of stored neurophysiology recording data.

The RUC recommended a work RVU of 0.45 for CPT code 95970 (Electronic analysis of implanted neurostimulator pulse generator/transmitter (*e.g.,* contact group(s),interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve neurostimulator pulse generator/transmitter, without programming)), which is identical to the current work RVU for this CPT code. The descriptor for this CPT code has been modified slightly, but the specialty societies affirmed that the work itself has not changed. To justify its recommendation, the RUC provided two references: CPT code 62368 (Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming), with intraservice time of 15 minutes, total time of 27 minutes, and a work RVU of 0.67; and CPT code 99213 (Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; or Medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the

presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family), with intraservice time of 15 minutes, total time of 23 minutes, and a work RVU of 0.97.

We disagreed with the RUC's recommendation because we did not believe that maintaining the work RVU, given a decrease of four minutes in total time, was appropriate. In addition, we noted that the reference CPT codes chosen have much higher intraservice and total times than CPT code 95970, and also have higher work RVUs, making them poor comparisons. Instead, we identified a crosswalk to CPT code 95930 (Visual evoked potential (VEP) checkerboard or flash testing, central nervous system except glaucoma, with interpretation and report) with 10 minutes intraservice time, 14 minutes total time, and a work RVU of 0.35. Therefore, we proposed a work RVU of 0.35 for CPT code 95970.

CPT code 95976 (Electronic analysis of implanted neurostimulator pulse generator/transmitter (*e.g.,* contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional) is a new CPT code replacing CPT code 95974 (Electronic analysis of implanted neurostimulator pulse generator system (*e.g.,* rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour). The description of the work involved in furnishing CPT code 95976 differs from that of the deleted CPT code in a few important ways, notably that the time parameter has been removed so that the CPT code no longer describes the first hour of programming. In addition, the new CPT code refers to simple rather than complex programming. Accordingly, the intraservice and total times for this CPT code are substantively different from those of the deleted CPT code. CPT code 95976 has an intraservice time of 11 minutes and a total time of 24 minutes, while CPT code 95974 has an intraservice time of 60 minutes and a total time of 110 minutes. The RUC recommended a work RVU of 0.95 for CPT code 95976. The RUC's top reference CPT code as chosen by the RUC survey participants was CPT code 95816 (Electroencephalogram (EEG); including recording awake and drowsy), with an intraservice time of 15 minutes, 26 minutes total time, and a work RVU of 1.08. The RUC indicated that the service is similar, but somewhat more complex than CPT code 95976.

We disagreed with the RUC's recommended work RVU for this CPT code because we did not believe that the large difference in time between the new CPT code and CPT code 95974 was reflected in the slightly smaller proportional decrease in work RVUs. The reduction in total time, from 110 minutes to 24 minutes is nearly 80 percent. However, the RUC's recommended work RVU reflects a reduction of just under 70 percent. We believe that a more appropriate crosswalk would be CPT code 76641 (Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete) with intraservice time of 12 minutes, total time of 22 minutes, and a work RVU of 0.73. Therefore, we proposed a work RVU of 0.73 for CPT code 95976.

CPT code 95977 describes the same work as CPT code 95976, but with complex rather than simple programming. The CPT Editorial Panel refers to simple programming of a neurostimulator pulse generator/transmitter as the adjustment of one to three parameter(s), while complex programming includes adjustment of more than three parameters. For purposes of applying the building block methodology and calculating intraservice and total time ratios, the RUC compared CPT code 94X84 with CPT code 95975 (Electronic analysis of implanted neurostimulator pulse generator system (*e.g.,* rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour), which is being deleted by the CPT Editorial Panel. We believe that this was an inappropriate comparison since it is time based (first hour of programming) and is an add-on code. Instead we believe that the RUC intended to compare CPT code 95977 with CPT code 95974 (Electronic analysis of implanted neurostimulator pulse generator system (*e.g.,* rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour), which has been recommended for deletion by the CPT Editorial Panel and is also the comparison for CPT code 95976. The RUC recommended a work RVU of 1.19 for CPT code 95977. The RUC disagreed with the two top reference services CPT code 99215 (Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive history; A comprehensive examination; or Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family) and CPT code 99202 (Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; an expanded problem focused examination; or straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 20 minutes are spent face-to-face with the patient and/or family) and instead compared CPT code 95977 to CPT code 99308 (Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; or Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication.

Typically, 15 minutes are spent at the bedside and on the patient's facility floor or unit.) with total time of 31 minutes, intraservice time of 15 minutes, and a work RVU of 1.16; and CPT code 12013 (Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.6 cm to 5.0 cm), with total time of 27 minutes, intraservice time of 15 minutes, and a work RVU of 1.22.

We disagreed with the RUC's recommended work RVU of 1.19 for CPT code 95977. Once the comparison CPT code is corrected to CPT code 95974, the reverse building block calculation indicates that a lower work RVU (close to 0.82) would be a better reflection of the work involved in furnishing this service. As an alternative to the RUC's recommendation, we added the difference in RUC-recommended work RVUs between CPT codes 95976 and 95977 (0.24 RVUs) to the proposed work RVU of 0.73 for CPT code 95976. Therefore, we proposed a work RVU of 0.97 for CPT code 95977.

CPT code 95983 (Electronic analysis of implanted neurostimulator pulse generator/transmitter (*e.g.,* contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, doe lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional) is the base code for add-on CPT code 95984 (Electronic analysis of implanted neurostimulator pulse generator/transmitter (*e.g.,* contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, doe lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional), which is an add-on CPT code and can only be billed with CPT code 95983. The RUC compared CPT code 95983 with CPT code 95978 (Electronic analysis of implanted neurostimulator pulse generator system (*e.g.,* rate, pulse amplitude and duration, battery status, electrode selectability and polarity, impedance and patient compliance measurements), complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming; first hour), which the CPT Editorial Panel is recommending for deletion. The primary distinction between the new and old CPT codes is that the new CPT code describes the first 15 minutes of programming while the deleted CPT code describes up to one hour of programming. The RUC recommended a work RVU of 1.25 for CPT code 95983 and a work RVU of 1.00 for CPT code 95984. For CPT code 95983, the RUC's recommendation is based on reference CPT codes 12013 (Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.6 cm to 5.0 cm), with total time of 27 minutes, intraservice time of 15 minutes, and a work RVU of 1.22; and CPT code 70470 (Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections) with 25 minutes of total time, 15 minutes of intraservice time, and a work RVU of 1.27.

We disagreed with the RUC's recommended work RVU for CPT code 95983 because we did not believe that the reduction in work RVU reflected the change in time described by the CPT code. Using the reverse building block methodology, we estimated that a work RVU of nearer to 1.11 would be more appropriate. In addition, if we were to sum the RUC-recommended RVUs for a single hour of programming using one of the base CPT codes and three of the 15 minute follow-on CPT codes, 1 hour of programming would be valued at 4.25 work RVUs. This contrasts sharply from the work RVU of 3.50 for 1 hour of programming using the deleted CPT code 95978. We believe that a more appropriate valuation of the work involved in furnishing this service is reflected by a crosswalk to CPT code 93886 (Transcranial Doppler study of the intracranial arteries; complete study), with total time 27 minutes, intraservice time of 17 minutes, and a work RVU of 0.91. Therefore, we proposed a work RVU of 0.91 for CPT code 95983.

The RUC's recommended work RVU of 1.00 for CPT code 95984 is based on the key reference service CPT code 64645 (Chemodenervation of one extremity; each additional extremity, 5 or more muscles), which has total time of 26 minutes, intraservice time of 25 minutes, and a work RVU 1.39. This new CPT code is replacing CPT code 95978 (Electronic analysis of implanted neurostimulator pulse generator system (*e.g.,* rate, pulse amplitude and duration, battery status, electrode selectability and polarity, impedance and patient compliance measurements), complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming; first hour), which is being deleted by the CPT Editorial Panel. If we were to add the incremental difference between CPT codes 95983 and 95984 to the proposed value for the base CPT code (95983, work RVU = 0.91), we estimated that this add-on CPT code would have a work RVU of 0.75. The building block methodology results in a recommendation of a slightly higher work RVU of 0.82. We proposed a work RVU of 0.80 for CPT code 95984, which falls between the calculated value using incremental differences and the calculation from the reverse building block, and is supported by a crosswalk to CPT code 51797 (Voiding pressure studies, intra-abdominal (ie, rectal, gastric, intraperitoneal)), which is an add-on CPT code with identical total and intraservice times (15 minutes) as CPT code 95984.

We did not propose any direct PE refinements for this code family.

The following is a summary of the public comments we received on our proposals involving the Neurostimulator Services family of codes.

Comment: We received a number of comments regarding our proposed work RVUs for CPT codes 95970, 95976, 95977, 95983, and 95984. Commenters suggested that CMS misunderstood the role of reference codes in the RUC's process, and that CMS should not be comparing the times for the surveyed code to the reference codes because they are not specifically intended to match in time.

Response: We appreciate the opportunity to clarify that we do not believe the reference codes provided by the RUC in the summary documents are being provided as a crosswalk. We did not state that we thought the two top reference codes, CPT code 62368 (total time of 27 minutes) and CPT code 99213 (total time of 23 minutes) were being used by the RUC as crosswalk codes (as that term is used in the RUC process). Instead, we pointed out that the two reference codes are generally not a particularly good comparison for a survey code with 15 minutes of total time. We understand that survey respondents, not the RUC, chose the reference codes, and that survey respondents do not have the physician times readily available when choosing from among services that they are familiar with. Nonetheless, we expect reference codes to generally have physician work times that are more similar to the survey code than an 80 percent difference (in the case of CPT

code 62368). When we make such an observation with regard to the times for reference codes in relation to a survey code, we are not disregarding parameters other than time. We also note that the RUC compares reference codes in terms of time or intensity relative to the survey code as a matter of common practice. We understand those comparisons to be intended by the RUC as one of several dimensions of a code's work RVU valuation.

As we have stated in the past, we believe that practitioners become more efficient at furnishing some services over time, shortening the amount of clinical time required. We still believe this is the case with regard to CPT code 95970, which has decreased in time without a significant change in intensity. We maintain that our crosswalk to CPT code 95930 with a work RVU of 0.35 for this CPT code is appropriate.

Comment: A commenter stated that, since CMS acknowledges that CPT code 95976 is different from CPT code 95974, which is being deleted, CMS should not compare the two codes for purpose of evaluating whether the decreased work time in the new code is appropriate in relation to the work involved in furnishing CPT code 95930. The commenter urged CMS to finalize the work RVU proposed by the RUC, which is 0.95.

Response: The major difference in the description of work involved in furnishing CPT code 95974 and CPT code 95976 involves a change from 'complex' to 'simple' programming. We do not believe that this change, which indicates a lower level of intensity for new CPT code 95976 than for deleted CPT code 95974, precludes us from using the deleted CPT code as the basis for evaluating whether the comparatively lower time involved in furnishing CPT code 95976 is adequately reflected by the RUC-recommended work RVU for this new CPT code. We continue to believe that the lower time in furnishing the work described by CPT code 95976, compared with the time in furnishing the service described by deleted CPT code 95974, should result in a lower work RVU than the value recommended by the RUC. Therefore, we are finalizing the work RVU for CPT code 95976 of 0.73 based on a crosswalk to CPT code 76641.

Comment: A commenter clarified that we incorrectly stated that the RUC compared the new CPT code 95977 with deleted CPT code 95975, which is an add-on code and would therefore not be an acceptable point of comparison.

Response: We appreciate the commenter informing us of the error and we agree that the RUC did not compare CPT code 95977 with the deleted code, CPT code 95975. Instead, the RUC compared the new code with several other codes: CPT code 99308 (Subsequent nursing facility care, per day, for the evaluation and management of a patient) with a work RVU of 1.16, 15 minutes of intra-service time and 31 minutes total time and CPT code 12013 (Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.6 cm to 5.0 cm) with a work RVU of 1.22, 15 minutes of intra-service time and 27 minutes total time. The RUC also cited the following two CPT codes for support: CPT code 93975 (Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study) with a work RVU of 1.16, 20 minutes of intra-service time and 30 minutes total time, and 67810 (Incisional biopsy of eyelid skin including lid margin), with a work RVU of 1.18, 13 minutes of intra-service time and 27 minutes total time. Despite having cited these numerous CPT codes as support for their recommended work RVU for CPT code 95977, we do not see why CPT code 95974 is not an entirely appropriate point of comparison for CPT code 95977 as we explained in making our proposal. The only difference between new CPT code 95977 and new CPT code 95976 is complex vs. simple programming and, since as we explained in response to comments above, we believe it is appropriate to use the deleted CPT code 95974 for a time comparison with CPT code 95976, we believe that code is equally valid as the basis for comparison to CPT code 95977. The building block methodology between CPT code 95977 and CPT code 95974 suggests that a work RVU in the area of 0.82 would better reflect both the time and intensity of furnishing this service. In identifying a more appropriate work RVU, we looked at the difference in the RUC-recommended work RVU between CPT codes 95976 and 95977, which differ by simple vs. complex programming, and added the increment to our proposed value for CPT code 95976. We continue to believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Given that we are finalizing our proposed work RVU for CPT code 95976 of 0.73, we believe a work RVU of 0.97 for CPT code 95977 is appropriate. We are finalizing a work RVU of 0.97 for CPT code 95977 as proposed.

Comment: A commenter expressed opposition to our use of the reverse building block methodology to evaluate the RUC-recommended work RVU for CPT code 95983 and to identify possible alternative crosswalk CPT codes. Consequently, the commenter stated that our crosswalk of CPT code 93886 is based on invalid reasoning about how the time parameter factors into the code valuation. The work involved in furnishing the service described by the crosswalk code, according to the commenter, is less intense than the work described by the survey code.

Response: We disagree with the commenter that the reverse building block methodology not an appropriate approach to assessing whether the RUC-recommended work RVU for a code is appropriate. We employed a reverse building block methodology to assess the reasonableness of the RUC's recommendation, not to value the code in the first instance. As the commenter noted, the work described by new CPT code 95983 is difficult to value in relation to both the deleted code and other codes on the fee schedule because of the 15 minute time parameter. However, having looked carefully at the work involved in furnishing the service described by our crosswalk code, CPT code 93886, we do not believe it is less intense than the survey code. The service described by CPT code 93886 is performed on patients with recent brain hemorrhage, which we believe is as complex to study as the work involved in programming adjustments to multiple parameters in real time. We continue to believe that CPT code 93886 is an appropriate crosswalk for CPT code 95983, and we are finalizing a work RVU for this code of 0.91.

Comment: A commenter stated that our approach for valuing CPT code 95984 ignored physician work intensity and complexity in favor of a random calculation involving code increments, which is a flawed methodology. CMS's choice of crosswalk code, according to the commenter, is invalid because it is based on this incorrect approach.

Response: We disagree that the use of incremental differences in work RVU between codes that have an established pattern of intensity or time, is inappropriate. We remind the commenter that our calculation of increments is based on the RUC's recommended work RVUs for the relevant CPT codes. We continue to believe that this approach is necessary to maintain intra-family relativity of the PFS, and we maintain that CPT code 51797 is an appropriate crosswalk to the

add-on CPT code 95984. We are finalizing a work RVU for CPT 95984 of 0.80.

Comment: One commenter stated that CMS reduced the nonfacility service cost for clinical labor for CPT code 95970 to zero. The commenter stated that this may be a potential oversight, given that the RUC recommended nonfacility clinical labor time be reduced from 44 to 15 minutes. The commenter stated that it was not consistent for CMS to recommend a nonfacility service cost of zero in light of the nonfacility exam table (EF023) equipment time of 15 minutes, and that this clinical labor should still be reflected in this service.

Response: We disagree with the commenter and note that the RUC did not recommend any clinical labor time for CPT code 95970, as we proposed the RUC-recommended direct PE inputs without refinement. We believe that the equipment time assigned for the exam table (EF023) and the neurostimulator programmer (EQ209) indicate that these equipment items are in use by the practitioner and not the clinical staff.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Neurostimulator Services family of codes as proposed.

(56) Psychological and Neuropsychological Testing (CPT Codes 96105, 96110, 96116, 96125, 96127, 96112, 96113, 96121, 96130, 96131, 96132, 96133, 96136, 96137, 9613896138, 96139, 96X11, and 96146)

In CY 2016, the Psychological and Neuropsychological Testing family of codes were identified as potentially misvalued using a high expenditure services screen across specialties with Medicare allowed charges of $10 million or more. The entire family of codes was referred to the CPT Editorial Panel to be revised, as the testing practices had been significantly altered by the growth and availability of technology, leading to confusion about how to report the codes. In June 2017, the CPT Editorial Panel revised five existing codes, added 13 codes to provide better description of psychological and neuropsychological testing, and deleted CPT codes 96101, 96102, 96103, 96111, 96118, 96119, and 96120. The RUC and HCPAC submitted recommendations for the 13 new codes and for the existing CPT codes 96105, 96110, 96116, 96125, and 96127.

We proposed the RUC- and HCPAC-recommend work RVUs for several of the CPT codes in this family: A work RVU of 1.75 for CPT code 96105; a work RVU of 1.86 for CPT code 96116; a work RVU of 1.70 for CPT code 96125; a work RVU of 1.71 for CPT code 96121; a work RVU of 0.55 for CPT code 96136; a work RVU of 0.46 for CPT code 96137; and a work RVU of 0.51 for CPT code 96X11. CPT codes 96110, 96127, 96138, 96139, and 96146 were valued by the RUC for PE only.

This code family contains a subset of codes that describe psychological and neuropsychological testing administration and evaluation, not including assessment of aphasia, developmental screening, or developmental testing. The CPT Editorial Panel's recommended coding for this subset of services consists of seven new codes: Two that describe either psychological or neuropsychological testing when administered by physicians or other qualified health professionals (CPT codes 96136 and 96137), and two for either type of testing when administered by technicians (CPT codes 96138 and 96139); and four new codes that describe testing evaluation by physicians or other qualified health care professionals (CPT codes 96130 through 96133). This new coding effectively unbundles codes that currently report the full course of testing into separate codes for testing administration (CPT codes 96136, 96137, 96138, and 96139) and evaluation (CPT codes 96130, 96131, and 96132). According to a stakeholder that represents the psychologist and neuropsychologist community, this new coding will result in significant reductions in payment for these services due to the unbundling of the testing codes into codes for physician-administered tests and technician-administered tests. The stakeholder noted that because the new coding includes testing codes with zero work RVUs for the technician administered tests and the work RVUs are lower than they believe to be accurate, this new valuation would ignore the clinical evaluation and decision making performed by the physician or other qualified health professional during the course of testing administration and evaluation. Furthermore, the net result of the code valuations for these new codes is a reduction in the overall work RVUs for this family of codes. In other words, the stakeholder's analysis found that the RUC recommendations result in a reduction in total work RVUs, even though the actual physician work of a testing battery has not changed.

In the interest of payment stability for these high-volume services, we proposed to implement work RVUs for this code family, which would eliminate the approximately 2 percent reduction in work spending. We proposed to achieve work neutrality for this code family by scaling the work RVUs upward from the RUC-recommended values so that the size of the pool of work RVUs would be essentially unchanged for this family of services. Therefore, we proposed: A work RVU of 2.56 for CPT code 96112, rather than the RUC-recommended work RVU of 2.50; a work RVU of 1.16 for CPT code 96113, rather than the RUC-recommended work RVU of 1.10; a work RVU of 2.56 for CPT code 96130, rather than the RUC-recommended work RVU of 2.50; a work RVU of 1.96 for CPT code 96131, rather than the RUC-recommended work RVU of 1.90; a work RVU of 2.56 for CPT code 96132, rather than the RUC-recommended work RVU of 2.50; and a work RVU of 1.96 for CPT code 96133, rather than the RUC-recommended work RVU of 1.90. We saw no evidence that the typical practice for these services has changed to merit a reduction in valuation of professional services.

The RUC made several revisions to the recommended direct PE inputs for the administration codes from their respective predecessor codes, including revisions to quantities of testing forms. For the supply item, ''psych testing forms, average'' there is a quantity of 0.10 in the predecessor CPT code 96101, and a quantity of 0.33 in the predecessor CPT code 96102. For the supply item ''neurobehavioral status forms, average,'' there is a quantity of 1.0 in the predecessor CPT code 96118 and a quantity of 0.30 for predecessor CPT code 96119, and for the supply item ''aphasia assessment forms, average,'' there is a quantity of 1.0 in the predecessor CPT code 96118 and a quantity of 0.30 in predecessor CPT code 96119. The RUC recommendation does not include any forms for CPT codes 96132 and 96133. The RUC has replaced the corresponding predecessor supply items with new items ''WAIS–IV Record Form,'' ''WAIS–IV Response Booklet #1,'' and ''WAIS–IV Response Booklet #2,'' and assigned quantities of 0.165 for each of these new supply items for CPT codes 96136 through 96139. In our analysis, we found that the RUC-recommended direct PE refinements contributed significantly to the reduction in the overall payment for this code family. We saw no compelling evidence that the quantities of testing forms used in a typical course of testing would have been reduced dramatically and, in the interest of payment stability, we proposed to refine the direct PE inputs for CPT codes 96132 through 96139 by including 1.0 quantity each of the supply items ''WAIS–IV Record

Form,'' ''WAIS–IV Response Booklet #1'', and ''WAIS–IV Response Booklet #2.'' We believe that a typical course of testing would involve use of one booklet for each of the relevant codes. In addition, these proposed refinements would largely mitigate potentially destabilizing payment reductions for these services. We solicited comments on our proposed work RVUs and proposed PE refinements for this family of services.

We also proposed to remove the equipment time for the CANTAB Mobile (ED055) equipment item from CPT code 96146. This item was listed at different points in the recommendations as a supply item with a cost of $28 per assessment and as an equipment item for a software license with a cost of $2,800 that could be used for up to 100 assessments. We were unclear as to how the CANTAB Mobile would typically be used in this procedure, and we proposed to remove the equipment time pending the submission of more data about the item. We solicited additional information about the use of this item and how it should best be included into the PE methodology. We were also interested in information as to whether the submitted invoice refers to the cost of the mobile device itself, or the cost of user licenses for the mobile device, which was unclear from the information submitted with the recommendations.

The following is a summary of the comments we received regarding our proposed work RVUs and proposed direct PE refinements for this family of services.

Comment: Many commenters supported our proposal to increase payment from the RUC recommendations in the interest of payment stability. These commenters stated this proposal will help mitigate reductions in reimbursement rates for psychologists.

According to some commenters, some psychologists will see slight decreases for neuropsychological testing services due to the new coding structure, which they say aligns psychological and neuropsychological testing services with other testing services in the program. Some commenters said that, due to the new coding structure, reimbursement will be lower for neuropsychological evaluation services that are provided by physicians than those provided by technicians. These commenters stated that physicians should not be reimbursed at a lesser rate than EEG or MRI technicians or other physician extenders.

Response: We note that our proposed values for the evaluation CPT codes 96130 through 96133 and the administration and scoring CPT codes 96136 through 96139 are generally higher for the physician-administered codes than for the analogous technician-administered codes. According to our proposed rates, however, the valuation of the add-on code for each additional 30 minutes of administration and scoring when performed by a technician reported with CPT code 96139 is, however, slightly higher than the valuation of the add-on code for each additional 30 minutes of administration and scoring when performed by a physician or other qualified health care professional, reported with CPT code 96137. We thank commenters for bringing this potential rank-order anomaly to our attention. We believe that clinical staff will typically be providing some support when the physician or other qualified health care professional is performing testing administration as described by CPT codes 96136 and 96137. We are therefore refining the direct PE inputs for these services by adding 10 minutes of clinical labor time for the CA021 clinical labor activity, ''Perform procedure/service—NOT directly related to physician work time'' for these codes. We believe this will more accurately reflect the clinical staff support that is typical when a physician is performing test administration, and it will preserve appropriate rank-order among this subset of services, while mitigating reductions to payment rates for testing administration services.

Comment: The RUC noted that in the February 5, 2018 RUC submission to CMS, the RUC rescinded its interim recommendation from October 2017, and stated that CPT code 96X11 is deleted and will not be a CPT code for CPT 2019. The RUC recommended that CMS delete this service and work RVU recommendation for the 2019 PFS.

Response: As CPT code 96X11 will not be a CPT code for CY 2019, we are deleting this code. Based on the RUC-recommended utilization crosswalk, our proposed rates included utilization assumptions that for all services currently reported with CPT codes 96103 and 96120, half of these services will be reported with the new CPT code 96X11 and half will be reported with CPT code 96146. As we are not finalizing 96X11, for the purposes of ratesetting, our utilization for these service will include the assumption that half of the services currently reported with 96103 and 96120 will be reported with CPT code 96136 and half with CPT code 96146.

Comment: A commenter requested clarification on how much time is considered typical for the neuropsychologist to perform record review and test selection in newly created CPT codes 96132 and 96133.

Response: For CPT code 96132, we proposed the RUC-recommended 5 minutes of pre-service work time which reflects activities such as preliminary selection of tests and record review. As CPT code 96133 is an add-on code for reporting each additional hour, it does not include additional pre-service work time, as the latter would be considered to be included in the corresponding base code.

Comment: Several commenters disagreed with the proposal to remove the equipment time for the CANTAB Mobile (ED055) equipment item from CPT code 96146. Commenters stated that the PE Subcommittee determined that this was a software license and it would be more appropriately classified as equipment than as a supply. Commenters stated that they had submitted paid invoices for two additional software license-based automated instruments typically used when furnishing CPT code 96146, and that they were resubmitting these same invoices with their comment letter.

Response: We appreciate the feedback from the commenter that the CANTAB Mobile (ED055) equipment item referred to a software license. We continue to believe that software licenses would typically be classified as a form of indirect PE under our methodology, and as a result we are finalizing our proposal to remove this equipment time from CPT code 96146.

Comment: A commenter requested clarification on why new CPT codes 96138, 96139, and 96146 do not include a facility fee, despite the fact that their respective source CPT codes 96102, 96119, 96103, and 96120 do have RVUs in the facility setting.

Response: The source codes mentioned by the commenter have associated work RVUs, while the new CPT codes do not, and they do not include physician work time. The new CPT coding effectively unbundles professional and technical services for some of these codes. Codes that do not have a physician work component would typically not be valued in the facility setting.

After consideration of the public comments, we are finalizing the work RVUs for the codes in the Psychological and Neuropsychological Testing family of codes as proposed. We are also finalizing the direct PE inputs as proposed, with the exception of the refinement to the CA021 clinical labor for CPT codes 96136 and 96137 as detailed above.

(57) Electrocorticography (CPT Code 95836)

CPT Code 95829 is used for Electrocorticogram performed at the time of surgery; however, a new code was needed to account for this non-face-to-face service for the review of a month's worth or more of stored data. CPT code 95836 (Electrocorticogram from an implanted brain neurostimulator pulse generator/transmitter, including recording, with interpretation and written report, up to 30 days) is a new code approved at the September 2017 CPT Editorial Panel Meeting to describe this service.

We disagreed with the RUC-recommended work RVU of 2.30 for CPT code 95836 and proposed a work RVU of 1.98 based on a direct crosswalk to the top reference, CPT code 95957 (Digital analysis of electroencephalogram (EEG) (*e.g.,* for epileptic spike analysis)). This is a recently-reviewed code with the same intraservice time of 30 minutes and a total time only 2 minutes lower than CPT code 95836. We agreed with the survey respondents that CPT code 95957 was an accurate valuation for this new code, and due to the clinically similar nature of the two procedures and their near-identical time values, we proposed to value both of them at the same work RVU of 1.98.

The RUC did not recommend, and we did not propose, any direct PE inputs for CPT code 95836.

The following is a summary of the public comments we received on our proposals involving CPT code 95836.

Comment: Many commenters disagreed with the proposed work RVU of 1.98 for CPT code 95836 and stated that CMS should finalize the RUC-recommended work RVU of 2.30. Commenters stated that the survey respondents chose CPT code 95957 as a reference service and not as a direct crosswalk. Commenters stated that the survey respondents pick from a list of 10–20 services to use as a comparison and then recommend a work RVU based on the intensity, complexity and physician time required to perform the surveyed code. Commenters stated that the median survey work RVU was actually 2.97, much higher than the key reference service, and that the respondents specifically indicated that CPT code 95836 is more intense and complex than CPT code 95957 on all measures.

Response: We disagree with the commenters that the key reference service of CPT code 95957 would be an inappropriate choice for a direct crosswalk, not least because the RUC commonly uses one of the key reference services in exactly this fashion. While it is true that the median survey work RVU was 2.97, we note that the RUC did not recommend this work valuation either, instead choosing to recommend a work RVU of 2.30 in recognition that the survey median would be a value that is too high to maintain relativity. Similarly, while the survey respondents specifically indicated that CPT code 95836 is more intense and complex than CPT code 95957 on all measures, we note that the survey respondents also indicated that CPT code 95836 is more intense and complex than the second key reference code, CPT code 95810 (Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist) which has a work RVU of 2.50. We proposed to use a crosswalk to CPT code 95957 not only because it was selected by the survey participants as the top key reference, but also because it is a recently-reviewed code with the same intraservice time of 30 minutes and a total time only 2 minutes lower than CPT code 95836. We continue to believe that this is the most accurate choice for work valuation.

Comment: Several commenters stated that although the specialty society did not submit any direct PE inputs, it is not a facility only code. Commenters stated that CPT code 95836 can be performed in both the nonfacility and the facility setting, and that the nonfacility is actually the typical setting for this service. Commenters stated that they understood that there would be no direct staffing, equipment or supply costs associated with this service and that indirect costs would be similar regardless of the setting in which the service is performed, but there would still be indirect practice expense associated with providing the service in the nonfacility. Commenters apologized for the misunderstanding and requested that CPT code 95836 should be valued in the nonfacility setting.

Response: We appreciate the additional information supplied by the commenters on this issue. We will remove the ''NA'' designation from the nonfacility setting for CPT code 95836. Due to the fact that there are no direct PE inputs for CPT code 95836, the PE RVU will be the same in both the nonfacility and facility settings because it is based solely on the indirect PE methodology.

After consideration of the public comments, we are finalizing the work RVU for CPT code 95836 as proposed. We are not finalizing any direct PE inputs for this code, but we will value it in both the facility and nonfacility settings as noted above.

(58) Chronic Care Remote Physiologic Monitoring (CPT Codes 99453, 99454, and 99457)

In the CY 2018 PFS final rule, we finalized separate payment for CPT code 99091 (Collection and interpretation of physiologic data (*e.g.,* ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time) (82 FR 53014). In that rule, we indicated that there would be new coding describing remote monitoring forthcoming from the CPT Editorial Panel and the RUC (82 FR 53014). In September 2017, the CPT Editorial Panel revised one code and created three new codes to describe remote physiologic monitoring and management, and the RUC provided valuation recommendations through our standard rulemaking process.

CPT codes 99453 (Remote monitoring of physiologic parameter(s) (*e.g.,* weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment) and 99454 (Remote monitoring of physiologic parameter(s) (*e.g.,* weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days) are both PE-only codes. We proposed the RUC-recommended work RVU of 0.61 for CPT code 99457 (Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month).

For the direct PE inputs, we proposed to accept the RUC-recommended direct PE inputs for CPT code 99453 and to remove the ''Monthly cellular and licensing service fee'' supply from CPT code 99454. We do not believe that these licensing fees will be allocated to the use of an individual patient for an individual service, and instead believe they can be better understood as forms of indirect costs similar to office rent or administrative expenses. Therefore, we proposed to remove this supply input as a form of indirect PE. We proposed the direct PE inputs for CPT code 99457 without refinement.

The following is a summary of the public comments we received on our

proposals involving the Chronic Care Remote Physiologic Monitoring family of codes.

Comment: Commenters were very supportive of CMS making separate payment for these services. Several commenters supported the proposal of the RUC-recommended work RVU of 0.61 for CPT code 99457. A few commenters stated that the proposed rates for these services were too low, and that given industry standards, reimbursement should be increased.

Response: We appreciate the support for our proposal from the commenters.

Comment: Several commenters disagreed with the proposal to remove the ''Monthly cellular and licensing service fee'' supply from CPT code 99454. Commenters stated that the monthly cellular and licensing service fee was a direct practice expense input as it is allocable to the patient for this service. Commenters stated that this fee is not a license for the entire practice; rather it is an individually allocable fee for the period that the patients is monitored and the physician would not incur such fees if the patient did have the wireless monitor. Commenters clarified that the fee is comprised of the monthly cost associated with encryption of data for safe HIPAA compliant transfer, programmed alerts, and the monthly cost of pre-loaded connectivity used to transmit patient generated physiological data from a specific patient to the provider's software. Commenters stated that reliance upon a patient's cellular connectivity or WIFI, which may or may not be operating based on patient technology capabilities, was not reliable for medical delivery purposes.

Response: We disagree with the commenters and we continue to believe that the monthly cellular and licensing service fee constitutes a form of indirect PE. We believe that licensing and data costs are administrative costs that are not unique to individual procedures, in the same fashion that we do not assign separate direct PE for higher electricity costs to diagnostic imaging procedures as compared to cognitive evaluation procedures. We continue to believe that these data costs are appropriately captured via the indirect PE methodology as opposed to being included as a separate direct PE input. We also note that other services that require around-the-clock monitoring, such as the home PT/INR monitoring described in HCPCS code G0249 (Provision of test materials and equipment for home inr monitoring of patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; includes: Provision of materials for use in the home and reporting of test results to physician; testing not occurring more frequently than once a week; testing materials, billing units of service include 4 tests), do not include additional direct PE inputs for data costs, and we do not believe it would be appropriate to include them for CPT code 99454.

Comment: One commenter stated that CMS should add the cost of equipment sanitation and reprocessing as a one-time cost that is directly attributable to a patient. The commenter stated that FDA device guidelines require that a reusable medical device be reprocessed, which includes sanitation or sterilization and ensuring that all personal data is 'wiped' or removed from the device. The commenter stated that this cost was not considered by the RUC, however, it is routinely part of the 'set up' costs that are onetime costs directly attributable to a patient.

Response: We disagree with the commenter that these expenses would constitute a separate form of direct PE. We agree with the RUC, which discussed the specialty society's recommended supply items, shipping costs and a device reprocessing fee, and determined that these expenses are not specifically allocable to the patient for this service, and would be considered indirect practice expenses.

Comment: One commenter stated that there was direct time spent by pharmacists for each patient, and the commenter requested that CMS factor pharmacist time into the PE valuation for CPT codes 99453, 99454, 99091, and 99457.

Response: We typically do not consider time spent by a pharmacist to be a part of the clinical labor time for purposes of direct PE. For additional information, we direct readers to the Practice Expense portion of this final rule (section II.B. of this final rule).

Comment: Many commenters pointed out that beneficiary cost sharing is a significant barrier to the use of non-face-to-face services, like remote patient monitoring. Commenters requested that CMS waive the cost sharing requirements for these codes.

Response: We do not have the authority to make changes to the applicable beneficiary cost sharing for most physicians' services, including these.

Comment: Many commenters requested that CMS clarify the kinds of technology covered under CPT codes 99453, 99454, and 99457. Commenters provided examples of the kinds of technology these codes should cover including software applications that could be integrated into a beneficiary's smart phone, Holter-Monitors, Fit-Bits, or artificial intelligence messaging. One commenter suggested that behavioral health data and data from wellness applications be included as well. Another commenter stated that the descriptor should include results of patients' self-care tasks. Many commenters stated that CMS should clarify certain elements in the scope of service and code descriptors and issue appropriate sub-regulatory guidance. Commenters inquired as to whether CPT code 99453 can be furnished via telecommunication technology, if it can be billed again if the number of parameters changed in the future. Commenters requested that CMS clarify the meaning of ''programmed alerts transmission'' in the descriptor for CPT code 99454, and whether it included transmissions that occurred other than daily. Commenters also encouraged CMS to allow flexibility in the time frame covered by these services.

Response: We plan to issue guidance to help inform practitioners and stakeholders on these issues.

Comment: Commenters requested that CMS clarify whether CPT code 99457 can be billed incident to a practitioner's professional services and asked that CMS make an exception to the direct supervision requirements, stating that general supervision is sufficient for these services.

Response: We note that CPT code 99457 describes professional time and therefore cannot be furnished by auxiliary personnel incident to a practitioner's professional services.

Comment: A few commenters suggested that additional medical professionals, including pharmacists, paramedics, chiropractors, physical therapists, occupational therapists and dentists should be allowed to bill Medicare for these services. Other commenters requested that CMS clarify the practitioners referred to as ''other qualified healthcare professionals'' in the code descriptor.

Response: We note that all practitioners must practice in accordance with applicable state law and scope of practice laws, and that some of the practitioners identified by the commenters are not authorized to bill Medicare independently for their services. We note that the term, ''other qualified healthcare professionals,'' used in the code descriptor is a defined by CPT, and that definition can be found in the CPT Codebook.

Comment: A few commenters provided specific suggestions for revising the code descriptors, including

the addition of secure messaging platforms, revision of the time thresholds, specifying that the follow-up should be written in all instances, including ''for medical consultative discussion and review'' in the descriptor for CPT codes 99446 through 99449, and striking ''referral services'' and rather, including language similar to the other codes regarding ''assessment and management'' services. Other commenters requested CMS clarify the definition of ''health record assessment'' in the descriptors for CPT codes 99451 and 99452. One commenter suggested that CMS add language about use of EHR to the existing CPT codes, rather than finalize separate payment for CPT codes 99451 and 99452.

Response: While we appreciate all of the specific suggestions regarding the code descriptions, we defer to the CPT to maintain code descriptors for CPT codes. Where additional clarification is needed, we may provide guidance in the future.

Comment: A few commenters urged CMS not to be prescriptive regarding the technology that could be used to perform consultations, including real-time video, a store-and-forward visit, or simply a patient-provider message via a patient portal.

Response: While we are sympathetic to the commenters' desire not to be overly prescriptive about the technology used to furnish these services, especially given the speed at which technology evolves, we note that we refer to the CPT code descriptors and guidance to ascertain the scope of technology that is used to furnish these services.

Comment: One commenter asked whether there were geographic restrictions on these services.

Response: There are no geographic restrictions, as these services are not Medicare telehealth services.

After considering the public comments, we are finalizing the RUC-recommended work RVU of 0.61 for CPT code 99457 and the direct PE inputs for all three codes as proposed.

(59) Interprofessional Internet Consultation (CPT Codes 99451, 99452, 99446, 99447, 99448, and 99449)

In September 2017, the CPT Editorial Panel revised four codes and created two codes to describe interprofessional telephone/internet/electronic medical record consultation services. CPT codes 99446 (Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 5–10 minutes of medical consultative discussion and review), 99447 (Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 11–20 minutes of medical consultative discussion and review), 99448 (Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 21–30 minutes of medical consultative discussion and review), and 99449 (Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 31 minutes or more of medical consultative discussion and review) describe assessment and management services in which a patient's treating physician or other qualified healthcare professional requests the opinion and/or treatment advice of a physician with specific specialty expertise to assist with the diagnosis and/or management of the patient's problem without the need for the face-to-face interaction between the patient and the consultant. These CPT codes are currently assigned a procedure status of B (bundled) and are not separately payable under Medicare. The CPT Editorial Panel revised these codes to include electronic health record consultations, and the RUC reaffirmed the work RVUs it had previously submitted for these codes. We reevaluated the submitted recommendations and, in light of changes in medical practice and technology, we proposed to change the procedure status for CPT codes 99446, 99447, 99448, and 99449 from B (bundled) to A (active). We also proposed the RUC re-affirmed work RVUs of 0.35 for CPT code 99446, 0.70 for CPT code 99447, 1.05 for CPT code 99448, and 1.40 for CPT code 99449.

The CPT Editorial Panel also created two new codes, CPT code 99452 (Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes) and CPT code 99451 (Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 or more minutes of medical consultative time). The RUC-recommended work RVUs are 0.50 for CPT code 99452 and 0.70 for 99451. Since the CPT code for the treating/requesting physician or qualified healthcare professional and the CPT code for the consultative physician have similar intraservice times, we believe that these CPT codes should have equal values for work. Therefore, we proposed a work RVU of 0.50 for both CPT codes 99452 and 99451.

We welcomed comments on this proposal. We also direct readers to section II.D. of this final rule, Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services, which includes additional detail regarding our policies for modernizing Medicare physician payment by recognizing communication technology-based services.

There are no recommended direct PE inputs for the codes in this family.

The following is a summary of the public comments we received on our proposals involving the Interprofessional Internet Consultation family of codes.

Comment: Almost all commenters were supportive of CMS' proposal to unbundle CPT codes 99446 through 99449 and make separate payment for CPT codes 99452 and 99451. Almost all commenters did not support lowering the RVU of CPT code 99451 to 0.50 as the work of the consulting physician in CPT code 99451 is more intense than the work of the treating physician in CPT code 99452. Commenters stated that the consulting practitioner exercises greater effort, both in judgment and technical skill to make a recommendation for the treatment of a previously unknown patient than the treating physician does in conveying the relevant information. A few commenters expressed concern that the proposed work RVU for CPT code 99452 is too low, and does not accurately reflect the resources associated with the work of the treating physician.

Response: We agree with commenters that the work of the consulting physician is significant, and we are persuaded by the additional descriptions of that work provided by commenters. We also agree with the commenters who suggested that the proposed work RVU of 0.50 for CPT code 99452 undervalues the work associated with aggregating patient information, communicating with the consulting practitioner, and

implementing the results of the consultation. We continue, however, to have concerns regarding the valuation of these services. We note that there are instances where the patient would not be new to the consulting practitioner, and therefore the intensity of the work would be reduced. We are also concerned that, given the similarity of intraservice times, CPT code 99452 is undervalued relative to CPT code 99451, especially since the code descriptor for CPT code 99452 specifies that the consulting practitioner can spend a minimum of 5 minutes providing the consultation. We believe that a work RVU of 0.50 more accurately describes the work associated with both services. Given the similarity of intraservice times and the information indicating that both codes may be undervalued at 0.50 RVUs, we are finalizing a work RVU of 0.70 for CPT codes 99451 and 99452.

Comment: A few commenters expressed concern that these codes were only payable in the facility setting.

Response: These codes are payable in both facility and non-facility settings.

Comment: One commenter requested that CMS include pharmacists as clinical staff in the direct PE.

Response: We direct readers to the discussion of this issue in the PE section of the rule (Section II.B. of this final rule). We also note that these codes do not have direct PE inputs.

(60) Chronic Care Management Services (CPT Code 99491)

In February 2017, the CPT Editorial Panel created a new code to describe at least 30 minutes of chronic care management services performed personally by the physician or qualified health care professional over one calendar month. CMS began making separate payment for CPT code 99490 (Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored) in CY 2015 (79 FR 67715). CPT code 99490 describes 20 minutes of clinical staff time spent on care management services for patients with 2 or more chronic conditions. CPT code 99490 also includes 15 minutes of physician time for supervision of clinical staff. For CY 2019, the CPT Editorial Panel created CPT code 99491 (Chronic care management services, provided personally by a physician or other qualified health care professional, at least 30 minutes of physician or other qualified health care professional time, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored) to describe situations when the billing practitioner is doing the care coordination work that is attributed to clinical staff in CPT code 99490. For CPT code 99491, the RUC recommended a work RVU of 1.45 for 30 minutes of physician time.

We believe this work RVU overvalues the resource costs associated with the physician performing the same care coordination activities that are performed by clinical staff in the service described by CPT code 99490. Additionally, this valuation of the work is higher than that of CPT code 99487 (Complex chronic care management services, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, establishment or substantial revision of a comprehensive care plan, moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month), which includes 60 minutes of clinical staff time, creating a rank order anomaly within the family of codes if we were to accept the RUC-recommended value.

CPT code 99490 has a work RVU of 0.61 for 15 minutes of physician time. Therefore, as CPT code 99491 describes 30 minutes of physician time, we proposed a work RVU of 1.22, which is double the work RVU of CPT code 99490.

We did not propose any direct PE refinements for this code family.

The following is a summary of the public comments we received on our proposals involving CPT code 99491.

Comment: Almost all commenters recommended that CMS finalize the RUC-recommended work value of 1.45 for 99491. The RUC stated that CPT code 99491 is different from the existing chronic care management (CCM) services codes because those codes are performed by clinical staff under the supervision of a physician, while CPT code 99491 is performed by the physicians themselves. Commenters also stated that the typical patient requiring that the physician personally perform the care management services is of greater acuity than the typical patient for whom CCM may be performed by clinical staff. Additionally, CPT code 99491 cannot be reported with CPT code 99490 or CPT code 99487, and must therefore account for all of the care management work in the month. Commenters also pointed out that there are multiple examples of CMS valuing the work of a physician more highly than clinical staff when they perform the same services, for example CPT codes 96101 (Psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, *e.g.,* MMPI, Rorschach, WAIS), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report) and 96102 (Psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, *e.g.,* MMPI and WAIS), with qualified health care professional interpretation and report, administered by technician, per hour of technician time, face-to-face.)

Response: We agree with commenters that a work RVU of 1.45 accurately captures the resources associated when a physician furnishes CCM. We agree that in most cases, the physician would perform CCM on patients with higher acuity and therefore the care planning and medical decision making would be of greater intensity. We also agree with commenters that the work associated with personally performing CCM as opposed to supervising clinical staff is also of greater intensity. Therefore, we are finalizing that value based on our review of comments received.

Comment: A few commenters requested that CMS clarify that CPT code 99491 can be performed incident to a practitioner's professional services.

Response: CPT code 99491 is specifically for use when the billing practitioner personally performs care management services, so this code cannot be furnished incident to a practitioner's professional services.

(61) Diabetes Management Training (HCPCS Codes G0108 and G0109)

HCPCS codes G0108 (Diabetes outpatient self-management training services, individual, per 30 minutes) and G0109 (Diabetes outpatient self-

management training services, group session (2 or more), per 30 minutes) were identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. For CY 2019, we proposed the HCPAC-recommended work RVU of 0.90 for HCPCS code G0108 and the HCPAC-recommended work RVU of 0.25 for HCPCS code G0109.

For the direct PE inputs, we noted that there was a significant disparity between the specialty recommendation and the final recommendation submitted by the HCPAC. We were concerned about the significant decreases in direct PE inputs in the final recommendation when compared to the current makeup of the two codes. The final HCPAC recommendation removed a series of different syringes and the patient education booklet that currently accompanies the procedure. We believe that injection training is part of these services and that the supplies associated with that training would typically be included in the procedures. Due to these concerns, we proposed to maintain the current direct PE inputs for HCPCS codes G0108 and G0109. Therefore, we proposed not to add the new supply item ''20x30 inch self-stick easel pad, white, 30 sheets/pad'' (SK129) to HCPCS code G0109 that was included in the final HCPAC recommendation, as it was not a current supply for HCPCS code G0109; however, we proposed to accept the submitted invoice price and to add the supply to our direct PE database.

The following is a summary of the public comments we received on our proposals involving the Diabetes Management Training family of codes.

Comment: Several commenters supported the proposal of the HCPAC-recommended work RVUs. Commenters also stated that they applauded CMS for recognizing and addressing the significant disparity in direct PE inputs between the specialty recommendations and the final recommendations submitted to CMS by the HCPAC.

Response: We appreciate the support for our proposals from the commenters.

Comment: One commenter expressed disappointment that CMS did not address barriers in Medicare that impact beneficiary utilization of the diabetes self-management training (DSMT) benefit. The commenter stated that CMS solicited comments from stakeholders in the CY 2017 PFS proposed rule on this subject, and the commenter has been part of ongoing conversations with CMS about this issue, through in-person meetings and written communications, over the past two years. The commenter stated that they were hopeful CMS would use this opportunity to address barriers to DSMT given that utilization of the DSMT benefit stands at only 5 percent of eligible Medicare beneficiaries.

Response: We appreciate the feedback from the commenter, and we will consider these issues for future rulemaking. However, we note that we did not specifically make any proposals associated with these subjects in the CY 2019 proposed rule.

Comment: One commenter stated that the final HCPAC recommendations removed a series of different syringes and the patient education booklet that currently accompany these procedures. The commenter stated that several anti-glycemic medications other than insulin require injection with a syringe and a significant number of persons with both type 1 and type 2 diabetes are prescribed these medications, however the list of supplies in the current direct PE inputs does not include syringes. The commenter therefore recommended that CMS add a series of different syringes to the direct PE inputs for HCPCS codes G0108 and G0109.

Response: We proposed to maintain the current direct PE inputs for HCPCS codes G0108 and G0109, which do not currently include the syringe supplies described by the commenter (supply codes SC051, SC052, and SC055). Although we are sensitive to the concerns raised by the commenter, we do not believe that adding these syringe supplies to the procedures would be consistent with our policy of maintaining the current direct PE inputs.

After consideration of the public comments, we are finalizing the work RVUs and the direct PE inputs for the codes in the Diabetes Management Training family of codes as proposed.

(62) External Counterpulsation (HCPCS Code G0166)

HCPCS code G0166 (External counterpulsation, per treatment session) was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. The RUC is not recommending a work RVU for HCPCS code G0166 because they found that there is no physician work involved in this service. After reviewing this code, we proposed a work RVU of 0.00 for HCPCS code G0166, and proposed to make the code valued for PE only. For the direct PE inputs, we proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving HCPCS code G0166.

Comment: A commenter agreed with the proposal that an individual treatment session would have no physician work and supported the proposed direct PE inputs. However, the commenter stated that future coding solutions may be necessary to recognize management of these services that is additional to that captured by E/M coding.

Response: We appreciate the feedback from the commenter, and we will consider this information for future rulemaking.

After consideration of the public comments, we are finalizing the work RVU and direct PE inputs for HCPCS code G0166 as proposed.

(63) Wound Closure by Adhesive (HCPCS Code G0168)

HCPCS code G0168 (Wound closure utilizing tissue adhesive(s) only) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. For CY 2019, the RUC recommended a work RVU of 0.45 based on maintaining the current work RVU.

We disagreed with the recommended value and we proposed a work RVU of 0.31 for HCPCS code G0168 based on a direct crosswalk to CPT code 93293 (Transtelephonic rhythm strip pacemaker evaluation(s) single, dual, or multiple lead pacemaker system, includes recording with and without magnet application with analysis, review and report(s) by a physician or other qualified health care professional, up to 90 days). CPT code 93293 is a recently-reviewed code with the same 5 minutes of intraservice time and 1 fewer minute of total time. In reviewing HCPCS code G0168, the recommendations stated that the work involved in the service had not changed even though the surveyed intraservice time was decreasing by 50 percent, from 10 minutes to 5 minutes. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. In the case of HCPCS code G0168, we believe that it would be more accurate to propose a work RVU of 0.31 based on

the aforementioned crosswalk to CPT code 93293 to account for these decreases in the surveyed work time. Maintaining the current work RVU of 0.45 despite a 50 percent decrease in the surveyed intraservice time would result in a significant increase in the intensity of HCPCS code G0168, and we have no reason to believe that the procedure has increased in intensity since the last time that it was valued.

For the direct PE inputs, we proposed to refine the equipment times in accordance with our standard equipment time formulas.

The following is a summary of the public comments we received on our proposals involving HCPCS code G0168.

Comment: Many commenters disagreed with the proposed work RVU of 0.31 for HCPCS code G0168 and stated that CMS should finalize the HCPAC-recommended work RVU of 0.45. Commenters stated that CMS should not compare the valid survey time to the current work time because the initial CMS/Other source data is flawed and maintains zero validity for comparison. Commenters stated that surveyed time was never obtained from physicians who perform this service and should not be used as a comparison.

Response: We agree that it is important to use the most recent data available regarding time, and we note that when many years have passed between when time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The times currently associated with codes play a very important element in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had routinely been overestimated, this would undermine the relativity of the work RVUs on the PFS in general, given the process under which codes are often valued by comparisons to codes with similar times and it undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS. Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times, used in the PFS ratesetting processes, are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we want to reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values in our methodology, we refer readers to our discussion of the subject in the CY 2017 final rule (81 FR 80273 through 80274).

Comment: Several commenters stated that HCPCS code G0168 should not be crosswalked to CPT code 93293, as this is an evaluation of pacemaker strips over a 90 day period. Commenters stated that the skill of closing a facial laceration, typically near the eye, using a surgical tissue adhesive for HCPCS code G0168 is more intense and complex to perform than CPT code 93293 and thus should be valued higher. Commenters stated that CPT code 51702 (Insertion of temporary indwelling bladder catheter; simple (*e.g.,* Foley)) would be a better reference service.

Response: We disagree with the commenters that CPT code 93293 would be an inappropriate choice for a crosswalk. CPT code 93293 describes a transtelephonic rhythm strip pacemaker evaluation(s) for a single, dual, or multiple lead pacemaker system. We do not agree that this crosswalk code has lower intensity or complexity due to the cognitive work involved in evaluating the patient correctly. Both CPT code 93293 and HCPCS code G0168 require skill on the part of the practitioner, only of different types. We also believe that our crosswalk to CPT code 92393 is a more accurate choice because it has the same intraservice work time (5 minutes) closely matches the total work time (13 minutes as opposed to 14 minutes) of HCPCS code G0168. By contrast, CPT code 51702 has nearly double the total work time at 25 minutes, which accounts for its higher work RVU of 0.50.

After consideration of the public comments, we are finalizing the work RVU and direct PE inputs for HCPCS code G0168 as proposed.

(64) Removal of Impacted Cerumen (HCPCS Code G0268)

HCPCS code G0268 (Removal of impacted cerumen (one or both ears) by physician on same date of service as audiologic function testing) was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000. For CY 2019, we proposed the RUC-recommended work RVU of 0.61 for HCPCS code G0268.

For the direct PE inputs, we proposed to remove the clinical labor time for the ''Clean surgical instrument package'' (CA026) activity. There is no surgical instrument pack included in the recommended equipment for HCPCS code G0268, and this code already includes the standard 3 minutes allocated for cleaning the room and equipment. In addition, all of the instruments used in the procedure appear to be disposable supplies that would not require cleaning since they would only be used a single time.

The following is a summary of the public comments we received on our proposals involving HCPCS code G0268.

Comment: Several commenters supported our proposal of the HCPAC-recommended work RVU as well as the refinement to the direct PE inputs.

Response: We appreciate the support for our proposals from the commenters.

After consideration of the public comments, we are finalizing the work RVU and direct PE inputs for HCPCS code G0268 as proposed.

(65) Structured Assessment, Brief Intervention, and Referral to Treatment for Substance Use Disorders (HCPCS Codes G0396, G0397, and G2011)

In response to the Request for Information in the CY 2018 PFS proposed rule (82 FR 34172), commenters requested that CMS pay separately for assessment and referral related to substance use disorders. In the CY 2008 PFS final rule (72 FR 66371), we created two G-codes to allow for appropriate Medicare reporting and payment for alcohol and substance abuse assessment and intervention services that are not provided as screening services, but that are performed in the context of the diagnosis or treatment of illness or injury. The codes are HCPCS code G0396 (Alcohol and/or substance (other than tobacco) abuse structured assessment (*e.g.,* AUDIT, DAST) and brief intervention, 15 to 30 minutes)) and HCPCS code G0397 (Alcohol and/or substance (other than tobacco) abuse structured assessment (*e.g.,* AUDIT, DAST) and intervention greater than 30 minutes)). In 2008, we instructed Medicare contractors to pay for these codes only when the services were considered reasonable and necessary.

Given the ongoing opioid epidemic and the current needs of the Medicare population, we expect that these services would often be reasonable and necessary. However, the utilization for these services is relatively low, which we believe is in part due to the service-specific documentation requirements for these codes (the current requirements are available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/SBIRT_Factsheet_ICN904084.pdf*). We believe that removing the additional documentation requirements will also ease the administrative burden on providers. Therefore, for CY 2019, we proposed to eliminate the service-specific documentation requirements for HCPCS codes G0397 and G0398. We welcomed comments on our proposal to change the documentation requirements for these codes.

The following is a summary of the comments we received regarding our proposal to change the documentation requirements for these codes.

Comment: The majority of commenters were supportive of this proposal, some noting that this will ease administrative burden and some noting that this will incentivize providers to deliver SBIRT services, thereby increasing access to this service. One commenter stated they believe that practitioners are not utilizing SBIRT for illicit drug use due to the absence of conclusive evidence to support use of this service for illicit drug use and therefore, support removing the service documentation requirements for SBIRT when used to screen for unhealthy alcohol use, but not when used to screen for illicit drug use.

Response: We thank the commenters for their feedback. We note that the services described by HCPCS codes G0397 and G0398 describe services for alcohol and/or substance abuse; we believe it would be administratively burdensome for practitioners were we to create varying rules for different diagnoses. Additionally, it is our intention to increase access to care for services that may be of use in addressing all substance use disorders, especially in light of the ongoing opioid epidemic. Therefore, we are finalizing our proposal to eliminate the service-specific documentation requirements for HCPCS codes G0397 and G0398.

Additionally, we proposed to create a third HCPCS code G2011with a lower time threshold in order to accurately account for the resource costs when practitioners furnish these services, but do not meet the minimum time requirements of the existing codes. We note that in the proposed rule we referred to this service as HCPCS code GSBR1, which was a placeholder code. The code will be described as G2011: Alcohol and/or substance (other than tobacco) abuse structured assessment (*e.g.,* AUDIT, DAST), and brief intervention, 5–14 minutes. We proposed a work RVU of 0.33, based on the intraservice time ratio between HCPCS codes G0396 and G0397. We welcomed comments on this code descriptor and proposed valuation for HCPCS code G2011.

The following is a summary of the comments we received on this code descriptor and proposed valuation for HCPCS code G2011.

Comment: Commenters were supportive of creating this code and the valuation proposed, and noted the lower time threshold will allow physicians the opportunity to provide brief counseling rather than 15 or more minutes of discussion, which requires extended interest from a patient who may not yet be ready for prolonged discussion and/or is receptive to being referred to another health care provider for treatment. One commenter recommended finalizing guidance that allows the newly proposed SBIRT HCPCS code to be used for alcohol, but not illicit drug use.

Response: We thank the commenters for their feedback. After considering these comments, we are finalizing the code descriptor and valuation for HCPCS code G2011 as proposed. We believe the code descriptor and guidance for this new SBIRT HCPCS code should be consistent with the existing SBIRT HCPCS codes. For future rulemaking we would consider recommendations on how to refine this family of codes under our standard process of reviewing codes.

(66) Prolonged Services (HCPCS Code GPRO1)

CPT codes 99354 (Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; first hour (List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service)) and 99355 (Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (List separately in addition to code for prolonged service)) describe additional time spent face-to-face with a patient. Stakeholders have shared with us that the threshold of 60 minutes for CPT code 99354 is difficult to meet and is an impediment to billing these codes. In response to stakeholder feedback and as part of our proposal as discussed in section II.I. of this final rule, Evaluation and Management Services, to implement a single PFS rate for E/M visit levels 2–5 while maintaining payment stability across the specialties, we proposed HCPCS code GPRO1 (Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; 30 minutes (List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service)), which could be billed with any level of E/M code. We noted that we did not propose to make any changes to CPT codes 99354 and 99355, which can still be billed, as needed, when their time thresholds and all other requirements are met. We proposed a work RVU of 1.17, which is equal to half of the work RVU assigned to CPT code 99354. Additionally, we proposed direct PE inputs for HCPCS code GPRO1 that are equal to one half of the values assigned to CPT code 99354, which can be found in the Direct PE Inputs public use file for this final rule.

Comment: As almost all commenters did not support the overall E/M coding and payment proposals, we did not receive many comments with specific suggestions on valuation for HCPCS code GPRO1. Of the commenters that supported creation of the code, most supported the proposed valuation while others, while supporting the creation of a 30-minute prolonged services code in principle, encouraged CMS to wait for recommendations from the CPT Editorial Panel and the RUC.

Response: For CY 2021, we are finalizing the proposed add-on code for HCPCS code GPRO1 using the input values, as proposed. We note that prior to implementation for 2021, we could consider, through rulemaking, the code and its valuation in the context of any potential changes to CPT codes and/or recommendations offered by stakeholders, including the RUC, as part of our annual process for valuing PFS services. See section II.I. of this final rule for further discussion of the E/M policy.

(67) Remote Pre-Recorded Services (HCPCS Code G2010)

For CY 2019, we proposed to make separate payment for remote evaluation services when a physician uses pre-recorded video and/or images submitted by a patient in order to evaluate a patient's condition through new HCPCS G-code G2010 (Remote evaluation of recorded video and/or images submitted by the patient (*e.g.,* store and forward), including interpretation with verbal follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment). We proposed to value this service by a direct crosswalk to CPT code 93793 (Anticoagulant management for a patient taking warfarin, must include review and interpretation of a new home, office, or lab international normalized ratio (INR) test result, patient instructions, dosage adjustment (as needed), and scheduling of additional test(s), when performed), as we believe the work described is similar in kind and intensity to the work performed as part of HCPCS code G2010. Therefore, we proposed a work RVU of 0.18, preservice time of 3 minutes, intraservice time of 4 minutes, and post service time of 2 minutes. We also proposed to add 6 minutes of clinical labor (L037D) in the service period. We solicited comment on the code descriptor and valuation for HCPCS code G2010. We direct readers to section II.D. of this final rule, which includes additional detail regarding our proposed policies for modernizing Medicare physician payment by recognizing communication technology-based services.

The following is a summary of the comments we received on the code descriptor and valuation for HCPCS code G2010.

Comment: Several commenters stated that the proposed payment rate is too low, citing that it is below market compared to the rate many asynchronous telemedicine companies pay their contracted/employed physician staff, and noted that new patients in particular require more resources, whereas others stated that the proposed valuation was appropriate.

Response: We believe that the proposed valuation accurately reflects the resources involved in furnishing this service and note that we are finalizing limiting this service to established patients. We also note that we plan to monitor the utilization of this code and routinely address recommended changes in values for codes paid under the PFS.

After considering the public comments, we are finalizing the work RVU and direct PE inputs for HCPCS code G2010 as proposed.

(68) Brief Communication Technology-Based Service, *e.g.* Virtual Check-In (HCPCS Code G2012)

We proposed to create a G-code, HCPCS code G2012 (Brief communication technology based service, *e.g.* virtual check-in, by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion) to facilitate payment for these brief communication technology-based services. We proposed to base the code descriptor and valuation for HCPCS code G2012 on existing CPT code 99441 (Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion), which is currently not separately payable under the PFS. As CPT code 99441 only describes telephone calls, we are proposing to create a new HCPCS code G2012 to encompass a broader array of communication modalities. We do, however, believe that the resource assumptions for CPT code 99441 would accurately account for the costs associated with providing the proposed virtual check-in service, regardless of the technology. We proposed a work RVU of 0.25, based on a direct crosswalk to CPT code 99441. For the direct PE inputs for HCPCS code G2012, we also proposed the direct PE inputs assigned to CPT code 99441. Given the breadth of technologies that could be described as telecommunications, we anticipated receiving public comments and working with the CPT Editorial Panel and the RUC to evaluate whether separate coding and payment is needed to account for differentiation between communication modalities. We solicited comment on the code descriptor, as well as the proposed valuation for HCPCS code G2012. We direct readers to section II.D. of this final rule, which includes additional detail regarding our proposed policies for modernizing Medicare physician payment by recognizing communication technology-based services.

The following is a summary of the comments we received on the code descriptor, as well as the proposed valuation for HCPCS code G2012.

Comment: Several commenters stated that the proposed payment rate would be inadequate for modalities that are both audio and visual capable, whereas other commenters stated that the proposed valuation was appropriate.

Response: We appreciate the input provided by the commenters. As noted in section II.D. of this final rule, we are finalizing the valuation for this service as proposed. We note that we are finalizing allowing audio-only real-time telephone interactions in addition to synchronous, two-way audio interactions that are enhanced with video or other kinds of data transmission. We believe the proposed valuation reflects the low work time and intensity and accounts for the resource costs and efficiencies associated with the use of communication technology. We recognize that the valuation of this service is relatively modest, especially compared to in-person services, however, we believe that the proposed valuation accurately reflects the resources involved in furnishing this service.

We plan to monitor the utilization of this code and note that we routinely address recommended changes in values for codes paid under the PFS and would expect to do this in future rulemaking.

After consideration of the public comments, we are finalizing the work RVU and direct PE inputs for HCPCS code G2012 as proposed.

(69) Visit Complexity Inherent to Certain Specialist Visits (HCPCS Code GCG0X)

We proposed to create a HCPCS G-code to be reported with an E/M service to describe the additional resource costs for specialties for whom E/M visit codes make up a large percentage of their total allowed charges and who we believe primarily bill level 4 and level 5 visits. The treatment approaches for these specialties generally do not have separate coding and are generally reported using the E/M visit codes. We proposed to create HCPCS code, GCG0X (Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or

interventional pain management-centered care (Add-on code, list separately in addition to an evaluation and management visit)). We proposed a valuation for HCPCS code GCG0X based on a crosswalk to 75 percent of the work RVU and time of CPT code 90785 (Interactive complexity), which would result in a proposed work RVU of 0.25 and a physician time of 8.25 minutes for HCPCS code GCG0X. CPT code 90785 has no direct PE inputs. Interactive complexity is an add-on code that may be billed when a psychotherapy or psychiatric service requires more work due to the complexity of the patient. We believe that this work RVU and physician time would be an accurate representation of the additional work associated with the higher level complex visits. For further discussion of proposals relating to this code, see section II.I. of this final rule. We solicited comment on the code descriptor, as well as the proposed valuation for HCPCS code GCG0X.

The following is a summary of the comments we received on the code descriptor, as well as the proposed valuation for HCPCS code GCG0X.

Comment: As almost all commenters did not support the overall E/M coding and payment proposals, we did not receive comments with specific suggestions on valuation for HCPCS code GCG0X.

Response: For CY 2021, we are finalizing the proposed add-on code for visit complexity inherent to non-procedural specialty care using the input values, as proposed. We note that prior to implementation for CY 2021, we could consider, through rulemaking, the code and its valuation in the context of any potential changes to CPT codes and/or recommendations offered by stakeholders, including the RUC, as part of our annual process for valuing PFS services. See section II.I. of this final rule for further discussion of the E/M policy.

(70) Visit Complexity Inherent to Primary Care Services (HCPCS Code GPC1X)

We proposed to create a HCPCS G-code for primary care services, GPC1X (Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to an evaluation and management visit)). This code describes furnishing a visit to a new or existing patient, and can include aspects of care management, counseling, or treatment of acute or chronic conditions not accounted for by other coding. HCPCS code GPC1X would be billed in addition to the E/M visit code when the visit involved primary care-focused services. We proposed a work RVU of 0.07, physician time of 1.75 minutes. This proposed valuation accounts for the additional work resource costs associated with furnishing primary care that distinguishes E/M primary care visits from other types of E/M visits and maintains work budget neutrality across the office/outpatient E/M code set. For further discussion of proposals relating to this code, see section II.I. of this final rule. We solicited comment on the code descriptor, as well as the proposed valuation for HCPCS code GPC1X.

The following is a summary of the comments we received on the code descriptor, as well as the proposed valuation for HCPCS code GPC1X.

Comment: We received a few comments suggesting that the primary care add-on was undervalued, particularly in comparison to the add-on code for specialty visit complexity. A few commenters suggested that, at the very least, we should equalize the value for these codes.

Response: We agree that the proposed inputs do not reflect the resources associated with furnishing primary care visits. For CY 2021, we are finalizing the proposed add-on code for visit complexity inherent to primary care using the inputs associated with HCPCS code GCG1X: A work RVU of 0.25 and a physician time of 8.25 minutes. We note that prior to implementation for 2021, we could consider, through rulemaking, the code and its valuation in the context of any potential changes to CPT codes and/or recommendations offered by stakeholders, including the RUC, as part of our annual process for valuing PFS services. See section II.I. of this final rule for further discussion of the E/M policy.

(71) Podiatric Evaluation and Management Services (HCPCS Codes GPD0X and GPD1X)

We proposed to create two HCPCS G-codes, HCPCS codes GPD0X (Podiatry services, medical examination and evaluation with initiation of diagnostic and treatment program, new patient) and GPD1X (Podiatry services, medical examination and evaluation with initiation of diagnostic and treatment program, established patient), to describe podiatric evaluation and management services. We proposed a work RVU of 1.36, a physician time of 28.19 minutes, and direct costs summing to $21.29 for HCPCS code GPD0X, and a work RVU of 0.85, physician time of 21.73 minutes, and direct costs summing to $15.87 for HCPCS code GPD1X. These values are based on the average rate for CPT codes 99201–99203 and CPT codes 99211–99212 respectively, weighted by podiatric volume. For further discussion of proposals relating to these codes, see section II.I. of this final rule.

Comment: As almost all commenters did not support the overall E/M coding and payment proposals and these codes specifically, we did not receive comments with specific suggestions on valuation.

Response: In response to comments, we are not finalizing HCPCS codes GPD0X and GPD1X for CY 2019. See section X of this final rule for further discussion of the E/M policy.

(72) Comment Solicitation on Superficial Radiation Treatment Planning and Management

In the CY 2015 PFS final rule with comment period (79 FR 67666 through 67667), we noted that changes to the CPT prefatory language limited the codes that could be reported when describing services associated with superficial radiation treatment (SRT) delivery, described by CPT code 77401 (radiation treatment delivery, superficial and/or ortho voltage, per day). The changes effectively meant that many other related services were bundled with CPT code 77401, instead of being separately reported. For example, CPT guidance clarified that certain codes used to describe clinical treatment planning, treatment devices, isodose planning, physics consultation, and radiation treatment management cannot be reported when furnished in association with SRT. Stakeholders informed us that these changes to the CPT prefatory language prevented them from billing Medicare for codes that were previously frequently billed with CPT code 77401. We solicited comments as to whether the revised bundled coding for SRT allowed for accurate reporting of the associated services. In the CY 2016 PFS final rule with comment period (80 FR 70955), we noted that the RUC did not review the inputs for SRT procedures, and therefore, did not assess whether changes in valuation were appropriate in light of the bundling of associated services. In addition, we solicited recommendations from stakeholders regarding whether it would be appropriate to add physician work for this service, even though physician work is not included in other radiation treatment services. In the CY 2018 PFS proposed rule (82 FR 34012) and the CY 2018 PFS final rule (82 FR 53082), we noted that the 2016 National Correct

Coding Initiative (NCCI) Policy Manual for Medicare Services states that radiation oncology services may not be separately reported with E/M codes. While this NCCI edit is no longer active stakeholders have stated that MACs have denied claims for E/M services associated with SRT based on the NCCI policy manual language. According to stakeholders, the bundling of SRT with associated services, as well as coding confusion regarding the appropriate use of E/M coding to report associated physician work, meant that practitioners were not being paid appropriately for planning and treatment management associated with furnishing SRT. Due to these concerns regarding reporting of services associated with SRT, in the CY 2018 PFS proposed rule (82 FR 34012 through 34013), we proposed to make separate payment for the professional planning and management associated with SRT using HCPCS code GRRR1 (Superficial radiation treatment planning and management related services, including but not limited to, when performed, clinical treatment planning (for example, 77261, 77262, 77263), therapeutic radiology simulation-aided field setting (for example, 77280, 77285, 77290, 77293), basic radiation dosimetry calculation (for example, 77300), treatment devices (for example, 77332, 77333, 77334), isodose planning (for example, 77306, 77307, 77316, 77317, 77318), radiation treatment management (for example, 77427, 77431, 77432, 77435, 77469, 77470, 77499), and associated E/M per course of treatment). We proposed that this code would describe the range of professional services associated with a course of SRT, including services similar to those not otherwise separately reportable under CPT guidance. Furthermore, we proposed that this code would have included several inputs associated with related professional services such as treatment planning, treatment devices, and treatment management. Many commenters did not support our proposal to make separate payment for HCPCS code GRRR1 for CY 2018, stating that our proposed valuation of HCPCS code GRRR1 would represent a significant payment reduction for the associated services as compared with the list of services that they could previously bill in association with SRT. Commenters voiced concern that the proposed coding would inhibit access to care and discourage the use of SRT as a non-surgical alternative to Mohs surgery. We received comments recommending a variety of potential coding solutions but without a consistent preferred alternative. In the CY 2018 PFS final rule (82 FR 53081–53083), we solicited further comment, and stated that we would continue our dialogue with stakeholders to address appropriate coding and payment for professional services associated with SRT.

Given stakeholder feedback that we have continued to receive following the publication of the CY 2018 PFS final rule, we continue to believe that there are potential coding gaps for SRT-related professional services. We generally rely on the CPT process to determine coding specificity, and we believe that deferring to this process in addressing potential coding gaps is generally preferable. As our previous attempt at designing a coding solution in the CY 2018 PFS proposed rule did not gain stakeholder consensus, and given that there were various, in some cases diverging, suggestions on a coding solution from stakeholders, we did not propose changes relating to SRT coding, SRT-related professional codes, or payment policies for CY 2019. However, we solicited comment on the possibility of creating multiple G-codes specific to services associated with SRT, as was suggested by one stakeholder following the CY 2018 PFS final rule. These codes would be used separately to report services including SRT planning, initial patient simulation visit, treatment device design and construction associated with SRT, SRT management, and medical physics consultation. We solicited comment on whether we should create such G-codes to separately report each of the services described previously, mirroring the coding of other types of radiation treatment delivery. For instance, HCPCS code G6003 (Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: Up to 5 mev) is used to report radiation treatment delivery, while associated professional services are billed with codes such as CPT codes 77427 (Radiation treatment management, 5 treatments), 77261 (Therapeutic radiology treatment planning; simple), 77332 (Treatment devices, design and construction; simple (simple block, simple bolus), and 77300 (Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician).

We stated that we consider contractor pricing such codes for CY 2019 because we believe that the preferable method to develop new coding is with multi-specialty input through the CPT and RUC process, and we prefer to defer nationally pricing such codes pending input from the CPT Editorial Panel and the RUC process to assist in determining the appropriate level of coding specificity for SRT-related professional services. Based on stakeholder feedback, we continue to believe there may be a coding gap for these services, and therefore, we solicited comment on whether we should create these G-codes and allow them to be contractor priced for CY 2019. This would be an interim approach for addressing the potential coding gap until the CPT Editorial Panel and the RUC can address coding for SRT and SRT-related professional services, giving the CPT Editorial Panel and the RUC an opportunity to develop a coding solution that could be addressed in future rulemaking.

The following is a summary of the comments we received on the possibility of creating multiple G-codes specific to services associated with SRT, which could be used separately to report services including SRT planning, initial patient simulation visit, treatment device design and construction associated with SRT, SRT management, and medical physics consultation, which would be contractor priced for CY 2019.

Comment: Many commenters urged CMS to make appropriate payment for SRT-related services, stating that it is a vital non-surgical alternative treatment for skin cancer. Many commenters also said that coding should recognize newer generation, Image Guided Superficial Radiation (IGSRT), stating that IGSRT is the most advanced form of this technology, and has far better outcomes compared to those achieved with SRT.

Some commenters recommended implementation of G-codes for SRT-related professional services, and they submitted alternative G-code scenarios that they believe would be preferable to adopting contractor-priced G-codes. These scenarios include one in which there would be one code for SRT-related treatment planning, with a value based on a crosswalk to CPT code 77261 (Therapeutic radiology treatment planning; simple), a code for SRT treatment device construction, with a value based on a crosswalk to CPT code 77332 (Treatment devices, design and construction; simple (simple block, simple bolus), and a code for SRT treatment management billed once per treatment, valued with a crosswalk to CPT code 99213 (Office or other outpatient visit for the evaluation and management of an established patient,

which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family.). According to this commenter, image guidance and tracking should not be billed with superficial treatments. Another commenter suggested a single code bundling SRT-related treatment management with SRT-related device construction as well as a code for SRT-related radiation treatment management, and a code representing treatment for multiple lesions. This commenter also urged us to either revalue CPT code 77401 or to create an additional G-code billable with CPT code 77401 to represent professional services associated with SRT. Another commenter suggested a code for SRT-related radiology treatment planning, and an SRT management code including five treatments. A commenter suggested a coding structure that recognizes Image-Guided Superficial Radiation Therapy as a newer generation of SRT, and would consist of CPT code 77401 for practitioners that utilize the SRT technologies; relying on human visualization for lesion(s) simulation, treatment and tracking, and a new G-code for providers who provide the newer generation technology relying on image-guided lesion simulation, treatment and tracking per fraction with Record and Verify precision tracking of treatment progress.

A commenter stated that any codes utilized as part of superficial radiation treatment delivery that include medical physics time should require that a qualified medical physicist perform the physics work.

A commenter stated that adopting contractor-priced G codes would be appropriate. Some other commenters, however, did not support our suggested adoption of contractor-priced codes. According to these commenters, we are correct in our belief that there are coding gaps in the current reimbursement structure, however a fuller evaluation that does not defer to Medicare contractors in determining reimbursement rates is appropriate. According to a commenter, contractor pricing creates unnecessary work for the Medicare Administrative Contractors and can also lead to wide variances in the valuing of codes across jurisdictions. Commenters expressed preference that coding for these services be developed through the CPT and RUC processes. Many commenters urged us not to change coding for CY 2019 for these services.

Response: We expect to take these comments into consideration for future rulemaking and we hope to continue a dialogue with stakeholders on these important services. We reiterate that we believe multi-specialty input through the CPT and RUC processes is the ideal way to develop coding specificity and evaluation, and we are not making any changes to payment policy based on this comment solicitation. In the interim, we refer readers to CPT guidance that states that CPT code 77401, when performed, may be reported with appropriate E/M codes, and this is the appropriate way to currently report professional work associated with SRT. Going forward, we will attempt to determine whether MACs are inappropriately denying billing of E/M codes with CPT code 77401, and we will instruct MACs accordingly.

(73) Adaptive Behavior Analysis Services

We note that we intended to assign a contractor price status in the Addendum B file of the proposed rule for the following CPT codes that describe adaptive behavior analysis services: CPT codes 97151, 97152, 97153, 97154, 97155, 97156, 97157, and 97158. These codes are formerly contractor priced Category III CPT codes that were converted to Category I for CY 2019. We inadvertently excluded these codes in the Addendum B file of the proposed rule, and have updated the Addendum B file for this final rule.

BILLING CODE 4120–01–P

TABLE 13: CY 2019 Work RVUs for New, Revised, and Potentially Misvalued Codes

HCPCS	Descriptor	CY 2018 Work RVU	Proposed CY 2019 Work RVU	Final CY 2019 Work RVU	CMS Work Time Refinement
0509T	Electroretinography (ERG) with interpretation and report, pattern (PERG)	NEW	0.40	0.40	No
10004	Fine needle aspiration biopsy; without imaging guidance; each additional lesion	NEW	0.80	0.80	No
10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	NEW	1.46	1.46	No
10006	Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion	NEW	1.00	1.00	No
10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	NEW	1.81	1.81	No
10008	Fine needle aspiration biopsy, including fluoroscopic guidance; each additional lesion	NEW	1.18	1.18	No
10009	Fine needle aspiration biopsy, including CT guidance; first lesion	NEW	2.26	2.26	No
10010	Fine needle aspiration biopsy, including CT guidance; each additional lesion	NEW	1.65	1.65	No
10011	Fine needle aspiration biopsy, including MR guidance; first lesion	NEW	C	C	No
10012	Fine needle aspiration biopsy, including MR guidance; each additional lesion	NEW	C	C	No
10021	Fine needle aspiration biopsy; without imaging guidance; first lesion	1.27	1.03	1.03	No
11102	Tangential biopsy of skin, (eg, shave, scoop, saucerize, curette), single lesion	NEW	0.66	0.66	No
11103	Tangential biopsy of skin, (eg, shave, scoop, saucerize, curette), each separate/additional lesion	NEW	0.29	0.38	No
11104	Punch biopsy of skin, (including simple closure when performed), single lesion	NEW	0.83	0.83	No
11105	Punch biopsy of skin, (including simple closure when performed), each separate/additional lesion	NEW	0.45	0.45	No
11106	Incisional biopsy of skin (eg, wedge), (including simple closure when performed), single lesion	NEW	1.01	1.01	No
11107	Incisional biopsy of skin (eg, wedge), (including simple closure when performed), each separate/additional lesion	NEW	0.54	0.54	No
11755	Biopsy of nail unit (eg, plate, bed, matrix, hyponychium, proximal and lateral nail folds)	1.31	1.08	1.25	No
20551	Injection(s); single tendon origin/insertion	0.75	0.75	0.75	No
20932	Allograft, includes templating, cutting, placement and internal fixation when performed; osteoarticular, including articular surface and contiguous bone	NEW	13.01	13.01	No
20933	Allograft, includes templating, cutting, placement and internal fixation when performed; hemicortical intercalary, partial (ie, hemicylindrical)	NEW	11.94	11.94	No
20934	Allograft, includes templating, cutting, placement and internal fixation when performed;	NEW	13.00	13.00	No

HCPCS	Descriptor	CY 2018 Work RVU	Proposed CY 2019 Work RVU	Final CY 2019 Work RVU	CMS Work Time Refinement
	intercalary, complete (ie, cylindrical)				
27369	Injection procedure for contrast knee arthrography or contrast enhanced CT/MRI knee arthrography	NEW	0.77	0.77	No
29105	Application of long arm splint (shoulder to hand)	0.87	0.80	0.80	No
29540	Strapping; ankle and/or foot	0.39	0.39	0.39	No
29550	Strapping; toes	0.25	0.25	0.25	No
31623	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with brushing or protected brushings	2.63	2.63	2.63	No
31624	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial alveolar lavage	2.63	2.63	2.63	No
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed	NEW	7.80	7.80	No
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular	NEW	8.59	8.59	No
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming	NEW	1.53	1.53	No
33286	Removal, subcutaneous cardiac rhythm monitor	NEW	1.50	1.50	No
33289	Transcatheter implantation of wireless pulmonary artery pressure sensor for long term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed	NEW	6.00	6.00	No
33440	Replacement, aortic valve; by translocation of autologous pulmonary valve and transventricular aortic annulus enlargement of the left ventricular outflow tract with valved conduit replacement of pulmonary valve (Ross-Konno procedure)	NEW	64.00	64.00	No
33866	Aortic hemiarch graft including isolation and control of the arch vessels, beveled open distal aortic anastomosis extending under one or more of the arch vessels, and total circulatory arrest or isolated cerebral perfusion	NEW	19.74	19.74	No
36568	Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, without imaging guidance; younger than 5 years of age	1.67	2.11	2.11	No
36569	Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, without imaging guidance; age 5 years or older	1.70	1.90	1.90	No
36572	Insertion of peripherally inserted central venous	NEW	1.82	1.82	No

HCPCS	Descriptor	CY 2018 Work RVU	Proposed CY 2019 Work RVU	Final CY 2019 Work RVU	CMS Work Time Refinement
	catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; younger than 5 years of age				
36573	Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; age 5 years or older	NEW	1.70	1.70	No
36584	Replacement, complete, of a peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, through same venous access, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the replacement	1.20	1.20	1.20	No
38531	Biopsy or excision of lymph node(s); open, inguinofemoral node(s)	NEW	6.74	6.74	No
38792	Injection procedure; radioactive tracer for identification of sentinel node	0.52	0.65	0.65	No
43762	Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; not requiring revision of gastrostomy tract	NEW	0.75	0.75	No
43763	Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; requiring revision of gastrostomy tract	NEW	1.41	1.41	No
45300	Proctosigmoidoscopy, rigid; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)	0.80	0.80	0.80	No
46500	Injection of sclerosing solution, hemorrhoids	1.42	1.74	1.74	No
49422	Removal of tunneled intraperitoneal catheter	6.29	4.00	4.00	No
50436	Dilation of existing tract, percutaneous, for an endourologic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, as well as post procedure tube placement, when performed;	NEW	2.78	2.78	No
50437	Dilation of existing tract, percutaneous, for an endourologic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, as well as post procedure tube placement, when performed; including new access into the renal collecting system	NEW	4.83	4.85	Yes
52334	Cystourethroscopy with insertion of ureteral guide wire through kidney to establish a percutaneous nephrostomy, retrograde	4.82	3.37	3.37	No

HCPCS	Descriptor	CY 2018 Work RVU	Proposed CY 2019 Work RVU	Final CY 2019 Work RVU	CMS Work Time Refinement
53850	Transurethral destruction of prostate tissue; by microwave thermotherapy	10.08	5.42	5.42	No
53852	Transurethral destruction of prostate tissue; by radiofrequency thermotherapy	10.83	5.93	5.93	No
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy	NEW	5.70	5.93	No
57150	Irrigation of vagina and/or application of medicament for treatment of bacterial, parasitic, or fungoid disease	0.55	0.50	0.50	No
57160	Fitting and insertion of pessary or other intravaginal support device	0.89	0.89	0.89	No
58100	Endometrial sampling (biopsy) with or without endocervical sampling (biopsy), without cervical dilation, any method (separate procedure)	1.53	1.21	1.21	No
58110	Endometrial sampling (biopsy) performed in conjunction with colposcopy	0.77	0.77	0.77	No
64405	Injection, anesthetic agent; greater occipital nerve	0.94	0.94	0.94	No
64455	Injection(s), anesthetic agent and/or steroid, plantar common digital nerve(s) (eg, Morton's neuroma)	0.75	0.75	0.75	No
65205	Removal of foreign body, external eye; conjunctival superficial	0.71	0.49	0.49	No
65210	Removal of foreign body, external eye; conjunctival embedded (includes concretions), subconjunctival, or scleral nonperforating	0.84	0.61	0.61	No
67500	Retrobulbar injection; medication (separate procedure, does not include supply of medication)	1.44	1.18	1.18	No
67505	Retrobulbar injection; alcohol	1.27	0.94	1.18	No
67515	Injection of medication or other substance into Tenon's capsule	1.40	0.75	0.75	No
72020	Radiologic examination, spine, single view, specify level	0.15	0.23	0.15	No
72040	Radiologic examination, spine, cervical; 2 or 3 views	0.22	0.23	0.22	No
72050	Radiologic examination, spine, cervical; 4 or 5 views	0.31	0.23	0.31	No
72052	Radiologic examination, spine, cervical; 6 or more views	0.36	0.23	0.36	No
72070	Radiologic examination, spine; thoracic, 2 views	0.22	0.23	0.22	No
72072	Radiologic examination, spine; thoracic, 3 views	0.22	0.23	0.22	No
72074	Radiologic examination, spine; thoracic, minimum of 4 views	0.22	0.23	0.22	No
72080	Radiologic examination, spine; thoracolumbar junction, minimum of 2 views	0.22	0.23	0.22	No
72100	Radiologic examination, spine, lumbosacral; 2 or 3 views	0.22	0.23	0.22	No
72110	Radiologic examination, spine, lumbosacral; minimum of 4 views	0.31	0.23	0.31	No
72114	Radiologic examination, spine, lumbosacral;	0.32	0.23	0.32	No

HCPCS	Descriptor	CY 2018 Work RVU	Proposed CY 2019 Work RVU	Final CY 2019 Work RVU	CMS Work Time Refinement
	complete, including bending views, minimum of 6 views				
72120	Radiologic examination, spine, lumbosacral; bending views only, 2 or 3 views	0.22	0.23	0.22	No
72200	Radiologic examination, sacroiliac joints; less than 3 views	0.17	0.23	0.17	No
72202	Radiologic examination, sacroiliac joints; 3 or more views	0.19	0.23	0.19	No
72220	Radiologic examination, sacrum and coccyx, minimum of 2 views	0.17	0.23	0.17	No
73070	Radiologic examination, elbow; 2 views	0.15	0.23	0.15	No
73080	Radiologic examination, elbow; complete, minimum of 3 views	0.17	0.23	0.17	No
73090	Radiologic examination; forearm, 2 views	0.16	0.23	0.16	No
73650	Radiologic examination; calcaneus, minimum of 2 views	0.16	0.23	0.16	No
73660	Radiologic examination; toe(s), minimum of 2 views	0.13	0.23	0.13	No
74210	Radiologic examination; pharynx and/or cervical esophagus	0.36	0.59	0.59	No
74220	Radiologic examination; esophagus	0.46	0.67	0.67	No
74230	Swallowing function, with cineradiography/videoradiography	0.53	0.53	0.53	No
74420	Urography, retrograde, with or without KUB	0.36	0.52	0.52	No
74485	Dilation of ureter(s) or urethra, radiological supervision and interpretation	0.54	0.83	0.83	No
76000	Fluoroscopy (separate procedure), up to 1 hour physician or other qualified health care professional time, other than 71023 or 71034 (eg, cardiac fluoroscopy)	0.17	0.30	0.30	No
76391	Magnetic resonance (e.g., vibration) elastography	NEW	1.10	1.10	No
76514	Ophthalmic ultrasound, diagnostic; corneal pachymetry, unilateral or bilateral (determination of corneal thickness)	0.17	0.14	0.14	No
76870	Ultrasound, scrotum and contents	0.64	0.64	0.64	No
76942	Ultrasonic guidance for needle placement (eg, biopsy, fine needle aspiration biopsy, injection, localization device), imaging supervision and interpretation	0.67	0.67	0.67	No
76978	Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); initial lesion	NEW	1.27	1.62	No
76979	Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); each additional lesion with separate injection	NEW	0.85	0.85	No
76981	Ultrasound, elastography; parenchyma (eg, organ)	NEW	0.59	0.59	No
76982	Ultrasound, elastography; first target lesion	NEW	0.59	0.59	No
76983	Ultrasound, elastography; each additional target lesion	NEW	0.50	0.50	No

HCPCS	Descriptor	CY 2018 Work RVU	Proposed CY 2019 Work RVU	Final CY 2019 Work RVU	CMS Work Time Refinement
77012	Computed tomography guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation	1.16	1.50	1.50	No
77021	Magnetic resonance guidance for needle placement (eg, for biopsy, fine needle aspiration biopsy, injection, or placement of localization device) radiological supervision and interpretation	1.50	1.50	1.50	No
77046	Magnetic resonance imaging, breast, without contrast material; unilateral	NEW	1.15	1.45	No
77047	Magnetic resonance imaging, breast, without contrast material; bilateral	NEW	1.30	1.60	No
77048	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD- real time lesion detection, characterization and pharmacokinetic analysis) when performed; unilateral	NEW	1.80	2.10	No
77049	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD- real time lesion detection, characterization and pharmacokinetic analysis) when performed; bilateral	NEW	2.00	2.30	No
77081	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)	0.22	0.20	0.20	No
85060	Blood smear, peripheral, interpretation by physician with written report	0.45	0.36	0.45	No
85097	Bone marrow, smear interpretation	0.94	0.94	0.94	No
85390	Fibrinolysins or coagulopathy screen, interpretation and report	0.37	0.75	0.75	No
92273	Electroretinography (ERG) with interpretation and report; full field (eg, ffERG, flash ERG, Ganzfeld ERG)	NEW	0.69	0.69	No
92274	Electroretinography (ERG) with interpretation and report; multifocal (mfERG)	NEW	0.61	0.61	No
93264	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional	NEW	0.70	0.70	No
93561	Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; with cardiac output measurement	0.25	0.60	0.95	No
93562	Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; subsequent measurement of	0.01	0.48	0.77	No

HCPCS	Descriptor	CY 2018 Work RVU	Proposed CY 2019 Work RVU	Final CY 2019 Work RVU	CMS Work Time Refinement
	cardiac output				
93571	Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel	1.80	1.38	1.38	No
93572	Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; each additional vessel	1.44	1.00	1.00	No
93668	Peripheral arterial disease (PAD) rehabilitation, per session	0.00	0.00	0.00	No
95800	Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (eg, by airflow or peripheral arterial tone), and sleep time	1.05	0.85	0.85	No
95801	Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and / respiratory analysis (eg, by airflow or peripheral arterial tone)	1.00	0.85	0.85	No
95806	Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (eg, thoracoabdominal movement)	1.25	0.93	0.93	No
95836	Electrocorticogram from an implanted brain neurostimulator pulse generator/transmitter, including recording, with interpretation and report, up to 30 days	NEW	1.98	1.98	No
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve neurostimulator pulse generator/transmitter, without programming	0.45	0.35	0.35	No
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	NEW	0.73	0.73	No

HCPCS	Descriptor	CY 2018 Work RVU	Proposed CY 2019 Work RVU	Final CY 2019 Work RVU	CMS Work Time Refinement
95977	95X84 Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	NEW	0.97	0.97	No
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator /transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional	NEW	0.91	0.91	No
95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional	NEW	0.80	0.80	No
96105	Assessment of aphasia (includes assessment of expressive and receptive speech and language function, language comprehension, speech production ability, reading, spelling, writing, eg, by boston diagnostic aphasia examination) with interpretation and report, per hour	1.75	1.75	1.75	No
96110	Developmental screening (eg, developmental milestone survey, speech and language delay screen) with scoring and documentation, per standardized instrument	0.00	0.00	0.00	No
96112	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or	NEW	2.56	2.56	No

HCPCS	Descriptor	CY 2018 Work RVU	Proposed CY 2019 Work RVU	Final CY 2019 Work RVU	CMS Work Time Refinement
	other qualified health care professional, with interpretation and report; first hour				
96113	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; each additional 30 minutes	NEW	1.16	1.16	No
96116	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; first hour	1.86	1.86	1.86	No
96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour	NEW	1.71	1.71	No
96125	Standardized cognitive performance testing (eg, ross information processing assessment) per hour of a qualified health care professional's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report	1.70	1.70	1.70	No
96127	96127 Brief emotional/behavioral assessment (eg, depression inventory, attention-deficit/hyperactivity disorder [ADHD] scale), with scoring and documentation, per standardized instrument	0.00	0.00	0.00	No
96130	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour	NEW	2.56	2.56	No
96131	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or	NEW	1.96	1.96	No

HCPCS	Descriptor	CY 2018 Work RVU	Proposed CY 2019 Work RVU	Final CY 2019 Work RVU	CMS Work Time Refinement
	caregiver(s), when performed; each additional hour				
96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour	NEW	2.56	2.56	No
96133	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour	NEW	1.96	1.96	No
96136	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method, first 30 minutes	NEW	0.55	0.55	No
96137	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method, each additional 30 minutes	NEW	0.46	0.46	No
96138	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes	NEW	0.00	0.00	No
96139	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes	NEW	0.00	0.00	No
96146	Psychological or neuropsychological test administration, with single automated instrument via electronic platform, with automated result only	NEW	0.00	0.00	No
97151	Behavior identification assessment, administered by a physician or other qualified health care professional, each 15 minutes of the physician's or other qualified health care professional's time face-to-face with patient and/or guardian(s)/caregiver(s) administering assessments and discussing findings and recommendations, and non-face-to-face analyzing past data, scoring/interpreting the assessment, and preparing the report/treatment plan	NEW	-	C	No
97152	Behavior identification-supporting assessment, administered by one technician under the direction of a physician or other qualified health care professional, face-to-face with the patient,	NEW	-	C	No

HCPCS	Descriptor	CY 2018 Work RVU	Proposed CY 2019 Work RVU	Final CY 2019 Work RVU	CMS Work Time Refinement
	each 15 minutes				
97153	Adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with one patient, each 15 minutes	NEW	-	C	No
97154	Group adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with two or more patients, each 15 minutes	NEW	-	C	No
97155	Adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, which may include simultaneous direction of technician, face-to-face with one patient, each 15 minutes	NEW	-	C	No
97156	Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (with or without the patient present), face-to-face with guardian(s)/caregiver(s), each 15 minutes	NEW	-	C	No
97157	Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes	NEW	-	C	No
97158	Group adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, face-to-face with multiple patients, each 15 minutes	NEW	-	C	No
99201	Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family.	0.48	0.48	0.48	No
99202	Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the	0.93	1.90	0.93	No

HCPCS	Descriptor	CY 2018 Work RVU	Proposed CY 2019 Work RVU	Final CY 2019 Work RVU	CMS Work Time Refinement
	problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 20 minutes are spent face-to-face with the patient and/or family.				
99203	Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family.	1.42	1.90	1.42	No
99204	Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family.	2.43	1.90	2.43	No
99205	Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family.	3.17	1.90	3.17	No
99211	Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services.	0.18	0.18	0.18	No
99212	Office or other outpatient visit for the evaluation	0.48	1.22	0.48	No

HCPCS	Descriptor	CY 2018 Work RVU	Proposed CY 2019 Work RVU	Final CY 2019 Work RVU	CMS Work Time Refinement
	and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family.				
99213	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family.	0.97	1.22	0.97	No
99214	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 25 minutes are spent face-to-face with the patient and/or family.	1.50	1.22	1.50	No
99215	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or	2.11	1.22	2.11	No

HCPCS	Descriptor	CY 2018 Work RVU	Proposed CY 2019 Work RVU	Final CY 2019 Work RVU	CMS Work Time Refinement
	family.				
99446	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified healthcare professional; 5-10 minutes of medical consultative discussion and review	B	0.35	0.35	No
99447	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified healthcare professional; 11-20 minutes of medical consultative discussion and review	B	0.70	0.70	No
99448	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified healthcare professional; 21-30 minutes of medical consultative discussion and review	B	1.05	1.05	No
99449	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified healthcare professional; 31 minutes or more of medical consultative discussion and review	B	1.40	1.40	No
99451	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 or more minutes of medical consultative time	NEW	0.50	0.70	No
99452	Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes	NEW	0.50	0.70	No
99453	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment	NEW	0.00	0.00	No
99454	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days	NEW	0.00	0.00	No
99457	Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare	NEW	0.61	0.61	No

HCPCS	Descriptor	CY 2018 Work RVU	Proposed CY 2019 Work RVU	Final CY 2019 Work RVU	CMS Work Time Refinement
	professional time in a calendar month requiring interactive communication with the patient/caregiver during the month				
99491	CCM provided personally by a physician / QHP	NEW	1.22	1.45	No
G0108	Diabetes outpatient self-management training services, individual, per 30 minutes	0.90	0.90	0.90	No
G0109	Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes	0.25	0.25	0.25	No
G0166	External counterpulsation, per treatment session	0.07	0.00	0.00	No
G0168	Wound closure utilizing tissue adhesive(s) only	0.45	0.31	0.31	No
G0268	Removal of impacted cerumen (one or both ears) by physician on same date of service as audiologic function testing	0.61	0.61	0.61	No
G2010	Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment	NEW	0.18	0.18	No
G2011	Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., audit, dast), and brief intervention, 5-14 minutes	NEW	0.33	0.33	No
G2012	Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion	NEW	0.25	0.25	No

TABLE 14: CY 2019 Direct PE Refinements

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
10005	Fna bx w/us gdn 1st les	EF015	mayo stand	NF		37	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
10005	Fna bx w/us gdn 1st les	EF023	table, exam	NF		37	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
10005	Fna bx w/us gdn 1st les	EQ250	ultrasound unit, portable	NF		37	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.26
10007	Fna bx w/fluor gdn 1st les	ED050	Technologist PACS workstation	NF		49	47	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.04
10007	Fna bx w/fluor gdn 1st les	EF015	mayo stand	NF		44	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
10007	Fna bx w/fluor gdn 1st les	EL014	room, radiographic-fluoroscopic	NF		44	34	E2: Refined equipment time to conform to established policies for highly technical equipment	-16.87
10009	Fna bx w/ct gdn 1st les	EF015	mayo stand	NF		52	50	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
10021	Fna bx w/o img gdn 1st les	EF015	mayo stand	NF		29	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
10021	Fna bx w/o img gdn 1st les	EF023	table, exam	NF		29	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
11102	Tangntl bx skin single les	EF015	mayo stand	NF		13	11	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
11102	Tangntl bx skin single les	EF031	table, power	NF		13	11	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
11102	Tangntl bx skin single les	EQ168	light, exam	NF		13	11	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
11102	Tangntl bx skin single les	L037D	RN/LPN/MTA	NF	Review home care instructions, coordinate visits/prescri ptions	2	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-0.74
11102	Tangntl bx skin single les	SB027	gown, staff, impervious	NF		2	1	S1: Duplicative; supply is included in SA043	-1.19
11102	Tangntl bx skin single les	SB034	mask, surgical, with face shield	NF		2	1	S1: Duplicative; supply is included in SA043	-1.22
11104	Punch bx skin single lesion	EF015	mayo stand	NF		19	17	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
11104	Punch bx skin single lesion	EF031	table, power	NF		19	17	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03
11104	Punch bx skin single lesion	EQ114	electrosurgical generator, up to 120 watts	NF		19	17	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.02
11104	Punch bx skin single lesion	EQ168	light, exam	NF		19	17	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
11104	Punch bx skin single lesion	EQ351	Smoke Evacuator(tubing, covering, etc.) with stand	NF		19	17	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
11104	Punch bx skin single lesion	L037D	RN/LPN/MTA	NF	Review home care instructions, coordinate visits/prescri ptions	2	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-0.74

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
11104	Punch bx skin single lesion	SB027	gown, staff, impervious	NF		2	1	S1: Duplicative; supply is included in SA043	-1.19
11104	Punch bx skin single lesion	SB034	mask, surgical, with face shield	NF		2	1	S1: Duplicative; supply is included in SA043	-1.22
11106	Incal bx skn single les	EF015	mayo stand	NF		33	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
11106	Incal bx skn single les	EF031	table, power	NF		33	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03
11106	Incal bx skn single les	EQ114	electrosurgical generator, up to 120 watts	NF		33	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.02
11106	Incal bx skn single les	EQ168	light, exam	NF		33	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
11106	Incal bx skn single les	EQ351	Smoke Evacuator(tubing, covering, etc.) with stand	NF		33	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
11106	Incal bx skn single les	L037D	RN/LPN/MTA	NF	Review home care instructions, coordinate visits/prescri ptions	2	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-0.74
11106	Incal bx skn single les	SB027	gown, staff, impervious	NF		2	1	S1: Duplicative; supply is included in SA043	-1.19
11106	Incal bx skn single les	SB034	mask, surgical, with face shield	NF		2	1	S1: Duplicative; supply is included in SA043	-1.22
11755	Biopsy nail unit	EF015	mayo stand	NF		29	25	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
11755	Biopsy nail unit	EF031	table, power	NF		29	25	E1: Refined equipment time to conform to established policies for non-highly	-0.06

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
								technical equipment	
11755	Biopsy nail unit	EQ137	instrument pack, basic ($500-$1499)	NF		39	31	E5: Refined equipment time to conform to established policies for surgical instrument packs	-0.02
11755	Biopsy nail unit	EQ168	light, exam	NF		29	25	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.02
20551	Inj tendon origin/insertion	EF023	table, exam	NF		19	15	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.02
20551	Inj tendon origin/insertion	L037D	RN/LPN/MTA	NF	Review home care instructions, coordinate visits/prescri ptions	2	1	G1: See preamble text	-0.37
20551	Inj tendon origin/insertion	L037D	RN/LPN/MTA	NF	Provide education/ob tain consent	3	1	G1: See preamble text	-0.74
27369	Njx cntrst kne arthg/ct/mri	EL014	room, radiographic-fluoroscopic	NF		22	23	E15: Refined equipment time to conform to changes in clinical labor time	1.69
27369	Njx cntrst kne arthg/ct/mri	L041B	Radiologic Technologist	NF	Scan exam documents into PACS. Complete exam in RIS system to populate images into work queue.	1	0	G1: See preamble text	-0.41
27369	Njx cntrst kne arthg/ct/mri	L041B	Radiologic Technologist	NF	Prepare room, equipment and supplies	2	3	G1: See preamble text	0.41

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
27369	Njx cntrst kne arthg/ct/mri	L041B	Radiologic Technologist	NF	Confirm order, protocol exam	1	0	G1: See preamble text	-0.41
29105	Apply long arm splint	EF031	table, power	NF		51	49	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03
29105	Apply long arm splint	EQ080	cast cart	NF		51	49	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.02
29105	Apply long arm splint	EQ081	cast cutter	NF		51	49	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
29105	Apply long arm splint	EQ082	cast vacuum	NF		51	49	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
29540	Strapping of ankle and/or ft	EF031	table, power	NF		20	17	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.05
29540	Strapping of ankle and/or ft	EQ168	light, exam	NF		20	17	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
29540	Strapping of ankle and/or ft	L037D	RN/LPN/MTA	NF	Review home care instructions, coordinate visits/prescri ptions	2	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-0.74
29540	Strapping of ankle and/or ft	L037D	RN/LPN/MTA	NF	Provide education/ob tain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
29550	Strapping of toes	EF031	table, power	NF		16	13	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.05
29550	Strapping of toes	EQ168	light, exam	NF		16	13	E1: Refined equipment time to conform	-0.01

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
								to established policies for non-highly technical equipment	
29550	Strapping of toes	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
29550	Strapping of toes	L037D	RN/LPN/MTA	NF	Review home care instructions, coordinate visits/prescriptions	2	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-0.74
31623	Dx bronchoscope/brush	EF031	table, power	NF		44	51	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.11
31623	Dx bronchoscope/brush	EQ004	CO2 respiratory profile monitor	NF		34	51	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.39
31623	Dx bronchoscope/brush	EQ235	suction machine (Gomco)	NF		34	51	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.03
31623	Dx bronchoscope/brush	ES017	fiberscope, flexible, bronchoscopy	NF		74	69	E4: Refined equipment time to conform to established policies for scopes	-0.43
31623	Dx bronchoscope/brush	ES031	scope video system (monitor, processor, digital capture, cart, printer, LED light)	NF		44	42	E19: Refined equipment time to conform to established policies for scope accessories	-0.28
31623	Dx bronchoscope/brush	L047C	RN/Respiratory Therapist	NF	Complete post-procedure diagnostic forms, lab and x-ray requisitions	4	2	L1: Refined time to standard for this clinical labor task	-0.94

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
31624	Dx bronchoscope/lavage	EF031	table, power	NF		44	51	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.11
31624	Dx bronchoscope/lavage	EQ004	CO2 respiratory profile monitor	NF		34	51	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.39
31624	Dx bronchoscope/lavage	EQ235	suction machine (Gomco)	NF		34	51	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.03
31624	Dx bronchoscope/lavage	ES017	fiberscope, flexible, bronchoscopy	NF		74	69	E4: Refined equipment time to conform to established policies for scopes	-0.43
31624	Dx bronchoscope/lavage	ES031	scope video system (monitor, processor, digital capture, cart, printer, LED light)	NF		44	42	E19: Refined equipment time to conform to established policies for scope accessories	-0.28
31624	Dx bronchoscope/lavage	L047C	RN/Respiratory Therapist	NF	Complete post-procedure diagnostic forms, lab and x-ray requisitions	4	2	L1: Refined time to standard for this clinical labor task	-0.94
33440	Rplcmt a-valve tlcj autol pv	L051A	RN	F	Perform regulatory mandated quality assurance activity (pre-service)	0	15	G1: See preamble text	7.65
33440	Rplcmt a-valve tlcj autol pv	L051A	RN	F	Provide pre-service education/obtain consent	26	20	L1: Refined time to standard for this clinical labor task	-3.06

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
33440	Rplcmt a-valve tlcj autol pv	L051A	RN	F	Schedule space and equipment in facility	12	8	L1: Refined time to standard for this clinical labor task	-2.04
33440	Rplcmt a-valve tlcj autol pv	L051A	RN	F	Coordinate pre-surgery services (including test results)	25	20	L1: Refined time to standard for this clinical labor task	-2.55
38792	Ra tracer id of sentinl node	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		18	19	E15: Refined equipment time to conform to changes in clinical labor time	0.05
38792	Ra tracer id of sentinl node	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		18	19	E15: Refined equipment time to conform to changes in clinical labor time	0.00
38792	Ra tracer id of sentinl node	ER027	dose calibrator (Atomlab)	NF		18	19	E15: Refined equipment time to conform to changes in clinical labor time	0.03
38792	Ra tracer id of sentinl node	ER033	gamma counter, automatic	NF		18	19	E15: Refined equipment time to conform to changes in clinical labor time	0.07
38792	Ra tracer id of sentinl node	ER053	radiation L-block tabletop shield	NF		18	19	E15: Refined equipment time to conform to changes in clinical labor time	0.00
38792	Ra tracer id of sentinl node	ER054	radiation survey meter	NF		18	19	E15: Refined equipment time to conform to changes in clinical labor time	0.00
38792	Ra tracer id of sentinl node	ER058	safe, storage, lead-lined	NF		18	19	E15: Refined equipment time to conform to changes in clinical labor time	0.01
38792	Ra tracer id of sentinl node	L049A	Nuclear Medicine Technologist	NF	Prepare room, equipment and supplies	2	3	G1: See preamble text	0.62
38792	Ra tracer id of sentinl node	L049A	Nuclear Medicine Technologist	NF	Confirm order,	1	0	G1: See preamble text	-0.62

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
					protocol exam				
43762	Rplc gtube no revj trc	EF023	table, exam	NF		22	23	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
43763	Rplc gtube revj gstrst trc	EF014	light, surgical	NF		34	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.01
43763	Rplc gtube revj gstrst trc	EF015	mayo stand	NF		34	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
43763	Rplc gtube revj gstrst trc	EF031	table, power	NF		34	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.02
45300	Proctosigmoidoscopy dx	EF031	table, power	NF		30	28	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03
45300	Proctosigmoidoscopy dx	EQ235	suction machine (Gomco)	NF		30	28	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
45300	Proctosigmoidoscopy dx	ES003	cart, endoscopy imaging equipment	NF		30	28	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.02
45300	Proctosigmoidoscopy dx	ES012	endoscope, rigid, sigmoidoscopy	NF		40	34	E4: Refined equipment time to conform to established policies for scopes	-0.03
46500	Injection into hemorrhoid(s)	ES002	anoscope with light source	NF		75	72	E4: Refined equipment time to conform to established policies for scopes	-0.09
46500	Injection into hemorrhoid(s)	L037D	RN/LPN/MTA	NF	Review home care instructions, coordinate visits/prescriptions	2	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-0.74
52334	Create passage to kidney	L041B	Radiologic Technologist	F	Confirm availability	2	0	G1: See preamble text	-0.82

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
					of prior images/studies				
58100	Biopsy of uterus lining	EF031	table, power	NF		26	22	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.06
58100	Biopsy of uterus lining	EQ168	light, exam	NF		26	22	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.02
58100	Biopsy of uterus lining	L037D	RN/LPN/MTA	NF	Review/read post-procedure x-ray, lab and pathology reports	2	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-0.74
64405	N block inj occipital	EF023	table, exam	NF		18	16	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
64455	N block inj plantar digit	EF023	table, exam	NF		19	17	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.01
72020	X-ray exam of spine 1 view	EL012	room, basic radiology	NF		10	8	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72040	X-ray exam neck spine 2-3 vw	EL012	room, basic radiology	NF		18	16	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72050	X-ray exam neck spine 4/5vws	EL012	room, basic radiology	NF		24	22	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72052	X-ray exam neck spine 6/>vws	EL012	room, basic radiology	NF		30	28	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72070	X-ray exam thorac spine 2vws	EL012	room, basic radiology	NF		15	13	E2: Refined equipment time to conform to established policies for highly	-1.19

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
								technical equipment	
72072	X-ray exam thorac spine 3vws	EL012	room, basic radiology	NF		18	16	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72074	X-ray exam thorac spine4/>vw	EL012	room, basic radiology	NF		21	19	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72080	X-ray exam thoracolmb 2/> vw	EL012	room, basic radiology	NF		15	13	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72100	X-ray exam l-s spine 2/3 vws	EL012	room, basic radiology	NF		18	16	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72110	X-ray exam l-2 spine 4/>vws	EL012	room, basic radiology	NF		24	22	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72114	X-ray exam l-s spine bending	EL012	room, basic radiology	NF		30	28	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72120	X-ray bend only l-s spine	EL012	room, basic radiology	NF		20	18	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72120	X-ray bend only l-s spine	SB026	gown, patient	NF		0	1	S5: Refined supply quantity to conform with other codes in the family	0.55
72200	X-ray exam si joints	EL012	room, basic radiology	NF		15	13	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72202	X-ray exam si joints 3/> vws	EL012	room, basic radiology	NF		18	16	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
72220	X-ray exam sacrum tailbone	EL012	room, basic radiology	NF		15	13	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
73070	X-ray exam of elbow	EL012	room, basic radiology	NF		13	11	E2: Refined equipment time to conform to established policies for highly	-1.19

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
								technical equipment	
73080	X-ray exam of elbow	EL012	room, basic radiology	NF		15	13	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
73090	X-ray exam of forearm	EL012	room, basic radiology	NF		13	11	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
73650	X-ray exam of heel	EL012	room, basic radiology	NF		13	11	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
73660	X-ray exam of toe(s)	EL012	room, basic radiology	NF		15	13	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
74210	Contrst x-ray exam of throat	EL014	room, radiographic-fluoroscopic	NF		22	20	E2: Refined equipment time to conform to established policies for highly technical equipment	-3.37
74220	Contrast x-ray esophagus	EL014	room, radiographic-fluoroscopic	NF		22	20	E2: Refined equipment time to conform to established policies for highly technical equipment	-3.37
74230	Cine/vid x-ray throat/esoph	EF008	chair with headrest, exam, reclining	NF		28	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.02
74230	Cine/vid x-ray throat/esoph	EL014	room, radiographic-fluoroscopic	NF		28	26	E2: Refined equipment time to conform to established policies for highly technical equipment	-3.37
74420	Contrst x-ray urinary tract	ED050	Technologist PACS workstation	NF		39	38	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
74420	Contrst x-ray urinary tract	ED053	Professional PACS Workstation	NF		20	18	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.12
74420	Contrst x-ray urinary tract	EL012	room, basic radiology	NF		35	33	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.19
74420	Contrst x-ray urinary tract	L041B	Radiologic Technologist	NF	Confirm order,	1	0	G1: See preamble text	-0.41

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
					protocol exam				
76000	Fluoroscopy <1 hr phys/qhp	ER031	fluoroscopic system, mobile C-Arm	NF		19	17	E2: Refined equipment time to conform to established policies for highly technical equipment	-0.51
76391	Mr elastography	ED050	Technologist PACS workstation	NF		52	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.04
76391	Mr elastography	EL008	room, MR	NF		38	36	E15: Refined equipment time to conform to changes in clinical labor time	-6.71
76391	Mr elastography	EL050	MR Elastography Package	NF		38	36	E15: Refined equipment time to conform to changes in clinical labor time	-0.84
76391	Mr elastography	L047A	MRI Technologist	NF	Prepare room, equipment and supplies	6	5	L1: Refined time to standard for this clinical labor task	-0.47
76391	Mr elastography	L047A	MRI Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	4	3	L1: Refined time to standard for this clinical labor task	-0.47
76870	Us exam scrotum	ED050	Technologist PACS workstation	NF		39	36	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.07
76870	Us exam scrotum	EL015	room, ultrasound, general	NF		29	28	E2: Refined equipment time to conform to established policies for highly technical equipment	-1.40
76870	Us exam scrotum	L051B	RN/Diagnostic Medical Sonographer	NF	Confirm order, protocol exam	1	0	G1: See preamble text	-0.51
76870	Us exam scrotum	L051B	RN/Diagnostic Medical Sonographer	NF	Prepare room, equipment	2	3	G1: See preamble text	0.51

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
					and supplies				
76978	Us trgt dyn mbubb 1st les	SL180	phosphate buffered saline (PBS)	NF		50	0	G1: See preamble text	-1.07
76979	Us trgt dyn mbubb ea addl	SL180	phosphate buffered saline (PBS)	NF		50	0	G1: See preamble text	-1.07
77012	Ct scan for needle biopsy	ED050	Technologist PACS workstation	NF		32	33	E18: Refined equipment time to conform to established policies for PACS Workstations	0.02
77012	Ct scan for needle biopsy	EL007	room, CT	NF		28	9	G1: See preamble text	-95.06
77012	Ct scan for needle biopsy	L041B	Radiologic Technologist	NF	Confirm order, protocol exam	1	0	G1: See preamble text	-0.41
77012	Ct scan for needle biopsy	L041B	Radiologic Technologist	NF	Prepare room, equipment and supplies	2	3	G1: See preamble text	0.41
77021	Mri guidance ndl plmt rs&i	ED050	Technologist PACS workstation	NF		62	65	E18: Refined equipment time to conform to established policies for PACS Workstations	0.07
77021	Mri guidance ndl plmt rs&i	L047A	MRI Technologist	NF	Prepare room, equipment and supplies	2	3	G1: See preamble text	0.47
77021	Mri guidance ndl plmt rs&i	L047A	MRI Technologist	NF	Confirm order, protocol exam	1	0	G1: See preamble text	-0.47
77046	Mri breast c-unilateral	ED050	Technologist PACS workstation	NF		55	51	E15: Refined equipment time to conform to changes in clinical labor time	-0.09
77046	Mri breast c-unilateral	EL008	room, MR	NF		43	36	E2: Refined equipment time to conform to established policies for highly technical equipment	-23.48

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
77046	Mri breast c-unilateral	EQ388	Breast coil	NF		43	36	E2: Refined equipment time to conform to established policies for highly technical equipment	-2.21
77046	Mri breast c-unilateral	L047A	MRI Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	7	3	G1: See preamble text	-1.88
77047	Mri breast c-bilateral	ED050	Technologist PACS workstation	NF		55	51	E15: Refined equipment time to conform to changes in clinical labor time	-0.09
77047	Mri breast c-bilateral	EL008	room, MR	NF		43	36	E2: Refined equipment time to conform to established policies for highly technical equipment	-23.48
77047	Mri breast c-bilateral	EQ388	Breast coil	NF		43	36	E2: Refined equipment time to conform to established policies for highly technical equipment	-2.21
77047	Mri breast c-bilateral	L047A	MRI Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	7	3	G1: See preamble text	-1.88
77048	Mri breast c-+ w/cad uni	ED050	Technologist PACS workstation	NF		79	75	E15: Refined equipment time to conform to changes in clinical labor time	-0.09
77048	Mri breast c-+ w/cad uni	ED056	CAD Workstation (CPU + Color Monitor)	NF		79	75	E15: Refined equipment time to conform to changes in clinical labor time	-0.19
77048	Mri breast c-+ w/cad uni	ED058	CAD Software	NF		79	75	E15: Refined equipment time to conform to changes in clinical labor time	-0.67
77048	Mri breast c-+ w/cad uni	EL008	room, MR	NF		62	55	E2: Refined equipment time to conform to established policies for highly technical equipment	-23.48

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
77048	Mri breast c-+ w/cad uni	EQ388	Breast coil	NF		62	55	E2: Refined equipment time to conform to established policies for highly technical equipment	-2.21
77048	Mri breast c-+ w/cad uni	L047A	MRI Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	9	5	G1: See preamble text	-1.88
77049	Mri breast c-+ w/cad bi	ED050	Technologist PACS workstation	NF		79	75	E15: Refined equipment time to conform to changes in clinical labor time	-0.09
77049	Mri breast c-+ w/cad bi	ED056	CAD Workstation (CPU + Color Monitor)	NF		79	75	E15: Refined equipment time to conform to changes in clinical labor time	-0.19
77049	Mri breast c-+ w/cad bi	ED058	CAD Software	NF		79	75	E15: Refined equipment time to conform to changes in clinical labor time	-0.67
77049	Mri breast c-+ w/cad bi	EL008	room, MR	NF		62	55	E2: Refined equipment time to conform to established policies for highly technical equipment	-23.48
77049	Mri breast c-+ w/cad bi	EQ388	Breast coil	NF		62	55	E2: Refined equipment time to conform to established policies for highly technical equipment	-2.21
77049	Mri breast c-+ w/cad bi	L047A	MRI Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	9	5	G1: See preamble text	-1.88
85097	Bone marrow interpretation	L030A	Lab Tech/MTA	NF	File specimen, supplies, and other materials	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.30

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
85097	Bone marrow interpretation	L030A	Lab Tech/MTA	NF	Accession and enter information	4	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-1.20
92273	Full field erg w/i&r	EQ390	mfERG and ffERG electrodiagnostic unit	NF		74	71	E15: Refined equipment time to conform to changes in clinical labor time	-0.94
92273	Full field erg w/i&r	EQ391	Contact lens electrode for mfERG and ffERG	NF		79	72	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
92273	Full field erg w/i&r	EQ391	Contact lens electrode for mfERG and ffERG	NF		79	72	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
92273	Full field erg w/i&r	L038A	COMT/COT/RN/CST	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-1.14
92273	Full field erg w/i&r	L038A	COMT/COT/RN/CST	NF	Technologist QC's images in PACS, checking for all images, reformats, and dose page	10	3	L1: Refined time to standard for this clinical labor task	-2.66
92273	Full field erg w/i&r	L038A	COMT/COT/RN/CST	NF	Confirm order, protocol exam	1	0	G1: See preamble text	-0.38
92273	Full field erg	L038A	COMT/COT/RN/C	NF	Clean	12	8	G1: See preamble text	-1.52

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	w/i&r		ST		room/equip ment by clinical staff				
92273	Full field erg w/i&r	L038A	COMT/COT/RN/C ST	NF	Review examination with interpreting MD/DO	5	2	L1: Refined time to standard for this clinical labor task	-1.14
92273	Full field erg w/i&r	L038A	COMT/COT/RN/C ST	F	Coordinate pre-surgery services (including test results)	3	0	G4: This input is not applicable in the facility setting	-1.14
92273	Full field erg w/i&r	L038A	COMT/COT/RN/C ST	F	Complete pre-service diagnostic and referral forms	3	0	G4: This input is not applicable in the facility setting	-1.14
92273	Full field erg w/i&r	L038A	COMT/COT/RN/C ST	F	Schedule space and equipment in facility	3	0	G4: This input is not applicable in the facility setting	-1.14
92273	Full field erg w/i&r	L038A	COMT/COT/RN/C ST	F	Complete pre-procedure phone calls and prescription	1	0	G4: This input is not applicable in the facility setting	-0.38
92273	Full field erg w/i&r	L038A	COMT/COT/RN/C ST	NF	Prepare room, equipment and supplies	2	3	G1: See preamble text	0.38
92274	Multifocal erg w/i&r	EQ390	mfERG and ffERG electrodiagnostic unit	NF		50	47	E15: Refined equipment time to conform to changes in clinical labor time	-0.94

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
92274	Multifocal erg w/i&r	EQ391	Contact lens electrode for mfERG and ffERG	NF		55	48	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
92274	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	NF	Technologist QC's images in PACS, checking for all images, reformats, and dose page	10	3	L1: Refined time to standard for this clinical labor task	-2.66
92274	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-1.14
92274	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	NF	Prepare room, equipment and supplies	2	3	G1: See preamble text	0.38
92274	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	NF	Confirm order, protocol exam	1	0	G1: See preamble text	-0.38
92274	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	NF	Clean room/equipment by clinical staff	12	8	G1: See preamble text	-1.52
92274	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	NF	Review examination	5	2	L1: Refined time to standard for this clinical labor task	-1.14

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
					with interpreting MD/DO				
92274	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	F	Coordinate pre-surgery services (including test results)	3	0	G4: This input is not applicable in the facility setting	-1.14
92274	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	F	Schedule space and equipment in facility	3	0	G4: This input is not applicable in the facility setting	-1.14
92274	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	F	Complete pre-service diagnostic and referral forms	3	0	G4: This input is not applicable in the facility setting	-1.14
92274	Multifocal erg w/i&r	L038A	COMT/COT/RN/CST	F	Complete pre-procedure phone calls and prescription	1	0	G4: This input is not applicable in the facility setting	-0.38
96132	Nrpsyc tst eval phys/qhp 1st	SK130	WAIS-IV Record Form	NF		0	1	S6: Refined supply quantity to what is typical for the procedure	5.25
96132	Nrpsyc tst eval phys/qhp 1st	SK131	WAIS-IV Response Booklet #1	NF		0	1	S6: Refined supply quantity to what is typical for the procedure	3.30
96132	Nrpsyc tst eval phys/qhp 1st	SK132	WMS-IV Response Booklet #2	NF		0	1	S6: Refined supply quantity to what is typical for the procedure	2.00
96133	Nrpsyc tst eval phys/qhp ea	SK130	WAIS-IV Record Form	NF		0	1	S6: Refined supply quantity to what is typical for the procedure	5.25
96133	Nrpsyc tst eval phys/qhp ea	SK131	WAIS-IV Response Booklet #1	NF		0	1	S6: Refined supply quantity to what is typical for the procedure	3.30

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
96133	Nrpsyc tst eval phys/qhp ea	SK132	WMS-IV Response Booklet #2	NF		0	1	S6: Refined supply quantity to what is typical for the procedure	2.00
96136	Psycl/nrpsyc tst phy/qhp 1st	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	0	10	G1: See preamble text	3.70
96136	Psycl/nrpsyc tst phy/qhp 1st	SK130	WAIS-IV Record Form	NF		0.165	1	S6: Refined supply quantity to what is typical for the procedure	4.38
96136	Psycl/nrpsyc tst phy/qhp 1st	SK131	WAIS-IV Response Booklet #1	NF		0.165	1	S6: Refined supply quantity to what is typical for the procedure	2.76
96136	Psycl/nrpsyc tst phy/qhp 1st	SK132	WMS-IV Response Booklet #2	NF		0.165	1	S6: Refined supply quantity to what is typical for the procedure	1.67
96137	Psycl/nrpsyc tst phy/qhp ea	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	0	10	G1: See preamble text	3.70
96137	Psycl/nrpsyc tst phy/qhp ea	SK130	WAIS-IV Record Form	NF		0.165	1	S6: Refined supply quantity to what is typical for the procedure	4.38
96137	Psycl/nrpsyc tst phy/qhp ea	SK131	WAIS-IV Response Booklet #1	NF		0.165	1	S6: Refined supply quantity to what is typical for the procedure	2.76
96137	Psycl/nrpsyc tst phy/qhp ea	SK132	WMS-IV Response Booklet #2	NF		0.165	1	S6: Refined supply quantity to what is typical for the procedure	1.67
96138	Psycl/nrpsyc tech 1st	SK130	WAIS-IV Record Form	NF		0.165	1	S6: Refined supply quantity to what is typical for the procedure	4.38
96138	Psycl/nrpsyc tech 1st	SK131	WAIS-IV Response Booklet #1	NF		0.165	1	S6: Refined supply quantity to what is typical for the procedure	2.76

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96138	Psycl/nrpsyc tech 1st	SK132	WMS-IV Response Booklet #2	NF		0.165	1	S6: Refined supply quantity to what is typical for the procedure	1.67
96139	Psycl/nrpsyc tst tech ea	SK130	WAIS-IV Record Form	NF		0.165	1	S6: Refined supply quantity to what is typical for the procedure	4.38
96139	Psycl/nrpsyc tst tech ea	SK131	WAIS-IV Response Booklet #1	NF		0.165	1	S6: Refined supply quantity to what is typical for the procedure	2.76
96139	Psycl/nrpsyc tst tech ea	SK132	WMS-IV Response Booklet #2	NF		0.165	1	S6: Refined supply quantity to what is typical for the procedure	1.67
96146	Psycl/nrpsyc tst auto result	ED055	CANTAB Mobile (per single automated assessment)	NF		10	0	G1: See preamble text	-0.11
99454	Rem mntr physiol param dev		Monthly cellular and licensing service fee	NF		1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-69.00
G0108	Diab manage trn per indiv	ED021	computer, desktop, w-monitor	NF		0	10	G1: See preamble text	0.09
G0108	Diab manage trn per indiv	EF009	chair, medical recliner	NF		0	15	G1: See preamble text	0.05
G0108	Diab manage trn per indiv	EF016	scale, high capacity (800 lb)	NF		0	1	G1: See preamble text	0.00
G0108	Diab manage trn per indiv	EF025	table, for seated OT therapy	NF		0	15	G1: See preamble text	0.27
G0108	Diab manage trn per indiv	EQ073	body analysis machine, bioimpedence	NF		0	2.5	G1: See preamble text	0.02
G0108	Diab manage trn per indiv	EQ123	food models	NF		0	10	G1: See preamble text	0.03
G0108	Diab manage trn per indiv	EQ187	nutrition therapy software (Nutritionist Pro)	NF		0	10	G1: See preamble text	0.02
G0108	Diab manage trn per indiv	L051A	RN	NF	Obtain vital signs	0	2	G1: See preamble text	1.02
G0108	Diab manage trn	SB022	gloves, non-sterile	NF		1	0	G1: See preamble text	-0.14

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	per indiv								
G0108	Diab manage trn per indiv	SK043	label for files-folders	NF		0	0.5	G1: See preamble text	0.04
G0108	Diab manage trn per indiv	SK057	paper, laser printing (each sheet)	NF		2	4	G1: See preamble text	0.02
G0108	Diab manage trn per indiv	SK062	patient education booklet	NF		0	0.5	G1: See preamble text	0.93
G0108	Diab manage trn per indiv	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		1	0	G1: See preamble text	-0.05
G0109	Diab manage trn ind/group	ED021	computer, desktop, w-monitor	NF		0	3	G1: See preamble text	0.03
G0109	Diab manage trn ind/group	ED038	notebook (Dell Latitute D600)	NF		30	0	G1: See preamble text	-0.26
G0109	Diab manage trn ind/group	EF016	scale, high capacity (800 lb)	NF		0	1	G1: See preamble text	0.00
G0109	Diab manage trn ind/group	EF025	table, for seated OT therapy	NF		0	10	G1: See preamble text	0.18
G0109	Diab manage trn ind/group	EF043	Set of 8 chairs	NF		30	0	G1: See preamble text	-0.31
G0109	Diab manage trn ind/group	EQ123	food models	NF		0	1	G1: See preamble text	0.00
G0109	Diab manage trn ind/group	EQ187	nutrition therapy software (Nutritionist Pro)	NF		0	1	G1: See preamble text	0.00
G0109	Diab manage trn ind/group	EQ282	PC projector	NF		30	0	G1: See preamble text	-0.32
G0109	Diab manage trn ind/group	EQ305	Diabetes education data tracking software	NF		2	4	G1: See preamble text	0.00
G0109	Diab manage trn ind/group	SK043	label for files-folders	NF		0	0.25	G1: See preamble text	0.02

HCPCS code	HCPCS code description	Input Code	Input code description	Non-facility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change (in dollars)
G0109	Diab manage trn ind/group	SK062	patient education booklet	NF		0	0.1	G1: See preamble text	0.19
G0168	Wound closure by adhesive	EF023	table, exam	NF		10	9	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
G0268	Removal of impacted wax md	L037D	RN/LPN/MTA	NF	Clean surgical instrument package	3	0	G1: See preamble text	-1.11

TABLE 15—CY 2019 INVOICES RECEIVED FOR EXISTING DIRECT PE INPUTS

CPT/HCPCS codes	Item name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
53850	kit, transurethral microwave thermotherapy.	SA036	1,149.00	1,000.00	−13	1	5,608
53852	kit, transurethral needle ablation (TUNA).	SA037	1,050.00	900.00	−14	2	2,476
85097	stain, Wright's Pack (per slide)	SL140	0.05	0.16	235	1	43,183
96116, 96118, 96119, 96125.	neurobehavioral status forms, average	SK050	5.77	4.00	−31	3	414,139
258 codes	scope video system (monitor, processor, digital capture, cart, printer, LED light).	ES031	33,391.00	36,306.00	9	.....	2,480,515

TABLE 16—CY 2019 NEW INVOICES

CPT/HCPCS codes	Item name	CMS code	Average price	Number of invoices	NF Allowed services
10011, 10012	MREYE Chiba Biopsy Needle	SC106	37.00	1	0
33285	subcutaneous cardiac rhythm monitor system.	SA127	5,032.50	4	280
36572, 36573, 36584	Turbo-Ject PICC Line	SD331	170.00	1	24,402
53854	kit, Rezum delivery device	SA128	1,150.00	1	121
53854	generator, water thermotherapy procedure	EQ389	27,538.00	10	121
58100	Uterine Sound	SD329	3.17	1	59,152
58100	Tenaculum	SD330	3.77	1	59,152
76391	MR Elastography Package	EL050	200,684.50	1	350
76978, 76979	bubble contrast	SD332	126.59	1	89
76978, 76979	Ultrasound Contrast Imaging Package	ER108	5,760.00	1	89
76981, 76982, 76983	sheer wave elastography software	ED060	9,600.00	1	493
77048, 77049	CAD Software	ED058	43,308.12	1	36,675
77046, 77047, 77048, 77049	Breast coil	EQ388	83,200.00	1	39,785
77048, 77049	CAD Workstation (CPU + Color Monitor)	ED056	12,031.52	1	36,675
85097	slide stainer, automated, hematology	EP121	8,649.43	1	34,559
92273	Sleep mask	SK133	9.95	1	10,266
92273, 92274	mfERG and ffERG electrodiagnostic unit	EQ390	102,400.00	1	25,602
92273, 92274	Contact lens electrode for mfERG and ffERG.	EQ391	1,440.00	1	25,602
96136, 96137, 96138, 96139	WAIS–IV Record Form	SK130	5.25	1	301,452
96136, 96137, 96138, 96139	WAIS–IV Response Booklet #1	SK131	3.30	1	301,452
96136, 96137, 96138, 96139	WMS–IV Response Booklet #2	SK132	2.00	1	301,452
96136, 96137, 96138, 96139	Wechsler Adult Intelligence Scale—Fourth Edition (WAIS–IV) Kit (less forms).	EQ387	971.30	1	301,452
99454	heart failure patient physiologic monitoring equipment package.	EQ392	1,000.00	1	58
G0109	20x30 inch self-stick easel pad, white, 30 sheets/pad.	SK129	0.00	0	93,576
none	needle holder, Mayo Hegar, 6″	SC105	3.03	1	0

TABLE 17—CY 2019 NO PE REFINEMENTS

HCPCS	Description
10004	Fna bx w/o img gdn ea addl.
10006	Fna bx w/us gdn ea addl.
10008	Fna bx w/fluor gdn ea addl.
10010	Fna bx w/ct gdn ea addl.
10011	Fna bx w/mr gdn 1st les.
10012	Fna bx w/mr gdn ea addl.
11103	Tangntl bx skin ea sep/addl.
11105	Punch bx skin ea sep/addl.
11107	Incal bx skn ea sep/addl.
33274	Tcat insj/rpl perm ldls pm.
33275	Tcat rmvl perm ldls pm.
33285	Insj subq car rhythm mntr.

TABLE 17—CY 2019 NO PE REFINEMENTS—Continued

HCPCS	Description
33286	Rmvl subq car rhythm mntr.
33289	Tcat impl wrls p-art prs snr.
36568	Insj picc <5 yr w/o imaging.
36569	Insj picc 5 yr+ w/o imaging.
36572	Insj picc rs&i <5 yr.
36573	Insj picc rs&i 5 yr+.
36584	Compl rplcmt picc rs&i.
38531	Open bx/exc inguinofem nodes.
49422	Remove tunneled ip cath.
50436	Dilat xst trc ndurlgc px.
50437	Dilat xst trc new access rcs.
53850	Prostatic microwave thermotx.

TABLE 17—CY 2019 NO PE REFINEMENTS—Continued

HCPCS	Description
53852	Prostatic rf thermotx.
53854	Trurl dstrj prst8 tiss rf wv.
57150	Treat vagina infection.
57160	Insert pessary/other device.
58110	Bx done w/colposcopy add-on.
65205	Remove foreign body from eye.
65210	Remove foreign body from eye.
67500	Inject/treat eye socket
67505	Inject/treat eye socket.
67515	Inject/treat eye socket.
74485	Dilation urtr/urt rs&i.
76514	Echo exam of eye thickness.

TABLE 17—CY 2019 NO PE REFINEMENTS—Continued

HCPCS	Description
76942	Echo guide for biopsy.
76981	Use parenchyma.
76982	Use 1st target lesion.
76983	Use ea addl. target lesion.
77081	Dxa bone density/peripheral.
93264	Rem mntr wrls p-art prs snr.
93668	Peripheral vascular rehab.
95800	Slp stdy unattended.
95801	Slp stdy unatnd w/anal.
95806	Sleep study unatt&resp efft.
95836	Ecog impltd brn npgt <30 d.
95970	Alys npgt w/o prgrmg.
95976	Alys smpl cn npgt prgrmg.
95977	Alys cplx cn npgt prgrmg.
95983	Alys brn npgt prgrmg 15 min.
95984	Alys brn npgt prgrmg addl 15.
96105	Assessment of aphasia.
96110	Developmental screen w/score.
96112	Devel tst phys/qhp 1st hr.
96113	Devel tst phys/qhp ea addl.
96116	Neurobehavioral status exam.
96121	Nubhvl xm phy/qhp ea addl hr.
96125	Cognitive test by hc pro.
96127	Brief emotional/behav assmt.
96130	Psycl tst eval phys/qhp 1st.
96131	Psycl tst eval phys/qhp ea.
99453	Rem mntr physiol param setup.
99457	Rem physiol mntr 20 min mo.
99491	Chrnc care mgmt svc 30 min.
G0166	Extrnl counterpulse, per tx.

I. Evaluation & Management (E/M) Visits

1. Background

a. E/M Visits Coding Structure

Physicians and other practitioners paid under the PFS bill for common office visits for evaluation and management (E/M) services under a relatively generic set of CPT codes (Level I HCPCS codes) that distinguish visits based on the level of complexity, site of service, and whether the patient is new or established. The CPT codes have three key components:

- History of Present Illness (History),
- Physical Examination (Exam) and
- Medical Decision Making (MDM).

These codes are broadly referred to as E/M visit codes. There are three to five E/M visit code levels, depending on site of service and the extent of the three components of history, exam and MDM. For example, there are three to four levels of E/M visit codes in the inpatient hospital and nursing facility settings, based on a relatively narrow degree of complexity in those settings. In contrast, there are five levels of E/M visit codes in the office or other outpatient setting based on a broader range of complexity in those settings.

Current PFS payment rates for E/M visit codes increase with the level of visit billed. As for all services under the PFS, the rates are based on the resources in terms of work (time and intensity), PE and malpractice expense required to furnish the typical case of the service. The current payment rates reflect typical service times for each code that are based on RUC recommendations.

In total, E/M visits comprise approximately 40 percent of allowed charges for PFS services, and office/outpatient E/M visits comprise approximately 20 percent of allowed charges for PFS services. Within these percentages, there is significant variation among specialties. According to Medicare claims data, E/M visits are furnished by nearly all specialties, but represent a greater share of total allowed services for physicians and other practitioners who do not routinely furnish procedural interventions or diagnostic tests. Generally, these practitioners include both primary care practitioners and specialists such as neurologists, endocrinologists and rheumatologists. Certain specialties, such as podiatry, tend to furnish lower level E/M visits more often than higher level E/M visits. Some specialties, such as dermatology and otolaryngology, tend to bill more E/M visits on the same day as they bill minor procedures.

Potential misvaluation of E/M codes is an issue that we have been carefully considering for several years. We have discussed at length in our recent PFS proposed and final rules that the E/M visit code set is outdated and needs to be revised and revalued (for example: 81 FR 46200 and 76 FR 42793). We have noted that this code set represents a high proportion of PFS expenditures, but has not been recently revalued to account for significant changes in the disease burden of the Medicare patient population and changes in health care practice that are underway to meet the Medicare population's health care needs (81 FR 46200). In the CY 2012 PFS proposed rule, we proposed to refer all E/M codes to the RUC for review as potentially misvalued (76 FR 42793). Many commenters to that rule were concerned about the possible inadequacies of the current E/M coding and documentation structure to address evolving chronic care management and to support primary care (76 FR 73060 through 73064). We did not finalize our proposal to refer the E/M codes for RUC review at that time. Instead, we stated that we would allow time for consideration of the findings of certain demonstrations and other initiatives to provide improved information for the valuation of chronic care management, primary care, and care transitions. We stated that we would also continue to consider the numerous policy alternatives that commenters offered, such as separate E/M codes for established visits for patients with chronic disease versus a post-surgical follow-up office visit.

Many stakeholders continue to similarly express to us through letters, meetings, public comments in past rulemaking cycles, and other avenues, that the E/M code set is outdated and needs to be revised. For example, some stakeholders recommend an extensive research effort to revise and revalue E/M services, especially physician work inputs (CY 2017 PFS final rule, 81 FR 80227–80228). In recent years, we have continued to consider the best ways to recognize the significant changes in health care practice, especially innovations in the active management and ongoing care of chronically ill patients, under the PFS. We have been engaged in an ongoing, incremental effort to identify gaps in appropriate coding and payment.

b. E/M Documentation Guidelines

For coding and billing E/M visits to Medicare, practitioners may use one of two versions of the E/M Documentation Guidelines for a patient encounter, commonly referenced based on the year of their release: the ''1995'' or ''1997'' E/M Documentation Guidelines. These guidelines are available on the CMS website.[3] They specify the medical record information within each of the three key components (such as number of body systems reviewed) that serves as support for billing a given level of E/M visit. The 1995 and 1997 guidelines are very similar to the guidelines that reside within the AMA's CPT codebook for E/M visits. For example, the core structure of what comprises or defines the different levels of history, exam, and medical decision-making are the same. However, the 1995 and 1997 guidelines include extensive examples of clinical work that comprise different levels of medical decision-making and do not appear in the AMA's CPT codebook. Also, the 1995 and 1997 guidelines do not contain references to preventive care that appear in the AMA's CPT codebook. We provide an example of how the 1995 and 1997 guidelines distinguish between level 2 and level 3 E/M visits in Table 18.

BILLING CODE 4120–01–P

[3] See *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/95Docguidelines.pdf*; *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/97Docguidelines.pdf*; and the Evaluation and Management Services guide at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf*.

TABLE 18: Key Component Documentation Requirements for Level 2 vs. 3 E/M Visit

Key Component*	Level 2 (1995)	Level 3 (1995)	Level 2 (1997)	Level 3 (1997)
History (History of Present Illness or HPI)	Review of Systems (ROS) n/a	Problem Pertinent ROS: inquires about the system directly related to the problem(s) identified in the HPI	No change from 1995	No change from 1995
Physical Examination (Exam)	A limited examination of the affected body area or organ system	A limited examination of the affected body area or organ system and other symptomatic or related organ system(s)	General multi-system exam: Performance and documentation of one to five elements in one or more organ system(s) or body area(s). Single organ system exam: Performance and documentation of one to five elements	General multi-system exam: Performance and documentation of at least six elements in one or more organ system(s) or body area(s). Single organ system exam: Performance and documentation of at least six elements
Medical Decision Making (MDM) Measured by:** 1. **Problem** – Number of diagnoses/treatment options 2. **Data -** Amount and/or complexity of data to be reviewed 3. **Risk-** Risk of complications and/or morbidity or mortality	Straightforward: 1. Minimal 2. Minimal or no data review 3. Minimal risk	Low complexity: 1. Limited 2. Limited data review 3. Low risk	No change from 1995	

* For certain settings and patient types, each of these three key components must be met or exceeded (for example, new patients; initial hospital visits). For others, only two of the three key components must be met or exceeded (for example, established patients, subsequent hospital or other visits).
** Two of three met or exceeded.

BILLING CODE 4120–01–C

According to both Medicare claims processing manual instructions and CPT coding rules, when counseling and/or coordination of care accounts for more than 50 percent of the face-to-face physician/patient encounter (or, in the case of inpatient E/M services, the floor time) the duration of the visit can be used as an alternative basis to select the appropriate E/M visit level (Pub. L. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.1.C available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf*; see also 2017 CPT Codebook Evaluation and Management Services Guidelines, page 10). Public Law 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.1.B states, ''Instruct physicians to select the code for the service based upon the content of the service. The duration of the visit is an ancillary factor and does not control the level of the service to be billed unless more than 50 percent of the face-to-face time (for non-inpatient services) or more than 50 percent of the floor time (for inpatient services) is spent providing counseling or coordination of care as described in subsection C.'' Subsection C states that ''the physician may document time spent with the patient in conjunction with the medical decision-making involved and a description of the coordination of care or counseling provided. Documentation must be in sufficient detail to support the claim.'' The example included in subsection C further states, ''The code selection is based on the total time of the face-to-face encounter or floor time, not just the counseling time. The medical record must be documented in sufficient detail

to justify the selection of the specific code if time is the basis for selection of the code.''

Both the 1995 and 1997 E/M guidelines contain guidelines that address time, which state that ''In the case where counseling and/or coordination of care dominates (more than 50 percent of) the physician/patient and/or family encounter (face-to-face time in the office or other outpatient setting or floor/unit time in the hospital or nursing facility), time is considered the key or controlling factor to qualify for a particular level of E/M services.'' The guidelines go on to state that ''If the physician elects to report the level of service based on counseling and/or coordination of care, the total length of time of the encounter (face-to-face or floor time, as appropriate) should be documented and the record should describe the counseling and/or activities to coordinate care.'' [4]

We note that other manual provisions regarding E/M visits that are cited in this final rule are housed separately within Medicare's Internet-Only Manuals, and are not contained within the 1995 or 1997 E/M documentation guidelines.

In accordance with section 1862(a)(1)(A) of the Act, which requires services paid under Medicare Part B to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, medical necessity is a prerequisite to Medicare payment for E/M visits. The Medicare Claims Processing Manual states, ''Medical necessity of a service is the overarching criterion for payment in addition to the individual requirements of a CPT code. It would not be medically necessary or appropriate to bill a higher level of evaluation and management service when a lower level of service is warranted. The volume of documentation should not be the primary influence upon which a specific level of service is billed. Documentation should support the level of service reported'' (Pub. L. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.1.A., available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf*).

Stakeholders have long maintained that all of the E/M documentation guidelines are administratively burdensome and outdated with respect to the practice of medicine. Stakeholders have provided CMS with examples of such outdated material (on history, exam and MDM) that can be found within all versions of the E/M guidelines (the AMA's CPT codebook, the 1995 guidelines and the 1997 guidelines). Stakeholders have told CMS that they believe the guidelines are too complex, ambiguous, fail to meaningfully distinguish differences among code levels, and are not updated for changes in technology, especially electronic health record (EHR) use. Prior attempts to revise the E/M guidelines were unsuccessful or resulted in additional complexity due to lack of stakeholder consensus (with widely varying views among specialties), and differing perspectives on whether code revaluation would be necessary under the PFS as a result of revising the guidelines, which contributed another layer of complexity to the considerations. For example, an early attempt to revise the guidelines resulted in an additional version designed for use by certain specialties (the 1997 version), and in CMS allowing the use of either the 1995 or 1997 versions for purposes of documentation and billing to Medicare. Another complication in revising the guidelines is that they are also used by many other payers, which have their own payment rules and audit protocols. Moreover, stakeholders have suggested that there is sometimes variation in how Medicare's own contractors (Medicare Administrative Contractors (MACs)) interpret and apply the guidelines as part of their audit processes.

As previously mentioned, in recent years, some clinicians and other stakeholders have requested a major CMS research initiative to overhaul not only the E/M documentation guidelines, but also the underlying coding structure and valuation. Stakeholders have reported to CMS that they believe the E/M visit codes themselves need substantial updating and revaluation to reflect changes in the practice of medicine, and that revising the documentation guidelines without addressing the codes themselves simply preserves an antiquated framework for payment of E/M services.

Last year, CMS sought public comment on potential changes to the E/M documentation rules, deferring making any changes to E/M coding itself in order to immediately focus on revision of the E/M guidelines to reduce unnecessary administrative burden (82 FR 34078 through 34080). In the CY 2018 PFS final rule (82 FR 53163 through 53166), we summarized the public comments we received and stated that we would take that feedback into consideration for future rulemaking. In response to commenters' request that we provide additional venues for stakeholder input, we held a listening session this year on March 18, 2018 (transcript and materials are available on the CMS website at *https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2018-03-21-Documentation-Guidelines-and-Burden-Reduction.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending*). We also sought input by participating in several listening sessions recently hosted by the Office of the National Coordinator for Health Information Technology (ONC) in the course of implementing section 4001(a) of the 21st Century Cures Act (Pub. L. 114–255). This provision requires the Department of Health and Human Services to establish a goal, develop a strategy, and make recommendations to reduce regulatory or administrative burdens relating to the use of EHRs. The ONC listening sessions sought public input on the E/M guidelines as one part of broader, related and unrelated burdens associated with EHRs.

Several themes emerged from this recent stakeholder input. Stakeholders commended CMS for undertaking efforts to revise the E/M guidelines and recommended a multi-year process. Many commenters advised CMS to obtain further input across specialties. They recommended town halls, open door forums or a task force that would come up with replacement guidelines that would work for all specialties over the course of several years. They urged CMS to proceed cautiously given the magnitude of the undertaking; past failed reform attempts by the AMA, CMS, and other payers; and the wide-ranging impact of any changes (for example, how other payers approach the issue).

We received substantially different recommendations by specialty. Based on this feedback, it is clear that any changes would have meaningful specialty-specific impacts, both clinical and financial. Based on this feedback, it also seems that the history and exam portions of the guidelines are most significantly outdated with respect to current clinical practice.

A few stakeholders seemed to indicate that the documentation guidelines on history and exam should be kept in their current form. Many stakeholders believed they should be simplified or reduced, but not eliminated. Some stakeholders indicated that the documentation guidelines on history and exam could be eliminated altogether, and/or that documentation of these parts of an E/M visit could be left

[4] Page 16 of the 1995 E/M guidelines and page 48 of the 1997 guidelines.

to practitioner discretion. We also heard from stakeholders that the degree to which an extended history and exam enables a given practitioner to reach a certain level of coding (and payment) varies according to their specialty. Many commenters advised CMS to increase reliance on medical decision-making (MDM) and time in determining the appropriate level of E/M visit, or to use MDM by itself, but many of these commenters noted that the MDM portions of the guidelines would need to be altered before being used alone. Commenters were divided on the role of time in distinguishing among E/M visit levels, and expressed some concern about potential abuse or inequities among more- or less-efficient practitioners. Some commenters expressed support for simplifying E/M coding generally into three levels such as low, medium and high, and potentially distinguishing those levels on the basis of time.

2. CY 2019 Final Policies

a. Overview

Having considered the public feedback to the CY 2018 PFS proposed rule (82 FR 53163 through 53166) and our other outreach efforts described above, in our CY 2019 proposed rule, we proposed several changes to E/M visit documentation and payment. We proposed that the changes would only apply to office/outpatient visit codes (CPT codes 99201 through 99215), except where we specify otherwise. We agreed with commenters that we should take a step-wise approach to these issues, and therefore, we limited proposed changes to the office/outpatient E/M code set. We understood from commenters that there are more unique issues to consider for the E/M code sets used in other settings such as inpatient hospital or emergency department care, such as unique clinical and legal issues and the potential intersection with hospital Conditions of Participation (CoPs). We may consider expanding our efforts more broadly to address sections of the E/M code set beyond the office/outpatient codes in future years.

We emphasized that, this year, we included our proposed E/M documentation changes in a proposed rule due to the longstanding nature of our instruction that practitioners may use either the 1995 or 1997 versions of the E/M guidelines to document E/M visits billed to Medicare, the magnitude of the proposed changes, and the associated payment policy proposals that require notice and comment rulemaking. We believed our proposed documentation changes for E/M visits were intrinsically related to our proposal to alter PFS payment for E/M visits, and the PFS payment proposal for E/M visits required notice and comment rulemaking. We noted that we were proposing a relatively broad outline of changes, and anticipated that many details related to program integrity and ongoing refinement would need to be developed over time through subregulatory guidance. This would afford flexibility and enable us to more nimbly and quickly make ongoing clarifications, changes and refinements in response to continued practitioner experience moving forward.

We put forth a key proposal that, at its core, strived to reduce the significant burden associated with documentation for payment purposes by eliminating the payment rules associated with the current primary means of varying payment among office/outpatient visits. Specifically, we proposed to develop single payment rates for the office/outpatient E/M visit levels 2 through 5 (one rate for established patients, and one rate for new patients), in order to mitigate the need for physicians and other practitioners to adhere to complex payment-specific documentation rules for each and every visit furnished to a Medicare beneficiary. If there were minimal payment variation based on the level of visit billed, then there would be minimal need to engage with the burdensome and outdated documentation guidelines and E/M visit coding to justify that the appropriate level visit was reported. Though we acknowledged a continued need to document information in the medical record for clinical and other purposes, our understanding based on extensive feedback from medical professionals was that the documentation specific to justifying the visit level reported to payers, including Medicare, was unduly and disproportionately burdensome among the many administrative burdens in current medical practice. To avoid the administrative burden and disruption of establishing a new G code to describe the level 2 through 5 combined visit, under our proposal practitioners would continue to report on the claim the CPT code associated with the level of visit the practitioner believed they furnished.

Along with eliminating payment variation for office/outpatient E/M visit levels 2 through 5, we proposed a series of corollary policies intended to vary payment for these visits based on a more meaningful set of attributes for visits. Our goal was that these payment variations, accomplished through new add-on and other coding changes, and multiple procedure payment reductions, would reflect the relative resource costs of furnishing E/M visits without requiring detailed documentation for purposes of justifying particular payment rates. We also expected these adjustments to offset some of the more significant potentially redistributive impacts of this proposal, especially among physicians and practitioners of different specialties. The potential redistributive impacts helped us to determine potential, initial values for the proposed add-on codes providing for the adjustments. Again, these proposals were intended to provide a more meaningful avenue for payment variation that would ease the documentation burdens currently faced by clinicians to justify the visit level that is reported for each and every visit with a beneficiary. These proposals reflected our longstanding beliefs that: There are certain complexities inherent in furnishing some kinds of E/M visits that are not currently accounted for in valuations for the current E/M code set, there are unaccounted-for efficiencies when E/M visits are billed on the same day as global procedure codes that are already valued to include resources associated with E/M services, and the current E/M coding system does not fully account for the variety of legitimate circumstances when the needs of individual patients require more time with their physicians. We also proposed to establish unique E/M visit codes for podiatric care and make changes to the PE methodology in order to standardize the amount of PE RVUs allocated for this series of codes, regardless of which specialties were assumed to bill them.

In conjunction with our proposal to effectively eliminate the variation in payment of choosing from among E/M visit levels 2 through 5 for office/outpatient visits, we proposed a minimum level of associated documentation that would apply for payment purposes across all level 2 through 5 office/outpatient E/M visits. We also proposed to allow practitioners a choice regarding the basis for their documentation for these visits: Current documentation guidelines (history, exam and MDM); MDM alone; or time alone. We proposed that, when using current documentation guidelines or MDM, the current guidelines for level 2 visits would apply. When using time to document a visit, the practitioner would be required to demonstrate the medical necessity of the visit and report the total amount of face-to-face time they spent with the beneficiary. We solicited public comment on what the total time

requirement should be when using time to document a level 2 through 5 visit. We presented several alternatives for determining the amount of time associated with each visit level: The new intra-service times associated with setting the payment rate for the visit codes, the midpoint of these new times, or the typical time for the CPT code reported on the claim (the time listed in the AMA/CPT codebook for that code) (83 FR 35837).

We sought feedback in particular on the option to document using time when prolonged E/M services are billed. We proposed that when a practitioner uses time to document the visit and also reports prolonged E/M services, we would require the practitioner to document that the typical time required for the base or ''companion'' visit is exceeded by the amount required to report prolonged services (83 FR 35837). We did not propose any changes to CPT codes 99354 and 99355, and under our proposal these codes could still be billed, as needed, when their time thresholds and all other requirements are met (83 FR 35774).

Since we proposed to create a single payment rate under the PFS that would be paid for services billed using the current CPT codes for level 2 through 5 visits, it would not be material to Medicare's payment decision which CPT code (of levels 2 through 5) would be reported on the claim, except to justify billing a level 2 or higher visit in comparison to a level 1 visit (providing the visit itself was reasonable and necessary) and when using certain potential approaches to documenting the visit using time (83 FR 35836 through 35837). However, we expected that for record keeping purposes or to meet requirements of other payers, practitioners would continue to choose and report the level of E/M visit they believed to be appropriate under the current CPT coding structure.

We also proposed to remove an existing manual provision for home visits requiring documentation in the patient's medical record of the medical necessity of furnishing the visit in the home. For all office/outpatient E/M visits, we also proposed several simplifications centered on reducing the need for duplicative, redundant data entry in the medical record.

Several thousand commenters responded to this series of proposals. Generally, the commenters stated appreciation for CMS' goal of reducing administrative burden and reforming E/M coding and payment, but expressed concern about many impacts of the proposals. Commenters largely objected to our proposal to eliminate payment differences for office/outpatient E/M visit levels 2 through 5 based on the level of visit complexity. Many commenters stated that they would experience payment cuts relative to the current payment structure. Commenters generally stated that the implementation timeframe for the changes as proposed was too aggressive, especially since stakeholders were uncertain as to whether other payers would follow Medicare's proposed policies. Many commenters suggested that CMS could implement the proposed documentation reduction without the coding/payment policies, or that these policies could be adopted on separate timeframes.

Many commenters suggested that the proposals did not specify the circumstances in which the proposed add-on codes for office/outpatient E/M visits could be used, and what documentation requirements might be adopted for them. Many commenters stated that it would be better if the physician community could consider a range of alternative coding and payment options to be modeled and thoroughly evaluated over several years instead of a single alternative during a 60-day public comment period.

Many commenters opposed our proposal to establish that clinicians billing an office/outpatient E/M visit level 2 through 5 need only document medical necessity as specified for a level 2 visit (unless time is used as the basis for the visit level). Some commenters supported allowing a choice of documentation methodologies, while others opposed it. The vast majority of commenters did not support having only a single payment level to distinguish visit complexity (other than level 1), despite the associated minimum documentation that we proposed for these codes. Most commenters noted that CMS did not provide enough specificity in its proposals for how clinicians would document using time, and that because the definitions and billing rules regarding the add-on codes were ambiguous, they questioned whether the codes would have clinical validity. Regarding the valuation of these services, some commenters stated that the proposal did not follow the statutory requirement regarding using relative resources to set PFS rates. Others perceived that some of the newly proposed codes would be required or restricted based on physician specialty, and that such limitations would violate statutory provisions prohibiting varying payment for the same physicians' service by physician specialty.

Many commenters recommended that CMS finalize the documentation proposals regarding home visits and redundant data recording for 2019, but defer other documentation reforms to future years after stakeholders provide additional input. Some commenters recommended that CMS finalize the proposed choice among documentation methodologies while stakeholders work with CMS to refine what the coding and payment changes should be.

After considering the comments, for 2019 we are finalizing several of our documentation proposals that will provide some significant and immediate burden reduction, but are unrelated to changes to payment and coding. Specifically, we are finalizing the proposals regarding home visits and redundant data recording (discussed further in this section), as proposed, effective January 1, 2019.

After considering the comments, especially those suggesting that implementation of significant payment and coding changes requires time for practitioners, vendors, health systems, and other stakeholders to prepare, we are finalizing modified changes in payment coding, and associated documentation rules for E/M office/outpatient visits for 2021. These changes, detailed below, incorporate many significant changes from our proposals based on suggestions from the many comments we received. In brief summation, we are finalizing a significant reduction in the current payment variation in office/outpatient E/M visit levels by paying a single rate for E/M office/outpatient visit levels 2, 3, and 4 (one for established and another for new patients) beginning in 2021. However, we are not finalizing the inclusion of E/M office/outpatient level 5 visits in the single payment rate, to better account for the care and needs of particularly complex patients. Also, after consideration of public comments, we are not finalizing aspects of our proposal that would have: Reduced payment when E/M office/outpatient visits are furnished on the same day as procedures, established separate podiatric E/M visit codes, or standardized the allocation of PE RVUs for the codes that describe these services. We are finalizing a policy for 2021 to adopt add-on codes that describe the additional resources inherent in visits for primary care and particular kinds of specialized medical care. As discussed further below, these codes will only be reportable with E/M office/outpatient level 2 through 4 visits, and their use generally will not impose new per-visit documentation requirements. These codes are neither required nor restricted by physician specialty, though we acknowledge that,

like many other physicians' services for which payment is made under the PFS, they are specifically intended to describe services that clinicians practicing in some specialties are more likely to perform than those in other specialties. We are also finalizing a policy for 2021 to adopt a new ''extended visit'' add-on code for use only with E/M office/outpatient level 2 through 4 visits to account for the additional resources required when practitioners need to spend extended time with the patient.

For CY 2019 and 2020, we will continue the current coding and payment structure for E/M office/outpatient visits, and, therefore, practitioners should continue to use either the 1995 or 1997 versions of the E/M guidelines to document E/M office/outpatient visits billed to Medicare for 2019 and 2020 (with the exception of our final policy to eliminate redundant data recording).

Beginning in 2021, for E/M office/outpatient levels 2 through 5 visits, we will allow for flexibility in how visit levels are documented, specifically a choice to use the current framework, MDM or time. For E/M office/outpatient level 2 through 4 visits, beginning in 2021 we will also apply a minimum supporting documentation standard associated with level 2 visits when practitioners use the current framework or MDM to document the visit.

We intend to engage in further discussions with the public over the next several years to potentially further refine our policies, through future notice and comment rulemaking, for 2021. We discuss the public comments, our responses to the specific concerns and perspectives offered by commenters, and final policies in greater detail in this section.

b. Public Comments and Responses

(1) Lifting Restrictions Related to E/M Documentation

(a) Eliminating Extra Documentation Requirements for Home Visits

Medicare pays for E/M visits furnished in the home (a private residence) under CPT codes 99341 through 99350. The payment rates for these codes are slightly more than for office visits (for example, approximately $30 more for a level 5 established patient, non-facility). The beneficiary need not be confined to the home to be eligible for such a visit. However, there is a Medicare Claims Processing Manual provision requiring that the medical record must document the medical necessity of the home visit made in lieu of an office or outpatient visit (Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.14.1.B., available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf*). Stakeholders have suggested that whether a visit occurs in the home or the office is best determined by the practitioner and the patient without applying additional rules. We agreed, so we proposed to remove the requirement that the medical record must document the medical necessity of furnishing the visit in the home rather than in the office. We welcomed public comments on this proposal, including any potential, unintended consequences of eliminating this requirement.

Comment: Commenters were generally supportive of our proposal to remove the requirement that the medical record must document the medical necessity of furnishing the visit in the home rather than in the office. Many commenters included this proposal in a list of appropriate changes CMS should make immediately regarding documentation of E/M visits, effective January 1, 2019.

Response: We are finalizing this policy change to remove the requirement that the medical record must document the medical necessity of furnishing the visit in the home rather than in the office, as proposed, effective January 1, 2019.

(b) Public Comment Solicitation on Eliminating Prohibition on Billing Same-Day Visits by Practitioners of the Same Group and Specialty

The Medicare Claims Processing Manual states, ''As for all other E/M services except where specifically noted, the Medicare Administrative Contractors (MACs) may not pay two E/M office visits billed by a physician (or physician of the same specialty from the same group practice) for the same beneficiary on the same day unless the physician documents that the visits were for unrelated problems in the office, off campus-outpatient hospital, or on campus-outpatient hospital setting which could not be provided during the same encounter'' (Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.7.B., available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf*).

This instruction was intended to reflect the idea that multiple visits with the same practitioner, or by practitioners in the same or very similar specialties within a group practice, on the same day as another E/M service would not be medically necessary. However, stakeholders have provided a few examples where this policy does not make sense with respect to the current practice of medicine as the Medicare enrollment specialty does not always coincide with all areas of medical expertise possessed by a practitioner—for example, a practitioner with the Medicare enrollment specialty of geriatrics may also be an endocrinologist. If such a practitioner was one of many geriatricians in the same group practice, they would not be able to bill separately for an E/M visit focused on a patient's endocrinological issue if that patient had another more generalized E/M visit by another geriatrician on the same day. Stakeholders have pointed out that in these circumstances, practitioners often respond to this instruction by scheduling the E/M visits on two separate days, which could unnecessarily inconvenience the patient. Given that the number and granularity of practitioner specialties recognized for purposes of Medicare enrollment continue to increase over time (consistent with the medical community's requests), the value to the Medicare program of the prohibition on same-day E/M visits billed by physicians in the same group and medical specialty may be diminishing, especially as we believe it is becoming more common for practitioners to have multiple specialty affiliations, but would have only one primary Medicare enrollment specialty. We believe that eliminating this policy may better recognize the changing practice of medicine while reducing administrative burden. The impact of this proposal on program expenditures and beneficiary cost sharing is unclear. To the extent that many of these services are currently merely scheduled and furnished on different days in response to the instruction, eliminating this manual provision may not significantly increase utilization, Medicare spending and beneficiary cost sharing.

We solicited public comment on whether we should eliminate the manual provision given the changes in the practice of medicine or whether there is concern that eliminating it might have unintended consequences for practitioners and beneficiaries.

We recognize that this instruction may be appropriate only in certain clinical situations, so we also solicited public comments on whether and how we should consider creating exceptions to, or modify this manual provision rather than eliminating it entirely. We also requested that the public provide additional examples and situations in

which the current instruction is not clinically appropriate.

Comment: We received many comments in response to this solicitation.

Response: We thank the commenters for all of the information submitted, and will review the many public comments we received on this topic and consider this issue further for potential future rulemaking.

(2) Documentation Changes for Office or Other Outpatient E/M Visits and Home Visits

(a) Providing Choices in Documentation—Medical Decision-Making, Time or Current Framework

Informed by comments and examples that we have received stating that the current E/M documentation guidelines are outdated with respect to the current practice of medicine, and in our efforts to simplify documentation for the purposes of coding E/M visit levels, we proposed to allow practitioners to choose, as an alternative to the current framework specified under the 1995 or 1997 guidelines, either MDM or time as a basis to determine the appropriate level of E/M visit. This would allow different practitioners in different specialties to choose to document the factor(s) that matter most given the nature of their clinical practice. It would also reduce the impact Medicare may have on the standardized recording of history, exam and MDM data in medical records, since practitioners could choose to no longer document many aspects of an E/M visit that they currently document under the 1995 or 1997 guidelines for history, physical exam and MDM. Although we initially considered reducing the number of key components that practitioners needed to document in choosing the appropriate level of E/M service to bill, feedback from the stakeholder community led us to believe that offering practitioners a choice to either retain the current framework or choose among new options that involve a reduced level of documentation would be less burdensome for practitioners, and would allow more stability for practitioners who may need time to prepare for any potential new documentation framework.

We sought to be clear that as part of this proposal, practitioners could use MDM, or time, or they could continue to use the current framework to document an E/M visit. In other words, we would be offering the practitioner the choice to continue to use the current framework by applying the 1995 or 1997 documentation guidelines for all three key components. However, our proposals on payment for office-based/outpatient E/M visits described later in this section would apply to all practitioners, regardless of their selected documentation approach. Under our proposal, all practitioners, even those choosing to retain the current documentation framework, would be paid at the proposed new payment rate described in the CY 2019 PFS proposed rule (one rate for new patients and another for established patients), and could also report applicable G-codes as we proposed (83 FR 35839 through 35843).

We also sought to be clear that we proposed to retain the current CPT coding structure for E/M visits (along with our proposal to create new replacement codes for podiatry office/outpatient E/M visits). Practitioners would report on the professional claim whatever level of visit (1 through 5) they believe they furnished using CPT codes 99201–99215. Because we believed the adoption of replacement G-codes to describe the visit levels 2 through 5 might result in unnecessary disruption to current billing systems and practices, we did not propose to modify the existing CPT coding structure for E/M visits. Since we proposed to create a single rate under the PFS that would be paid for services billed using the current CPT codes for level 2 through 5 E/M visits, under our proposal, it would not have been material to Medicare's payment decision which CPT code (of levels 2 through 5) is reported on the claim, except to justify billing a level 2 or higher visit in comparison to a level 1 visit (provided the visit itself was reasonable and necessary). We stated that we expected that, for record keeping purposes or to meet requirements of other payers, many practitioners would continue to choose and report the level of E/M visit they believed to be appropriate under the CPT coding structure.

Even though under our proposal, there would have been no payment differential for E/M visits based on which of the codes describing visit levels 2 through 5 were reported, we believed we would still need to simplify and change our documentation requirements to better align with the current practice of medicine and eliminate unnecessary aspects of the current documentation framework. As a corollary to our proposal to adopt a single payment amount for office/outpatient E/M visit levels 2 through 5 (83 FR 35839 through 35843), we proposed to apply a minimum documentation standard where, for the purposes of PFS payment for an office/outpatient E/M visit, practitioners would only need to meet documentation requirements currently associated with a level 2 visit for history, exam and/or MDM, except when using time to document the service. Practitioners could choose to document more information for clinical, legal, operational or other purposes, and we anticipated that for those reasons, practitioners would continue generally to seek to document medical record information that is consistent with the level of care furnished. For purposes of our medical review, however, for practitioners using the current documentation framework or, as we proposed, MDM, Medicare would only require documentation to support the medical necessity of the visit and the documentation that is associated with the current level 2 CPT visit code.

For example, for a practitioner choosing to document using the current framework (1995 or 1997 guidelines), our proposed minimum documentation for any billed level of E/M visit from levels 2 through 5 could include: (1) A problem-focused history that does not include a review of systems or a past, family, or social history; (2) a limited examination of the affected body area or organ system; and (3) straightforward medical decision making measured by minimal problems, data review, and risk (two of these three). If the practitioner was choosing to document based on MDM alone, Medicare would only require documentation supporting straightforward medical decision-making measured by minimal problems, data review, and risk (two of these three).

Some commenters had suggested that the current framework of guidelines for the MDM component of visits would need to be changed before MDM could be relied upon by itself to distinguish visit levels. We proposed to allow practitioners to rely on MDM in its current form to document their visit, and solicited public comment on whether and how guidelines for MDM might be changed in subsequent years.

As described earlier, we currently allow time or duration of visit to be used as the governing factor in selecting the appropriate E/M visit level only when counseling and/or coordination of care accounts for more than 50 percent of the face-to-face physician/patient encounter (or, in the case of inpatient E/M services, the floor time). Our proposal to allow practitioners the choice of using time to document office/outpatient E/M visits would have meant that this time-based standard is not limited to E/M visits in which counseling and/or care coordination

accounts for more than 50 percent of the face-to-face practitioner/patient encounter. Rather, the amount of time personally spent by the billing practitioner face-to-face with the patient could be used to document the E/M visit regardless of the amount of counseling and/or care coordination furnished as part of the face-to-face encounter.

Some commenters had raised concerns with reliance on time to distinguish visit levels, for example the potential for abuse, inequities among more- or less-efficient practitioners, and specialties for which time is less of a factor in determining visit complexity. We noted in the proposed rule that relying on time as the basis for identifying the E/M visit level would also raise the issue of what would be required by way of supporting documentation; for example, what amount of time should be documented, and whether the specific activities comprising the time need to be documented and to what degree. However, a number of stakeholders had suggested that, within their specialties, time is a good indicator of the complexity of the visit or patient, and requested that we allow practitioners to use time as the single factor in all E/M visits, not just when counseling or care coordination dominate a visit. We agreed that for some practitioners and patients, time may be a good indicator of complexity of the visit, and proposed to allow practitioners the option to use time as the single factor in selecting visit level and documenting the E/M visit, regardless of whether counseling or care coordination dominate the visit. We stated that if finalized, we would monitor the results of this policy for any program integrity issues, administrative burden or other issues.

For practitioners choosing to support their coding and payment for an E/M visit by documenting the amount of time spent with the patient, we proposed to require the practitioner to document the medical necessity of the visit and show the total amount of time spent by the billing practitioner face-to-face with the patient. We solicited public comment on what that total time should be for payment of the single, new rate for E/M visits levels 2 through 5. We presented the typical time for our proposed new single payment for E/M visit levels 2 through 5 (the weighted average of the intra-service times across the current E/M visit utilization) and suggested we could use this time. We noted that currently the PFS does not require the practitioner to spend or document a specified amount of time with a given patient in order to receive payment for an E/M visit, unless the visit is dominated by counseling/care coordination and, on that account, the practitioner is using time as the basis for code selection. The times for E/M visits and most other PFS services in the physician time files, which are used to set PFS rates, are typical times rather than requirements, and were recommended by the AMA RUC and then reviewed and either adopted or adjusted for Medicare through our usual ratesetting process as ''typical,'' but not strictly required.

We presented a potential alternative to apply the AMA's CPT codebook provision that, for timed services, a unit of time is attained when the mid-point is passed,[5] such that we would require documentation that at least 16 minutes for an established patient (more than half of 31 minutes) and at least 20 minutes for a new patient (more than half of 38 minutes) were spent face-to-face by the billing practitioner with the patient, to support making payment at the proposed single rate for visit levels 2 through 5 when the practitioner chose to document the visit using time.

We presented another potential alternative to require documentation that the typical time for the CPT code that is reported (which is also the typical time listed in the AMA's CPT codebook for that code) was spent face-to-face by the billing practitioner with the patient. For example, a practitioner reporting CPT code 99212 (a level 2 established patient visit) would be required to document having spent a minimum of 10 minutes, and a practitioner reporting CPT code 99214 (a level 4 established patient visit) would be required to document having spent a minimum of 25 minutes. Under this approach, the total amount of time spent by the billing practitioner face-to-face with the patient would inform the level of E/M visit (of levels 2 through 5) coded by the billing practitioner. We noted that in contrast to other proposed documentation approaches discussed above, this approach of requiring documentation of the typical time associated with the CPT visit code reported on the claim would introduce unique payment implications for reporting that code, especially when the time associated with the billed E/M code is the basis for reporting prolonged E/M services.

We solicited public comments on the use of time as a framework for documentation of office/outpatient E/M visits, and whether we should adopt any of these approaches or specify other requirements with respect to the proposed option for documentation using time.

In providing us with feedback, we requested that commenters take into consideration ways in which the time associated with, or required for, the billing of any add-on codes (especially the proposed prolonged E/M visit add-on code(s) described in the CY 2019 PFS proposed rule (83 FR 35844)) would intersect with the time spent for the base E/M visit, when the practitioner is documenting the E/M visit using only time. Currently, when reporting prolonged E/M services, we expect the practitioner to exceed the typical time assigned for the base E/M visit code (also commonly referred to as the companion code). For example, in the CY 2017 PFS final rule (81 FR 80229), we expressed appreciation for the commenters' suggestion to display the typical times associated with relevant services. We also discussed, and in response to those comments, decided to post a file annually that notes the times assumed to be typical for purposes of PFS ratesetting for practitioners to use as a reference in deciding whether time requirements for reporting prolonged E/M services are met. We stated that although these typical times are not required for a practitioner to bill the displayed base codes, we expect that only time spent in excess of these times will be reported using a non-face-to-face prolonged service code. We proposed to formalize this policy in the case where a practitioner uses time to document a visit, since there would be a stricter time requirement associated with the base E/M code. Specifically, we proposed that, when a practitioner chooses to document using time and also reports prolonged E/M services, we would require the practitioner to document that the typical time required for the base or ''companion'' visit is exceeded by the amount required to report prolonged services. Further discussion of our proposal regarding reporting prolonged E/M services is available in the CY 2019 PFS proposed rule (83 FR 35844).

We believed that allowing practitioners to choose the most appropriate basis for distinguishing among the levels of E/M visits and applying a minimum documentation requirement, together with reducing the payment variation among E/M visit levels, would significantly reduce administrative burden for practitioners, and would avoid the current need to make coding and documentation decisions based on codes and documentation guidelines that are not a good fit with current medical practice. The practitioner could choose to use

[5] 2017 CPT Codebook Introduction, p.xv.

MDM, time or the current documentation framework, and could also apply the proposed policies discussed below regarding redundancy and who can document information in the medical record.

We solicited public comment on these proposals to provide practitioners choice in the basis for documenting E/M visits in an effort to allow for documentation alternatives that better reflect the current practice of medicine and to alleviate documentation burden. We stated our interest in receiving public comments on practitioners' ability to avail themselves of these choices for how they would impact clinical workflows, EHR templates, and other aspects of practitioner work.

Stakeholders had requested that CMS not merely shift burden by implementing another framework that might avoid issues caused by the current guidelines, but that would be equally complex and burdensome. Our primary goal was to reduce administrative burden so that the practitioner can focus on the patient, and we were interested in commenters' opinions as to whether our E/M visit proposals would, in fact, support and further this goal. We believed our proposals would allow practitioners to exercise greater clinical judgment and discretion in what they document, focusing on what is clinically relevant and medically necessary for the patient rather than what will illustrate that the appropriate visit level was reported. Although we proposed to no longer apply much of the E/M documentation guidelines involving history, physical exam and, for those choosing to document based on time, documentation of medical decision-making, we stated our expectation that practitioners would continue to perform as medically necessary for the patient and document E/M visits to ensure quality and continuity of care. For example, we believed that it remains an important part of care for the practitioner to understand the patient's social history, even though certain documentation options we proposed would no longer require that history to be re-documented to bill Medicare for the visit.

Comment: Many commenters supported the proposal to allow choice in documentation between the current framework, medical decision making or time. However, some commenters stated that such a policy would introduce too much variation in medical record format and content, or too many potential frameworks against which an auditor might review a claim. Commenters were unsure whether CMS envisioned the choice being made on a case-by-case basis or with some regularity. Other commenters noted that time alone is not an accurate measure of visit complexity or would be subject to gaming, or that CMS did not provide enough detail regarding time thresholds and documentation requirements to allow them to assess potential impact.

Many of the commenters did not support the proposal, as a corollary to our proposal to adopt a single payment amount for office-outpatient E/M visit levels 2 through 5, to apply a minimum level 2 documentation standard. These commenters were concerned that this standard would result in inadequate documentation for patient care, legal and other purposes. They noted that CMS overestimated the associated reduction in burden that would result from this proposal, and instead believe the level 2 documentation standard would reduce burden to a lesser degree than we estimated, or potentially increase burden. They indicated that there would be costs in terms of time and resources to update EHRs and train staff, and that they expected there would be the need to continue documenting many elements included in the current code definitions for patient care and other purposes, including other payers. Many commenters expressed concern that the documentation could potentially increase due to misalignment in documentation rules between payers, as they presume that Medicaid, commercial payers and secondary payers would not likely adopt Medicare's payment changes, at least not immediately. Several commercial payers or their associations expressed similar concerns and recommended implementing a more limited set of documentation changes and ongoing monitoring.

MedPAC and a few other commenters recommended paying for visits on the basis of time alone. MedPAC recommended requiring the time spent to be reported on the claim so CMS can collect data on current times actually spent and use it to more accurately set rates in the future.

A few commenters indicated what the time requirement should be when using time to document. Most of these commenters noted that CMS should require the typical time associated with the CPT code reported on the claim. One commenter who opposed the single payment rate stated that if CMS did finalize a single payment rate, then CMS should require only the time associated with the level 2 CPT codes (10 minutes for an established patient and 20 minutes for a new patient). Some commenters expressed support for requiring that this time be spent by the billing practitioner face-to-face with the patient, and a few commenters expressed support for allowing time spent by individuals other than the billing practitioner and/or time spent furnishing non-face-to-face care to count.

Response: For CY 2019 and 2020, we will continue the current coding and payment structure for E/M office/outpatient visits, and, therefore, practitioners should continue to use either the 1995 or 1997 versions of the E/M guidelines to document E/M office/outpatient visits billed to Medicare for 2019 and 2020 (with the exception of our final policy to eliminate redundant data recording).

We appreciate the issues raised by commenters but continue to believe our proposals allowing for flexibility in how E/M office/outpatient visit levels are documented and the applying of a minimum documentation standard as a corollary to establishing single payment rates for E/M office/outpatient visits will significantly reduce burden for clinicians and support them in making coding and documentation decisions that better align with current medical practice. Beginning in 2021, for E/M office/outpatient levels 2 through 5 visits, we will allow for flexibility in how visit levels are documented, allowing billing practitioners the choice to use the current framework, MDM or time. Specifically, for level 5 visits, for PFS payment purposes a practitioner can use the current framework with the documentation requirements applicable to a level 5 visit or the current definition of level 5 MDM. As an another alternative, the practitioner can document using time, which will require documentation of the medical necessity of the visit and that the billing practitioner personally spent at least the typical time associated with the level 5 CPT code that is reported face-to-face with the patient (40 minutes for an established patient and 60 minutes for a new patient). Since there will be no new intra-service time associated with the level 5 visit codes, we are finalizing our proposed alternative to use the typical time associated with the CPT code reported on the claim, consistent with current policy when counseling and/or coordination of care accounts for more than 50 percent of the face-to-face physician/patient encounter.

For E/M office/outpatient level 2 through 4 visits, in 2021 we will also allow choice of documentation methodology (current framework, MDM or time). For practitioners using the current documentation framework or

MDM, for PFS payment purposes, we will apply a minimum supporting documentation standard associated with E/M office/outpatient level 2 visits such that we only require documentation that is associated with the current level 2 CPT visit code (new or established patient, as applicable). For example, if the practitioner is choosing to document based on MDM alone, for PFS payment purposes we will only require documentation supporting straight forward medical decision-making measured by minimal problems, data review, and risk (two of these three). If choosing to document using time, for PFS payment purposes we will require the billing practitioner to document that the visit was medically reasonable and necessary and that the billing practitioner personally spent the current typical time for the CPT code reported (for example, 15 minutes when reporting CPT code 99213 (a level 3 established patient visit)). For administrative simplicity, it may be most straight forward to track to the typical time for the CPT code.

We address the public comments on our burden reduction estimate and changes to our estimate based on our final policies further below (see section VII. of this final rule, Regulatory Impact Analysis). We intend to engage in further discussions with the public over the next several years to potentially further refine our policies for 2021.

As we noted in the CY 2019 PFS proposed rule, we heard from a few commenters on the CY 2018 PFS proposed rule that some practitioners rely on unofficial Marshfield clinic or other criteria to help them document E/M visit levels. These commenters conveyed that the Marshfield ''point system'' is commonly used to supplement the E/M documentation guidelines, because of a lack of concrete criteria for certain elements of medical decision making in the 1995 and 1997 guidelines or in CPT guidance. Accordingly, in the CY 2019 PFS proposed rule, we solicited public comment on whether Medicare should use or adopt any aspects of other E/M documentation systems that may be in use among practitioners, such as the Marshfield tool. We were interested in feedback as to whether the 1995 and 1997 guidelines contain adequate information for practitioners to use in documenting visits under our proposals, or whether these versions of the guidelines would need to be supplemented in any way.

The following is a summary of the comments we received on whether Medicare should use or adopt any aspects of other E/M documentation systems that may be in use among practitioners, such as the Marshfield tool, and also whether the 1995 and 1997 guidelines contain adequate information for practitioners to use in documenting visits under our proposals, or whether these versions of the guidelines would need to be supplemented in any way.

Comment: We received a few comments clarifying how the Marshfield tool is currently used, but the commenters provided reasons not to use it as a replacement standard for current measures of visit complexity specified in the 1995 and 1997 documentation guidelines. A few commenters suggested new methods that could be used to support the level of E/M visit reported, such as risk adjustment with CMS's Hierarchical Condition Category scores used in Medicare Advantage; and some commenters recommended that CMS use medical decision making alone or in combination with time to distinguish visit/patient complexity. A few commenters recommended ways in which medical decision making could be relied upon, and ways that it should be changed, suggesting that history and physical exam might be incorporated with medical decision making. Many commenters recommended that CMS should continue to work with the AMA/CPT, specialty associations and other stakeholders to come up with revised measures of visit complexity, recommending between three to five levels.

Response: We appreciate commenters' feedback on this solicitation, and we considered it in the context of making a final decision. As stated previously, we are finalizing a significant reduction in the current payment variation in office/outpatient E/M visit levels by paying a single rate for E/M office/outpatient visit levels 2, 3, and 4 (one for established and another for new patients). However, we are not finalizing the inclusion of E/M office/outpatient level 5 visits in the single payment rate, in order to better account for the care and needs of particularly complex patients. Beginning in 2021, for E/M office/outpatient levels 2 through 5 visits, we will allow for flexibility in how visit levels are documented, specifically a choice to use the current framework, MDM or time, discussed previously. For E/M office/outpatient level 2 through 4 visits, in 2021 we will also apply a minimum supporting documentation standard associated with level 2 visits, also discussed previously. We intend to engage in further discussions with the public over the next several years to potentially further refine our policies for 2021.

(b) Removing Redundancy in E/M Visit Documentation

Stakeholders have recently expressed that CMS should not require documentation of information in the billing practitioner's note that is already present in the medical record, particularly with regard to history and exam. Currently, both the 1995 and 1997 guidelines provide such flexibility for certain parts of the history for established patients, stating, ''A Review of Systems ''ROS'' and/or a pertinent past, family, and/or social history (PFSH) obtained during an earlier encounter does not need to be re-recorded if there is evidence that the physician reviewed and updated the previous information. This may occur when a physician updates his/her own record or in an institutional setting or group practice where many physicians use a common record. The review and update may be documented by:

- Describing any new ROS and/or PFSH information or noting there has been no change in the information; and
- Noting the date and location of the earlier ROS and/or PFSH.

Documentation Guidelines ''DG'': The ROS and/or PFSH may be recorded by ancillary staff or on a form completed by the patient. To document that the physician reviewed the information, there must be a notation supplementing or confirming the information recorded by others (*https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/95Docguidelines.pdf*; *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/97Docguidelines.pdf*).

We proposed to expand this policy to further simplify the documentation of history and exam for established patients such that, for both of these key components, when relevant information is already contained in the medical record, practitioners would only be required to focus their documentation on what has changed since the last visit or on pertinent items that have not changed, rather than re-documenting a defined list of required elements such as review of a specified number of systems and family/social history. Practitioners would still review prior data, update as necessary, and indicate in the medical record that they had done so. Practitioners would conduct clinically relevant and medically necessary elements of history and physical exam, and conform to the general principles of medical record documentation in the 1995 and 1997 guidelines. However,

practitioners would not need to re-record these elements (or parts thereof) if there is evidence that the practitioner reviewed and updated the previous information.

Comment: Commenters were very supportive of this proposal. Many commenters included this proposal in a list of appropriate changes CMS should make immediately regarding documentation of E/M visits, effective January 1, 2019.

Response: We are finalizing this policy to simplify the documentation of history and exam for established patients for E/M office/outpatient visits as proposed, effective January 1, 2019. Accordingly, when relevant information is already contained in the medical record, practitioners may choose to focus their documentation on what has changed since the last visit, or on pertinent items that have not changed, and need not re-record the defined list of required elements if there is evidence that the practitioner reviewed the previous information and updated it as needed. Practitioners should still review prior data, update as necessary, and indicate in the medical record that they have done so. We note that this policy to simplify and reduce redundancy in documentation is optional for practitioners, and they may choose to continue the current process of entering, re-entering and bringing forward information (83 FR 35838). The option to continue current documentation processes may be particularly important for practitioners who lack time to adjust workflows, templates and other aspects of their work by January 1, 2019.

We solicited comment on whether there may be ways to implement a similar provision for any aspects of medical decision-making, or for new patients, such as when prior data is available to the billing practitioner through an interoperable EHR or other data exchange. We stated our belief that there would be special challenges in realizing documentation efficiencies with new patients, since they may not have received exams or histories that were complete or relevant to the current complaint(s), and the information in the transferred record could be more likely to be incomplete, outdated or inaccurate.

Comment: A few commenters indicated that there might be ways to recognize some documentation efficiencies for referred new patients or situations where data are available through an interoperable EHR, but did not provide detail about what kinds of data are commonly available and how they might be relevant to the receiving practitioner for purposes of visit documentation.

Response: We appreciate the commenters' feedback in this area and will continue to consider this issue.

We similarly proposed that for both new and established patients, practitioners would no longer be required to re-enter information in the medical record regarding the chief complaint and history that are already entered by ancillary staff or the beneficiary. The practitioner could simply indicate in the medical record that they reviewed and verified this information. Our goal was to allow practitioners more flexibility to exercise greater clinical judgment and discretion in what they document, focusing on what is clinically relevant and medically necessary for the patient.

Comment: Commenters were very supportive of this proposal. Many commenters included this proposal in a list of appropriate changes CMS should make immediately regarding documentation of E/M visits, effective January 1, 2019.

Response: We are finalizing our proposal that, effective January 1, 2019, for new and established patients for E/M office/outpatient visits, practitioners need not re-enter in the medical record information on the patient's chief complaint and history that has already been entered by ancillary staff or the beneficiary. The practitioner may simply indicate in the medical record that he or she reviewed and verified this information. We note that this policy to simplify and reduce redundancy in documentation is optional for practitioners, and they may choose to continue the current process of entering, re-entering and bringing forward information (83 FR 35838). The option to continue current documentation processes may be particularly important for practitioners who lack time to adjust workflows, templates and other aspects of their work by January 1, 2019.

(c) Podiatry Visits

As described in the CY 2019 PFS proposed rule (83 FR 35843), as part of our proposal to improve payment accuracy by creating a single PFS payment rate for E/M visit levels 2 through 5 (with one proposed rate for new patients and one proposed rate for established patients), we proposed to create separate coding for podiatry visits that are currently reported as E/M office/outpatient visits. We proposed that, rather than reporting visits under the general E/M office/outpatient visit code set, podiatrists would instead report visits under new G-codes that more specifically identify and value their services. We proposed to apply substantially the same documentation standards for these proposed new podiatry-specific codes as we proposed for other office/outpatient E/M visits.

If a practitioner chose to use time to document a podiatry office/outpatient E/M visit, we proposed to apply substantially the same rules as those we proposed for documenting on the basis of time for other office/outpatient E/M visits. For practitioners choosing to use time to provide supporting documentation for the podiatry visit, we would require documentation supporting the medical necessity of the visit and showing the total amount of time spent by the billing practitioner face-to-face with the patient. We solicited public comment on what that total time would be for payment of the proposed new podiatry G-codes. The typical times for these proposed codes were 22 minutes for an established patient and 28 minutes for a new patient, and we noted we could use these times. Alternatively, we noted we could apply the AMA's CPT codebook provision that, for timed services, a unit of time is attained when the mid-point is passed,[6] such that we would require documentation that at least 12 minutes for an established patient (more than half of 22 minutes) or at least 15 minutes for a new patient (more than half of 28 minutes) were spent face-to-face by the billing practitioner with the patient, to support making payment for these codes when the practitioner chose to document the visit using time. We solicited comment on the use of time as a basis for documentation of our proposed podiatric E/M visit codes, and whether we should adopt any of these approaches or further specify other requirements with respect to this proposed option for podiatric practitioners to document their visits using time.

Comment: We did not receive any comments on how the proposed podiatric codes should be documented. A few commenters noted that our proposal to apply the same documentation rules to the proposed new podiatric codes as for all other office/outpatient E/M visits demonstrated that these visits were essentially the same, and that podiatry should not be singled out for the creation of separate codes.

Response: We believe the absence of comments on our proposals for documentation of the proposed podiatric codes is due to a lack of general support for creation of the new

[6] 2017 CPT Codebook Introduction, p.xv.

codes to describe podiatric E/M visits, as noted below in the comment summary on that topic. As discussed below, we are not finalizing our proposal to create new codes to describe podiatric E/M visits, and accordingly, we are not finalizing any rules regarding documentation of those codes.

(3) Minimizing Documentation Requirements by Simplifying Payment Amounts

As we have explained above, and in prior rulemaking, we believe that the coding, payment, and documentation requirements for E/M visits are overly burdensome and no longer aligned with the current practice of medicine. We believe the current set of 10 CPT codes for new and established office-based and outpatient E/M visits and their respective payment rates no longer appropriately reflect the complete range of services and resource costs associated with furnishing E/M services to all patients across the different physician specialties, and that documenting these services using the current guidelines has become burdensome and out of step with the current practice of medicine. To alleviate the effects and mitigate the burden associated with continued use of the outdated CPT code set, we proposed to simplify the office-based and outpatient E/M payment rates and documentation requirements, and create new add-on codes to better capture the differential resources involved in furnishing certain types of E/M visits.

In conjunction with our proposal to reduce the documentation requirements for E/M visit levels 2 through 5, we proposed to simplify the payment for those services by paying a single rate for the level 2 through 5 E/M visits. The visit level of the E/M service is tied to the documentation requirements in the 1995 and 1997 Documentation Guidelines for E/M Services, which may not be reflective of changes in technology or, in particular, the ways that electronic medical records have changed documentation and the patient's medical record. Additionally, current documentation requirements may not account for changes in care delivery, such as a growing emphasis on team based care, increases in the number of recognized chronic conditions, or increased emphasis on access to behavioral health care. However, based on the feedback we have received from stakeholders, it was clear to us that the burdens associated with documenting the selection of the level of E/M service arise from not only the documentation guidelines, but also from the coding structure itself. Like the documentation guidelines, the distinctions between visit levels reflect a reasonable assessment of variations in care, effort, and resource costs as identified and articulated several decades ago. We believed that the most important distinctions between the kinds of visits furnished to Medicare beneficiaries are not well reflected by the current E/M visit coding. Most significantly, we have understood from stakeholders that current E/M coding does not reflect important distinctions in services and differences in resources. At present, we believed the current payment for E/M visit levels, generally distinguished by common elements of patient history, physical exam, and MDM, that may have been good approximations for important distinctions in resource costs between kinds of visits in the 1990s, when the CPT developed the E/M code set, are increasingly outdated in the context of changing models of care and information technologies.

As described earlier in this section, we proposed to change the documentation requirements for E/M levels such that practitioners have the choice to use the 1995 guidelines, 1997 guidelines, time, or MDM to determine the E/M level. We believed that these proposed changes would better reflect the current practice of medicine and represent significant reductions in burdens associated with documenting visits using the current set of E/M codes.

In alignment with our proposed documentation changes, we proposed to develop a single set of RVUs under the PFS for E/M office-based and outpatient visit levels 2 through 5 for new patients (CPT codes 99202 through 99205) and a single set of RVUs for visit levels 2 through 5 for established patients (CPT codes 99212 through 99215). Although we considered creating new HCPCS G-codes that would describe the services associated with these proposed payment rates, given the wide and longstanding use of these visit codes by both Medicare and private payers, we believed it would have created unnecessary administrative burden to propose new coding. Therefore, we instead proposed to maintain the current code set. Of the five levels of office-based and outpatient E/M visits, the vast majority of visits are reported as levels 3 and 4. In CY 2016, CPT codes 99203 and 99204 (or E/M visit level 3 and level 4 for new patients) made up around 32 percent and 44 percent, respectively, of the total allowed charges for CPT codes 99201–99205. In the same year, CPT codes 99213 and 99214 (or E/M visit level 3 and 4 for established patients) made up around 39 percent and 50 percent, respectively, of the allowed charges for CPT codes 99211–99215. If our proposals to simplify the documentation requirements and to pay a single PFS rate for new patient E/M visit levels 2 through 5 and a single rate for established patient E/M visit levels 2 through 5 were finalized, practitioners would still bill the CPT code for whichever level of E/M service they furnished and they would be paid at the single PFS rate. However, we believed that eliminating the distinction in payment between visit levels 2 through 5 would eliminate the need to audit against the visit levels, and therefore, would provide immediate relief from the burden of documentation. A single payment rate would also eliminate the increasingly outdated distinction between the kinds of visits that are reflected in the current CPT code levels in both the coding and the associated documentation rules.

In order to set RVUs for the proposed single payment rate for new and established patient office/outpatient E/M visit codes, we proposed to develop resource inputs based on the current inputs for the individual E/M codes, generally weighted by the frequency at which they are currently billed, based on the 5 most recent years of Medicare claims data (CY 2012 through CY 2017). Specifically, we proposed a work RVU of 1.90 for CPT codes 99202 through 99205, a physician time of 37.79 minutes, and direct PE inputs that sum to $24.98, each based on an average of the current inputs for the individual codes weighted by 5 years of accumulated utilization data. Similarly, we proposed a work RVU of 1.22 for CPT codes 99212 through 99215, with a physician time of 31.31 minutes and direct PE inputs that sum to $20.70. These inputs were based on an average of the inputs for the individual codes, weighted by volume based on utilization data from the past 5 years (CY 2012 through CY 2017). Tables 19 and 20 reflect the payment rates in dollars that would result from the approach described above were it to have been implemented for CY 2018. In other words, the dollar amounts in the charts below reflect how the changes we proposed for CY 2019 would have impacted payment rates for CY 2018.

TABLE 19—PRELIMINARY COMPARISON OF PAYMENT RATES FOR OFFICE VISITS

[New patients]

HCPCS code	CY 2018 non-facility payment rate	CY 2018 non-facility payment rate under the proposed methodology
99201	$45	$44
99202	76	135
99203	110	
99204	167	
99205	211	

TABLE 20—PRELIMINARY COMPARISON OF PAYMENT RATES FOR OFFICE VISITS

[Established patients]

HCPCS code	Current non-facility payment rate	Proposed non-facility payment rate
99211	$22	$24
99212	45	93
99213	74	
99214	109	
99215	148	

Although we believed that the proposed rates for E/M visit levels 2 through 5 represent the valuation of a typical E/M service, we also recognized that the current E/M code set itself does not appropriately reflect differences in resource costs between certain types of E/M visits. As a result, we believed that the way we currently value the resource costs for E/M services through the existing HCPCS CPT code set for office-based and outpatient E/M visits does not appropriately reflect the resources used in furnishing the range of E/M services that are provided through the current the practice of medicine. Based on stakeholder comments and examples and our review of the literature on E/M services, we identified three types of E/M visits that differ from the typical E/M visit and are not appropriately reflected in the current office/outpatient E/M code set and valuation. Rather, these three types of E/M visits can be distinguished by the mode of care provided and, as a result, have different resource costs. The three types of E/M visits that differ from the typical E/M service are (1) separately identifiable E/M visits furnished in conjunction with a global procedure, (2) primary care E/M visits for continuous patient care, and (3) certain types of specialist E/M visits, including those with inherent visit complexity. We addressed each of these distinguishable visit types in the proposed rule.

The following is a summary of the comments we received on the proposed blended payment rate for new and established office/outpatient E/M visit levels 2 through 5.

Comment: While many commenters agreed that the current E/M coding for office/outpatient visits is flawed and some agreed that the current coding and valuation systematically undervalues primary care visits and visits furnished in the context of non-procedural specialty care, most commenters opposed this proposal. Many commenters stated that using a single payment rate for new and established office/outpatient E/M visit levels 2 through 5 could have highly variable negative repercussions at the specialty, practice, and practitioner level. Some commenters suggested that the proposed single payment rate for these visits was inherently not resource-based. Many commenters stated that the proposed single payment rate that did not vary based on patient complexity from levels 2 through 5 was insufficient to account for the resource differential associated with treating complex patients, and that, without accurate payment, physicians would be likely to either schedule multiple visits or stop taking on complex patients all together.

The few commenters who supported the proposal stated that the negative payment implications of the single proposed payment rate are outweighed by the reduction in documentation burden. While acknowledging that the initial years following adoption of a single payment rate for the level 2 through 5 E/M visit codes would be challenging, these commenters noted that over time, potential reductions in payment would be offset by the time saved from unnecessary documentation. Other commenters, while urging CMS not to finalize the proposed single payment rate for these codes, did provide suggested alternative coding structures. Of these comments, there was a consensus that three levels of coding for office and outpatient E/M services is preferable to two, whether that be accomplished through blended payment rates for levels 2 through 3 and 4 through 5, or through a blended rate for levels 2 through 4. Most commenters pointed to the joint CPT/AMA E/M workgroup formed in response to CMS' proposal, and urged CMS to wait for forthcoming coding and documentation definitions generated by that group and recommendations regarding valuation developed through the RUC process.

Response: We appreciate the number and broad range of interested commenters who responded to our proposal. After reviewing all of the comments received, we understand the broad consensus regarding the potential negative implications of the proposal for patients with the most complex needs and the clinicians who serve them. In attempting to eliminate the reliance on the current outmoded E/M coding structure as it is used for purposes of payment, we recognize that the alternative coding and payment structure we proposed lacked an element that we agree is critical in making accurate payment: Namely, accounting for resource costs for the most complex patients. While we believe that our proposal to address the inherent complexity involved in furnishing certain kinds of care combined with our proposed payment for visits that take additional time might have accounted for a significant portion of the resource costs associated with particularly complex patients, we recognize the concerns expressed by commenters that these payment adjustments might be insufficient in some cases. We also recognize the potential negative consequences to clinicians and access to care that could result if we do not ensure that coding and payment appropriately account for patients with the most complex needs.

We do not believe, however, that appropriate care for complex patients currently requiring visit levels 2 through 4 are nearly as dependent on the current payment variations for these services. Given that the significant majority of the volume is concentrated in the level 3 and 4 new and established patient visits, we believe the concerns expressed by commenters about potential shifts in practitioner behavior would be likely to occur. We believe it would simply not be practical for clinicians to prioritize seeing the relatively few potential patients requiring level 2 visits in order to maximize their revenue relative to per patient costs. Likewise, because the level 4 established patient E/M visit is the most commonly reported code among the 5 levels for both new and established patients, any effort to avoid treating patients requiring care that is currently reported as a level 4 visit would likely result in significantly reduced volume and overall revenue for physician practices. We will, however, monitor utilization of these services and make any necessary adjustments through future rulemaking. Additionally, we recognize that because level 5 visits represent a very small proportion of visits reported under current E/M coding, maintaining

differential payment rates and documentation for these visits will strike an appropriate balance, simplifying and reducing the burden in distinguishing among CPT codes for the vast majority of E/M visits, while retaining a separate payment rate for the level of care furnished to the most complex patients.

On that basis, we are finalizing for 2021, a single payment rate for levels 2 through 4 E/M office/outpatient visits (one rate for new, and one for established patients) and maintaining separate payment rates for new and established patients for level 5 E/M office/outpatient visits to account for the most complex patients and visits. We are finalizing a policy, modified from our proposal, to develop a set of single payment rates for visit levels 2 through 4 (one each for new and established patients), instead of levels 2 through 5, as proposed. We are finalizing development of payment rates for levels 2 through 4 visits using the weighted average of the current inputs (work RVUs, direct PE inputs, time and specialty mix) assigned to the individual codes, based on the most recent 5 years of utilization for each of the constituent codes. For the level 1 and level 5 office/outpatient E/M visits we are finalizing payment rates that rely on current inputs. The inputs we will use (in the absence of intervening changes to CPT coding or the development of other considerations) to develop proposed values for these services for 2021 appear in the Table 21.

TABLE 21—FINALIZED INPUTS FOR E/M OFFICE/OUTPATIENT CODES FOR 2021

HCPCS	Physician time	Work RVU	Malpractice RVU	Sum of direct PE inputs
99201	17.00	0.48	0.05	$13.97
99202	34.43	1.76	0.17	24.37
99203	34.43	1.76	0.17	24.37
99204	34.43	1.76	0.17	24.37
99205	67.00	3.17	0.28	30.92
99211	7.00	0.18	0.01	11.31
99212	30.26	1.18	0.08	20.41
99213	30.26	1.18	0.08	20.41
99214	30.26	1.18	0.08	20.41
99215	55.00	2.11	0.14	27.83

We are also finalizing separate, add-on payments for visit complexity inherently associated with primary care and non-procedural specialty care, as well as separate payment for extended visits via HCPCS G-codes. These codes and the associated policies will be discussed in greater detail in the discussion below. We recognize that many commenters, including the AMA, the RUC, and specialties that participate as members in those committees, have stated intentions of the AMA and the CPT Editorial Panel to revisit coding for E/M office/outpatient services in the immediate future. We note that the 2-year delay in implementation will provide the opportunity for us to respond to the work done by the AMA and the CPT Editorial Panel, as well as other stakeholders. We will consider any changes that are made to CPT coding for E/M services, and recommendations regarding appropriate valuation of new or revised codes, through our annual rulemaking process.

(4) Recognizing the Resource Costs for Different Types of E/M Visits

As a corollary to our proposal to adopt a single payment rate for office and outpatient E/M services for level 2 through 5 E/M visits, we stated that we could better capture differential resource costs and minimize reporting and documentation burden by proposing several additional payment policies and ratesetting adjustments. These additional proposals were intended to reflect the important distinctions between the kinds of visits furnished to Medicare beneficiaries, and to reduce the burden of billing and documentation rules to effectuate payment.

In response to the CY 2018 comment solicitation on burden reduction for E/M visits (82 FR 53163 through 53166), we received several comments that highlighted the inadequacy of the E/M code set to accurately pay for the resources associated with furnishing visits, particularly for primary care visits, and visits associated with treating patients with particular conditions for which there is not additional procedural coding. One commenter stated that the current structure and valuation of the E/M code set inadequately describes the range of services provided by different specialties, and in particular primary care services. This commenter noted that although the 10 office/outpatient E/M codes make up the bulk of the services reported by primary care practitioners, the valuation does not reflect their particular resource costs. Another commenter pointed out that for specialties that principally rely on E/M visit codes to bill for their professional services, the complex medical decision making and the intensity of their visits is not reflected in the E/M code set or documentation guidelines.

In view of the comments we received, we proposed the following adjustments to better capture the variety of resource costs associated with different types of care provided in E/M visits: (1) An E/M multiple procedure payment adjustment to account for duplicative resource costs when E/M visits and procedures with global periods are furnished together; (2) HCPCS G-code add-ons to recognize additional relative resources for primary care visits and inherent visit complexity that require additional work beyond that which is accounted for in the single payment rates for new and established patient levels 2 through level 5 visits; (3) HCPCS G-codes to describe podiatric E/M visits; (4) an additional prolonged face-to-face services add-on HCPCS G-code; and (5) a technical modification to the PE methodology to stabilize the allocation of indirect PE for visit services.

(a) Accounting for E/M Resource Overlap Between Stand-Alone Visits and Global Periods

Under the PFS, E/M services are generally paid in one of two ways: As standalone visits using E/M visit codes, or included in global procedural codes. In both cases, RVUs are allocated to the services to account for the estimated relative resources involved in furnishing professional E/M services. In the case of procedural codes with global periods,

the overall resource inputs reflect the costs of the E/M work considered to be typically furnished with the procedure. Therefore, the standalone E/M visit codes are not billable on the same day as the procedure codes unless the billing professional specifically indicates that the visit is separately identifiable from the procedure.

In cases where a physician furnishes a separately identifiable E/M visit to a beneficiary on the same day as a procedure, payment for the procedure and the E/M visit is based on rates generally developed under the assumption that these services are typically furnished independently. In CY 2017 PFS rulemaking, we noted that the current valuation for services with global periods may not accurately reflect much of the overlap in resource costs (81 FR 80209). We were particularly concerned that when a standalone E/M visit occurs on the same day as a 0-day global procedure, there are significant overlapping resource costs that are not accounted for. We believe that separately identifiable visits occurring on the same day as 0-day global procedures have resources that are sufficiently distinct from the costs associated with furnishing one of the 10 office/outpatient E/M visits to warrant payment adjustment. There are other existing policies under the PFS where we reduce payments if multiple procedures are furnished on the same day to the same patient. Medicare has a longstanding policy to reduce payment by 50 percent for the second and subsequent surgical procedures furnished to the same patient by the same physician on the same day, largely based on the presence of efficiencies in PE and pre- and post-surgical physician work. Effective January 1, 1995, the MPPR policy, with the same percentage reduction, was extended to nuclear medicine diagnostic procedures (CPT codes 78306, 78320, 78802, 78803, 78806, and 78807). In the CY 1995 PFS final rule with comment period (59 FR 63410), we indicated that we would consider applying the policy to other diagnostic tests in the future. In the CYs 2009 and 2010 PFS proposed rules (73 FR 38586 and 74 FR 33554, respectively), we stated that we planned to analyze nonsurgical services commonly furnished together (for example, 60 to 75 percent of the time) to assess whether an expansion of the MPPR policy could be warranted. MedPAC encouraged us to consider duplicative physician work, as well as PE, in any expansion of the MPPR policy. Finally, in the CY 2011 PFS final rule with comment period, CMS finalized the application of the MPPR to always-therapy services on the justification that there was significant overlap in the PE portion of these services (75 FR 73233).

Using the surgical MPPR as a template, we proposed that, as part of our proposal to make payment for the E/M levels 2 through 5 at a single PFS rate, we would reduce payment by 50 percent for the least expensive global procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day as a separately identifiable E/M visit, currently identified on the claim by an appended modifier –25. We believed that the efficiencies associated with furnishing an E/M visit in combination with a same-day global procedure were similar enough to those accounted for by the surgical MPPR to merit a reduction in the relative resources of 50 percent. We estimated that, based on CY 2017 Medicare claims data, applying a 50 percent MPPR to E/M visits furnished as separately identifiable services on the same day as a global procedure would reduce expenditures under the PFS by approximately 6.7 million RVUs. To accurately reflect resource costs of the different types of E/M visits that we previously identified while maintaining work budget neutrality within this proposal, we proposed to allocate those RVUs toward the values of the add-on codes that reflect the additional resources associated with E/M visits for primary care and inherent visit complexity, similar to existing policies. As we articulated in the CY 2012 PFS final rule with comment period, where the aggregate work RVUs within a code family change but the overall actual physician work associated with those services does not change, we make work budget neutrality adjustments to hold the aggregate work RVUs constant within the code family, while maintaining the relativity of values for the individual codes within that set (76 FR 73105).

Comment: Many commenters opposed this proposal. Commenters generally objected to the underlying principle of the application of an MPPR to office/outpatient E/M codes billed on the same day as a minor procedure. Many of these commenters stated that the current billing rules allow these services to be billed only when modifier –25 is used, and that modifier makes it clear that the visits are significant and separately identifiable. Consequently, these commenters stated that no payment adjustment should apply. Many commenters pointed to the RUC review process wherein procedures that are typically furnished with a same day visit are subject to adjustments to account for any resource costs that the RUC considers to be typically duplicative. Commenters stated that by applying an MPPR adjustment to these services, CMS was making an unwarranted second adjustment to account for efficiencies the RUC already considers to be addressed. A few commenters stated that CMS provided insufficient rationale for the choice to propose a 50 percent payment reduction instead of other potential adjustments. Several commenters also pointed out that there are a number of 0-day global procedure codes that are valued not to include any evaluation and management, such as CPT codes 98925–98929 (Osteopathic manipulative treatment (OMT)). Commenters urged CMS to exempt these codes from the MPPR adjustment.

Many commenters, including both physician specialty organizations and patient advocacy groups, expressed concerns about how physicians would respond to the financial incentives resulting from the application of an MPPR adjustment in the context of patient care. Commenters noted that it is often convenient for both the beneficiary and the practitioner to address multiple concerns in a single visit. Many commenters stated that there would be a strong financial incentive to bring patients back for necessary visits on a different day so as to avoid triggering the payment reduction. This would result in inconvenience to the beneficiary, as they would experience treatment delays and be forced to return for a visit. Some commenters suggested this approach would result in additional cost sharing for patients.

Several commenters also highlighted programmatic concerns, stating that an MPPR adjustment would incentivize fractured care and undermine the goals of patient-centered and value-based care. Commenters also requested that CMS clarify whether certain other visits, such as the annual wellness visit, would also be subject to the MPPR adjustment. Others stated that inconsistent guidance, differing policies, and varying edits among the MACs would result in confusion and administrative burden in the implementation of this proposal.

A few commenters, including MedPAC, supported the proposal. MedPAC stated that when a standalone E/M visit occurs on the same day as a procedure, there are efficiencies (for example, in pre-service and post-service clinician work and practice expense) that are not accounted for in the current payment system. MedPAC concluded

that applying an MPPR to the procedure or visit would account for these efficiencies. Additional commenters suggested alternative percentages for the reduction, such as 5 percent or 25 percent. A few commenters stated that, if the MPPR were to be implemented, services performed by primary care specialties such as internal medicine, family practice, geriatrics, and pediatrics should be exempt.

Response: We appreciate commenters' feedback on this aspect of the proposal, particularly the comments regarding the potentially troublesome incentives and undesirable consequences associated with the financial incentives.

We continue to have significant concerns about the appropriate payment when codes with global periods, especially 0 and 10-day global periods, are billed on the same day as an E/M visit. Generally, we understand that the global codes are valued to include the typical amount of evaluation and management furnished to patients as part of the service. We understand that when these codes are reported, the –25 modifier is used with an E/M code to report a significant, separately identifiable E/M visit that is furnished on the same day. We also note that the CPT descriptor of the –25 modifier includes language suggesting that the modifier can be used whenever care beyond the usual preoperative and postoperative care associated with the procedure is performed. We note further that the values for global codes are intended to incorporate the typical amount of pre- and post-operative care. However, given the CPT description of the –25 modifier, a separately reportable visit could be billed in any case where the pre- or post-operative care exceeds the typical amount. In contrast, there does not appear to be a way to similarly account for cases where the needs of a particular patient require less than the typical amount of preoperative and postoperative work.

Although many commenters suggested that the overlapping resource costs between global codes and E/M visits billed on the same day have already been accounted for, we are not persuaded by the statements that the RUC process has achieved this goal, and we agree with MedPAC's assessment of the significant problem with valuation of codes that describe global services. We acknowledge and appreciate the efforts of the RUC to address overlaps when they recognize that a code is usually reported with a same day E/M visit. However, as observers to the RUC process, we have noted a general tendency for the RUC to recommend only minor adjustments in physician time and direct PE inputs to account for overlap. We also often make adjustments to the RUC recommended valuation in cases where the agency believes there is overlap between services frequently billed together that has not been adequately addressed through the RUC process. More importantly, even if the RUC valuation process better accounted for the overlapping resource costs, those adjustments would be made to national valuation of particular codes based on snapshot, national claims data for a given year, and would apply to all physicians reporting the services regardless of whether or not these particular physicians were achieving the efficiencies that occur when visits are reported on the same day as codes with global periods. Because this dynamic is an inherent part of valuation based on the typical case for discrete services, we routinely prioritize review of high-volume services. However, we believe the application of this methodology in valuing global services is particularly problematic because there are several thousand codes with global periods and it is impractical to conduct these kinds of code-level reviews as frequently as would be necessary to improve the accuracy of accounting for these efficiencies.

We agree with commenters that if practitioners began deliberately scheduling visits on separate days, when they could be furnished together on the same day, in order to avoid the payment adjustment that could create a significant undue burden for beneficiaries. We have heard this concern before regarding other MPPRs. We note that we have major concerns about this kind of manipulation of patient scheduling, especially as it relates to the fundamental requirement that Medicare payment may be made only for reasonable and necessary medical care, and intend to consider this concern more broadly for future rulemaking. Because we are obligated to develop PFS payments based on the relative resources involved in furnishing services, we believe the total of payments to practitioners for physicians' services from both Medicare and beneficiaries should reflect efficiencies inherent in furnishing two services that can be furnished together without prompting manipulative scheduling practices that result in inconvenience and potential medical risks to Medicare beneficiaries.

After consideration of the public comments, we recognize that we must balance concerns about appropriate valuation with the potential disruptions to patient care suggested by commenters. Though we find the possible practice of scheduling medical services to maximize payment without regard to patient needs or costs to be highly problematic, we take these concerns seriously given the broad-based consensus within the medical and stakeholder community regarding likely behavioral changes in response to the proposal. After weighing these concerns, we are not finalizing the proposal to apply an MPPR to a separately identifiable office/outpatient E/M visit furnished on the same day as a global procedure. We intend to consider ways to address the practice of scheduling patients to avoid payment adjustments in future rulemaking.

Given the variety of comments we received regarding the valuation of specific codes, especially codes with global periods that are perceived to include no resource costs associated with evaluation and management, we intend to reconsider the appropriate global period assigned to certain services. We welcome stakeholder input regarding appropriate global period assignment through our routine valuation processes. We will also continue to consider how to address what we believe to be a significant problem of accurately accounting for duplicative resource costs in ways that will protect Medicare beneficiaries' access to appropriate care.

(b) HCPCS G-Code Add-Ons To Recognize Additional Relative Resources for Certain Kinds of Visits

The distribution of E/M visits is not uniform across medical specialties. We have found that certain specialists, like neurologists and endocrinologists, for example, bill higher level E/M codes more frequently than procedural specialists, such as dermatologists. We believed this tendency reflects a significant and important distinction between the kinds of E/M visits furnished by professionals whose treatment approaches are primarily reported using visit codes versus those professionals whose treatment approaches are primarily reported using available procedural or testing codes. However, based on feedback we received from the medical professionals who furnish primary care and have visits with greater complexity, we did not believe the current visit definitions and the associated documentation burdens are the most accurate descriptions of the variation in work. Instead, we believed these professionals have been particularly burdened by the documentation requirements, given that so much of their medical treatment is

described imperfectly by relatively generic visit codes.

Similarly, stakeholders such as the commenters responding to the CY 2018 PFS proposed rule have articulated persuasively that visits furnished for the purpose of primary care also involve distinct resource costs. In developing this proposal, we consulted a variety of resources, including the American Academy of Family Physicians (AAFP) definition of primary care that states that the resource costs associated with furnishing primary care services particularly include time spent coordinating patient care, collaborating with other physicians, and communicating with patients (see *https://www.aafp.org/about/policies/all/primary-care.html*). Despite our efforts in recent years to pay separately for certain aspects of primary care services, such as through the chronic care management or the transitional care management services, the currently available coding still does not adequately reflect the full range of primary care services, nor does it allow payment to fully capture the resource costs involved in furnishing a face-to-face primary care E/M visit. We recognized that primary care services frequently involve substantial non-face-to-face work, and noted that there is currently coding available to account for many of those resources, such as chronic care management (CCM), behavioral health integration (BHI), and prolonged non-face-to-face services. In light of the existing coding, our proposal only addressed the additional resources involved in furnishing the face-to-face portion of a primary care service. As the point of entry for many patients into the healthcare system, primary care visits frequently require additional time for communicating with the patient, patient education, consideration and review of the patient's medical needs. We believed the proposed value for the single payment rate for the E/M levels 2 through 5 new and established patient visit codes does not reflect these additional resources inherent to primary care visits, as evidenced by the fact that primary care visits are generally reported using level 4 E/M codes. Therefore, to more accurately account for the type and intensity of E/M work performed in primary care-focused visits, we proposed to create a HCPCS add-on G-code that could be billed with the generic E/M code set to adjust payment to account for additional costs beyond the typical resources accounted for in the single payment rate for the levels 2 through 5 visits.

We proposed to create a HCPCS G-code for primary care services, HCPCS code GPC1X (Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to an established patient evaluation and management visit)). As we believe a primary care visit is partially defined by an ongoing relationship with the patient, this code would describe furnishing a visit to an established patient. HCPCS code GPC1X could also be reported for other forms of face-to-face care management, counseling, or treatment of acute or chronic conditions not accounted for by other coding. We noted that we believed the additional resources to address inherent complexity in E/M visits associated with primary care services are associated only with stand-alone E/M visits as opposed to separately identifiable visits furnished within the global period of a procedure. Separately identifiable visits furnished within a global period are identified on the claim using modifier –25, and would be subject to the MPPR. We noted that we created separate coding that describes non-face-to-face care management and coordination, such as CCM and BHI; however, these services describe non-face-to-face care and can be provided by any specialty as long as they meet the requirements for those codes. HCPCS code GPC1X was intended to capture the additional resource costs, beyond those involved in the base E/M codes, of providing face-to-face primary care services for established patients. HCPCS code GPC1X would be billed in addition to the E/M visit for an established patient when the visit includes primary care services. For HCPCS code GPC1X, we proposed a work RVU of 0.07, physician time of 1.75 minutes, no direct PE inputs, and an MP RVU of 0.01. This proposed valuation accounted for the additional resource costs associated with furnishing primary care that distinguishes E/M primary care visits from other types of E/M visits, and would maintain work budget neutrality across the office/outpatient E/M code set. Furthermore, the proposed add-on G-code for primary care-focused E/M services would help to mitigate potential payment instability that could result from our adoption of single payment rates that apply for E/M code levels 2 through 5. As this add-on G-code would account for the inherent resource costs associated with furnishing primary care E/M services, we anticipated that it would be billed with every primary care-focused E/M visit for an established patient. Although we expected that this code would mostly be utilized by the primary care specialties, such as family practice or pediatrics, we were also aware that, in some instances, certain specialists function as primary care practitioners—for example, an OB/GYN or a cardiologist. Although the definition of primary care is widely agreed upon by the medical community and we intended for this G-code to account for the resource costs of performing those types of visits, regardless of Medicare enrollment specialty, we also solicited comment on how best to identify whether or not a primary care visit was furnished, particularly in cases where a specialist is providing those services. For especially complex patients, we also expected that this G-code would be billed alongside the new code we proposed for prolonged E/M services described later in this section.

We also solicited comment on whether this policy adequately addresses the deficiencies in CPT coding for E/M services in describing current medical practice, and concerns about the impact on payment for primary care and other services under the PFS.

We also proposed to create a HCPCS G-code to be reported with an E/M service to describe the additional resource costs for specialty professionals for whom E/M visit codes make up a large percentage of their overall allowed charges and whose treatment approaches we believed are generally reported using the level 4 and level 5 E/M visit codes rather than procedural coding. Due to these factors, the proposed single payment rate for E/M levels 2 through 5 visit codes would not necessarily reflect the resource costs of those types of visits. Therefore, we proposed to create a new HCPCS code GCG0X (Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, or interventional pain management-centered care (Add-on code, list separately in addition to an evaluation and management visit)). Given their billing patterns, we believed that these are specialties that apply predominantly non-procedural approaches to complex conditions that are intrinsically diffuse to multi-organ or neurologic diseases. Although some of these specialties are surgical in nature, we believed these surgical specialties are providing increased non-procedural care of high complexity in the Medicare population. The high complexity of these services is reflected

in the large proportion of level 4 and level 5 visits that we believed are reported by these specialties, and the extent to which E/M visits are a high proportion of these specialties' total allowed charges. Consequently, these are specialties for which the resource costs of the visits they typically perform are not fully captured in the proposed single payment rate for the levels 2 through level 5 office/outpatient visit codes. When billed in conjunction with standalone office/outpatient E/M visits for new and established patients, the combined valuation more accurately accounts for the intensity associated with higher level E/M visits. To establish a value for this add-on service to be applied with a standalone E/M visit, we proposed a crosswalk to 75 percent of the work and time of CPT code 90785 (Interactive complexity), which would result in a work RVU of 0.25, no direct PE inputs, and an MP RVU of 0.01, as well as 8.25 minutes of physician time based on the CY 2018 valuation for CPT code 90785. Interactive complexity is an add-on code that may be billed when a psychotherapy or psychiatric service requires more resources due to the complexity of the patient. We believed that the proposed valuation for CPT code 90785 would be an accurate representation of the additional work associated with the higher level complex visits. We noted that we believed the additional resources to address inherent complexity in E/M visits are associated with stand-alone E/M visits. Additionally, we acknowledged that resource costs for primary care are reflected with the proposed HCPCS code GPC1X, as opposed to the proposed HCPCS code GCG0X. We note that there are additional codes available that include face-to-face and non-face-to-face work, depending on the code, that previously would have been considered part of an E/M visit, such as the codes for CCM, BHI, and CPT code 99483 (Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination; Medical decision making of moderate or high complexity; Functional assessment (*e.g.,* basic and instrumental activities of daily living), including decision-making capacity; Use of standardized instruments for staging of dementia (*e.g.,* functional assessment staging test [FAST], clinical dementia rating [CDR]); Medication reconciliation and review for high-risk medications; Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s); Evaluation of safety (*e.g.,* home), including motor vehicle operation; Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks; Development, updating or revision, or review of an Advance Care Plan; Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neuro-cognitive symptoms, functional limitations, and referral to community resources as needed (*e.g.,* rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 50 minutes are spent face-to-face with the patient and/or family or caregiver), which were developed to reflect the additional work of those practitioners furnishing primary care visits. Likewise, we proposed that practitioners in the specialty of psychiatry would not use either add-on code because psychiatrists may utilize CPT code 90785 to describe work that might otherwise be reported with a level 4 or level 5 E/M visit.

Given the broad scope of our proposals related to E/M services, we solicited feedback on any unintended consequences of those proposals. We also solicited comment on any other concerns related to primary care that we might consider for future rulemaking.

Comment: Many commenters stated that CMS needed to clarify the definition of primary care services that would fall under the scope of the primary care complexity add-on.

Some commenters suggested that ambiguity around the definition of the primary care add-on would create additional documentation burden and concern regarding audit risk. For example, many commenters presented examples of physicians of many different specialties furnishing particular services that might be considered to be primary care, such as when a dermatologist prescribes an anti-hypertensive medication, and what documentation would be required to justify billing of the add-on code.

In response to CMS' solicitation for accepted definitions of primary care, the AAFP stated that primary care services are performed by practitioners ''specifically trained for and skilled in comprehensive first contact and continuing care for persons with any undiagnosed sign, symptom, or health concern.'' The primary care physician ''provides definitive care to the undifferentiated patient at the point of first contact and takes continuing responsibility for providing the patient's comprehensive care.'' Because the definition of a primary care service hinges on the ongoing relationship with the patient, the AAFP recommended that the add-on code not be limited to established patients, but expanded to new patients when the physician has an expectation that an ongoing relationship will develop.

In response to CMS' request for comment on the circumstances when it would be appropriate for a specialist to bill for primary care services, the AAFP stated that while physicians who are not trained in the core primary care specialties can provide services focused on ''specific patient care needs related to prevention, health maintenance, acute care, chronic care, or rehabilitation'' but not within the context of ''comprehensive, first contact, and continuing care.'' Therefore, the AAFP stated that these practitioners were not providing primary care.

Response: We are appreciative of the concerns commenters shared regarding the potential risks of ambiguity in knowing when the code, as proposed, would be appropriately reported, and how the documentation would need to justify its appropriateness. The proposal to use an add-on code to account for the inherent complexity associated with primary care visits was intended to account for appropriate resource variation between primary care and other kinds of visits without imposing additional documentation to justify its being reported for each and every visit with a beneficiary. We note that this proposal was in keeping with our longstanding assessment that there are certain complexities inherent in furnishing some kinds of E/M visits that the current E/M coding and visit levels do not fully recognize. We also believe that in almost all cases where physicians and other professionals are furnishing primary care, information already in the medical record or on the claim, such as physician specialty, diagnosis codes, other service codes billed (chronic care or transitional care management services), or patient relationship codes would serve as sufficient documentation that the furnished visit met the primary care description. For example, we would expect that most practitioners enrolled in such specialties as family medicine, internal medicine, pediatrics, and geriatrics would be billing the primary care visit complexity add-on with every office/outpatient E/M visit. The visits themselves would still need to be

medically reasonable and necessary in order for the practitioner to report the service, and the documentation would need to illustrate medical necessity of the visit, but we believe the appropriateness of using the primary care add-on to the visit would not necessitate additional documentation. We also agree with the AAFP that billing this code should not be limited to established patients, as a primary care visit may also be a new patient visit where the expectation of an ongoing relationship is present.

For example, a 68-year-old woman with progressive congestive heart failure (CHF), diabetes and gout on multiple medications transfers care to a new primary care clinician. During a visit to establish care, the clinician discusses the patient's current health issues that includes confirmation that her CHF symptoms have remained stable over the past 3 months. She also denies symptoms to suggest hyper or hypoglycemia, but does note pain in her right wrist and knee. Based on the patient's history, physical exam findings and discussion, the clinician adjusts the dosage of some of the patient's medications, instructs the patient to take acetaminophen for her joint pain, request copies of prior diagnostic studies from his former providers, and orders laboratory tests to assess glycemic control, metabolic status and kidney function. The practitioner also discusses age appropriate prevention with the patient and orders a pneumonia vaccination and screening colonoscopy.

In this case, since the practitioner is furnishing care for conditions across a spectrum of diagnoses and organ systems and coordinating the patient's care among multiple health care providers, the practitioner would report the primary care resource add-on with the appropriate E/M code. We anticipate that the issues addressed by a physician will often track with the physician's specialty training. Therefore, it would not be unexpected for this physician to be reporting the primary care resource add-on code for almost all E/M visits, provided they are furnishing primary care during those visits. We would expect that claims records would include the billing physician's specialty and that the medical record would include the diagnoses for the patient, and the clinician's assessment and plan for that visit. This information would serve as sufficient documentation that the furnished visit met the primary care complexity description and so there would be no need to provide additional documentation.

We agree with AAFP that the vast majority of visits billed with the primary care complexity add-on would be performed by the previously mentioned specialties; however, we also recognize that there is not consensus among medical specialties on this definition. We also believe that there are clinical scenarios when a specialist may perform primary care. For example:

A cardiologist serving beneficiaries in a rural location provides care for complex cardiac conditions as well as primary care in her clinical practice. This practitioner sees a 75-year-old female with hypertension, coronary artery disease, and osteoarthritis for routine follow up care. During the visit, the patient describes a worsening pain in her hip and dizziness for the past month. The clinician notes gait instability and painful motion of her hip, and significant orthostasis upon standing. The clinician observes that the patient has made errors in filling her pill box, and has a new counter anti-histamine that the patient obtained from her friend to help with sleep. The clinician conducts a brief cognitive test, ascertains that the patient had not fallen, and recommends stopping the anti-cholinergic medication, and adjustment of her blood pressure medications with close follow-up monitoring. In addition to reviewing the patients' cardiac status, initiating imaging to evaluate the hip, the clinician also recommends a home safety evaluation and schedules a follow-up visit to include her adult daughter who lives nearby. In this case, since the clinician is furnishing primary care services as well as specialty cardiology services, the physician would appropriately be reporting the primary care complexity add-on in addition to the appropriate E/M visit code. We would expect that the claims record would include the billing physician's specialty. The medical record would also include the diagnoses for the patient and clinician's assessment and plan for that visit.

This information would serve as sufficient documentation that the furnished visit met the primary care and non-procedural specialty care complexity adjustment descriptions and so there would be no need to provide additional documentation.

Comment: Some commenters supported the creation of an add-on code for primary care visit complexity, but pointed out that, as proposed, the primary care add-on code was significantly undervalued, particularly in comparison to the add-on code for visit complexity associated with specialty care. Commenters were critical of the approach CMS used to value the proposed primary care add-on code. A few commenters suggested that CMS should equalize the values between the two add-on codes.

The AAFP did not support the add-on code, and instead suggested that CMS provide a 15 percent increase in payment to physicians who list their primary practice designation as family medicine, internal medicine, pediatrics, or geriatrics.

Response: The proposed valuation for the primary care complexity add-on code was based on the application of family budget neutrality to the proposed changes in other codes and payment policies—most notably applying an MPPR to E/M office/outpatient visit codes furnished in the same day as a procedure. While we continue to believe that budget neutrality within the code family can be an appropriate approach to assess relative resources under the PFS, we appreciate and agree with commenters' concerns regarding the asymmetry between the proposed values for the add-on codes for non-procedural specialty care complexity and primary care complexity. We also note that we are not finalizing the proposed multiple procedure payment adjustment for these E/M office/outpatient visit codes.

Comment: Many commenters did not support separate payment for an add-on code to account for the resource costs for the inherent complexity associated with furnishing non-procedural specialty visits. Commenters assumed that billing the visit complexity add-on code was limited to the specialties included in the code descriptor, constituting specialty-specific payment prohibited by statute. Commenters also stated that CMS was unclear about the rationale for which specialties were included in the code descriptor, and that the explanation provided was ambiguous and not clinically derived. Several commenters expressed concern that CMS did not include the work of a number of specialties that routinely furnish non-procedural specialist care and that primarily report that care through the office/outpatient E/M code set. Many commenters representing these specialties requested that CMS include them in the code descriptor. These include: Nephrology, infectious disease, gastroenterology, psychiatry, ophthalmology, pediatric ophthalmology, orthopedic surgery, sports medicine, neuro-ophthalmology, hepatology, interventional radiology, pulmonology, dermatology, medical oncology, Hematopoietic Cell Transplantation and Cellular Therapy (HCTCT), hospice, and palliative medicine. Some commenters also noted

that nurse practitioners are frequently specialized and recommended that they be eligible to bill for the specialty complexity add-on. A few commenters stated that Medicare enrollment specialty was a poor proxy for patient complexity, and that instead, CMS should rely on the patient's diagnosis. Several commenters did not agree with the proposed values for the add-on code, but none provided alternatives for CMS to consider.

Many commenters were also concerned about the documentation requirements that would be associated with the new coding, stating that CMS was replacing the burden of documenting the level of E/M visit with the burden of documenting proper use of the visit complexity add-ons. A few commenters did support the add-on codes in concept as a useful way of adjusting payment for different types of visits, although several commenters pointed out that the add-on codes were not valued sufficiently to overcome any reduction in payment due to the proposed single payment rate for visit levels. Commenters requested that CMS clarify whether the add-on codes could be billed concurrently for the same visit.

Response: We are appreciative of the concerns commenters shared regarding the potential risks of ambiguity in knowing when the code, as proposed, would be appropriately reported, and how the documentation would need to justify its appropriateness. The proposal to use an add-on code to account for the inherent complexity associated with non-procedural specialty care visits was intended to account for appropriate resource variation between non-procedural specialty care and other kinds of visits without imposing additional documentation to justify its being reported for each and every visit with a beneficiary. We noted that this proposal was in keeping with our longstanding assessment that there are certain complexities inherent in furnishing some kinds of E/M visits that the visit levels do not fully recognize. We also believed that in almost all cases where physicians and other professionals are furnishing specialty care that is centered around separately reportable office/outpatient visit codes (as opposed to procedural codes with global periods, for example), information already in the medical record or in the claims history for that practitioner, such as physician specialty, diagnosis codes, and/or other service codes billed (chemotherapy administration) would serve as sufficient documentation that the furnished visit met the description of non-procedural specialty care. For example, we would expect that most practitioners enrolled in the specialties used as descriptive examples in the proposed descriptor would report the complexity add-on with every office/outpatient E/M visit. The visits themselves would still need to be medically reasonable and necessary in order for the practitioner to report the service, and the documentation would need to illustrate medical necessity of the visit, but we believe the appropriateness of routinely using the add-on to the visit would not necessitate additional documentation for each and every visit.

A clinical scenario for the use of this proposed add-on code would be a 72-year-old female with colon cancer who sees her oncologist to discuss her treatment plan, including surgical and chemotherapeutic options. Since this E/M visit focuses on oncologic care, the physician would report the specialty care add-on in addition to the appropriate E/M visit code. It would not be unexpected for this physician to be reporting the non-procedural specialty care complexity add-on code for almost all E/M visits, provided they are providing oncologic care during those visits. We would expect that the claims record would include the billing physician's specialty. The medical record would also include the diagnoses for the patient and clinician's assessment and plan for that visit. This information would serve as sufficient documentation that the furnished visit met the description of non-procedural specialty care complexity and so there would be no need to provide additional documentation.

We also agree with commenters that the code descriptor omitted several specialties that provide this type of visit, such as nephrology, psychiatry, pulmonology, infectious disease, and hospice and palliative care medicine. We also believe that there are circumstances where specialties not included in the code descriptor would appropriately bill this add-on code for inherent visit complexity. As discussed previously, appropriate reporting of the specialty care resource add-on code should be apparent based on the nature of the clinical issues addressed at the E/M visit, and not limited by the practitioner's specialty.

In cases where appropriate reporting of the add-on code is not as apparent, we understand that some degree of visit-specific documentation might be necessary for purposes of demonstrating that the add-on code was reported appropriately. For example, a physician enrolled in Medicare as a pathologist may serve a broader role in a rural community, including furnishing primary care. In this instance, we expect that there would be documentation in the medical record to illustrate that it was appropriate for this physician to bill using the primary care complexity add-on. However, we do not believe that such scenarios would represent the majority of instances of appropriate use of the code. Additionally, we note that information usually included in medical documentation, combined with diagnosis coding, would likely suffice for purposes of documentation.

After consideration of the comments, we are finalizing for 2021 the proposal to introduce add-on codes that would adjust payment for new and established E/M office/outpatient visits to account for inherent complexity in primary care and non-procedural specialty care. We are finalizing the code descriptor for the add-on code for inherent complexity of E/M furnished primary care (HCPCS code GPC1X) as described in Table 22. We are also finalizing the code descriptor for the add-on code for inherent complexity of E/M furnished with non-procedural specialty care (HCPCS code GCG0X) in Table 22, and we note that we have included refinements to refer to additional kinds of non-procedural specialty care as suggested by commenters and clarifying that it could be reported for both new and established patients. We note that we are not including in the descriptor references to specialty care that routinely involves significant procedural interventions, such as interventional radiology and dermatology, since we do not agree with commenters that these kinds of specialty care are routinely considered to be ''non-procedural specialist care.'' However, we note that when clinical circumstances support it, practitioners not enrolled among the specialties expressly listed within the code descriptor may bill the inherent visit complexity add-on codes. We are also finalizing as proposed the code descriptor for inherent complexity of E/M furnished with primary care (HCPCS code GPC1X) with the refinement of including that it could be reported for both new and established patients. The add-on codes to account for inherent complexity in primary care and non-procedural specialty care could only be reported with E/M office/outpatient levels 2 through 4 visits. We note that for this and the other HCPCS G-codes we are finalizing for CY 2021, we are retaining the placeholder HCPCS code numbers until they are replaced through our standard process.

TABLE 22—FINALIZED CODE DESCRIPTORS FOR VISIT COMPLEXITY ADD-ONS

HCPCS	Descriptor
GPC1X	Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to level 2 through 4 office/outpatient evaluation and management visit, new or established).
GCG0X	Visit complexity inherent to evaluation and management associated with non-procedural specialty care including endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, interventional pain management, cardiology, nephrology, infectious disease, psychiatry, and pulmonology (Add-on code, list separately in addition to level 2 through 4 office/outpatient evaluation and management visit, new or established).

We again note that we are finalizing the add-on codes for primary care and non-procedural specialized care complexity adjustment, as well as other payment and coding changes to be implemented for E/M office/outpatient visits for CY 2021. We are specifying the later date, in great part, so that we have an opportunity to fully consider public comments and other important input from stakeholders on potential refinements in code and service definitions that can be used with ease, when appropriate, and by practitioners whom we currently believe are disproportionately burdened under the current coding and documentation requirements and, more generally, other important information involving coding and payment for E/M services.

After considering the public comments, we agree that the complexity associated with furnishing a primary care visit is equivalent to that associated with furnishing a non-procedural specialty care visit, and therefore, the two codes should be valued equally. We are finalizing, for 2021, the input values for these two codes as reflected in Table 23.

We note that these inputs reflect our proposed valuation of the non-procedural specialty complexity code, based on a modified crosswalk from CPT code 90785 as discussed in the CY 2019 PFS proposed rule (83 FR 35842).

TABLE 23—INPUTS FOR HCPCS CODES GCG0X AND GPC1X FINALIZED FOR 2021

HCPCS	Physician time	Work RVU	MP RVU
GCG0X	8.25	0.25	0.02
GPC1X	8.25	0.25	0.02

We also note that, while our policy will result in our inclusion of these input values in developing proposed rates for CY 2021, we also recognize that we routinely accept recommendations from the RUC and other stakeholders regarding appropriate valuation for PFS services, and would consider such recommendations regarding appropriate valuation for these services under our usual, annual process for receiving recommendations for PFS services.

In response to the commenters' concerns regarding the interactions between this code and the other codes that describe more complex E/M visits, we are clarifying that these add-on codes are intended to serve as a corollary to the single payment rate for E/M office/outpatient visit codes defined as levels 2 through 4 to provide for more appropriate recognition of the variations in resources involved in furnishing those services, and not to be used in association with E/M office/outpatient level 1 or level 5 visits.

While we believe that in most cases practitioners would only be reporting either the primary care complexity code or non-procedural specialty care complexity code, we believe there are some very rare circumstances where use of both codes might be appropriate. We return to our example of the cardiologist serving beneficiaries in a rural location who provides care for complex cardiac conditions as well as primary care in her clinical practice. Since the needs of the community prompt this physician to provide primary care services as well as specialty cardiology services, we would expect that she would report the primary care complexity add-on code and non-procedural specialty care complexity add-on code in addition to the appropriate E/M visit code when both primary care and non-procedural specialty care are furnished in connection with E/M visits.

(c) HCPCS G-Coded To Describe Podiatric E/M Visits

As described earlier, the vast majority of podiatric visits are reported using lower level E/M codes, with most E/M visits billed at a level 2 or 3, reflecting the type of work done by podiatrists as part of an E/M visit. Therefore, while the proposed consolidation of documentation and payment for E/M code levels 2 through 5 was intended to better reflect the universal elements of E/M visits across specialties and patients, we believed that podiatric E/M visits were not accurately represented by the consolidated E/M structure. In order for payment to reflect the resource costs of podiatric visits, we proposed to create two HCPCS G codes, HCPCS codes GPD0X (Podiatry services, medical examination and evaluation with initiation of diagnostic and treatment program, new patient) and GPD1X (Podiatry services, medical examination and evaluation with initiation of diagnostic and treatment program, established patient), to describe podiatric E/M services. Under this proposal, podiatric E/M services would be billed using these G-codes instead of the generic office/outpatient E/M visit codes (CPT codes 99201 through 99205 and 99211 through 99215). We proposed to create these separate G-codes for podiatric E/M services to differentiate the resources associated with podiatric E/M visits rather than propose a negative add-on adjustment relative to the proposed single payment rates for the generic E/M levels 2 through 5 codes. Therefore, we proposed to create separate coding to describe these services, taking into account that most podiatric visits are billed as level 2 or 3 E/M codes. We based the coding structure and code descriptor on CPT codes 92004 (Ophthalmological services: Medical examination and evaluation with initiation of diagnostic and treatment program; comprehensive, new patient, 1 or more visits) and 92012

(Ophthalmological services: Medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; intermediate, established patient), which describe visits specific to ophthalmology. To accurately reflect payment for the resource costs associated with podiatric E/M visits, we proposed a work RVU of 1.35, a physician time of 28.11 minutes, and direct PE inputs totaling $22.53 for HCPCS code GPD0X, and a work RVU of 0.85, physician time of 21.60 minutes, and direct PE inputs totaling $17.07 for HCPCS code GPD1X. These values were based on the average rate for the level 2 and 3 E/M codes (CPT codes 99201–99203 and CPT codes 99211–99212, respectively), weighted by podiatric volume.

Comment: Commenters opposed making separate payment for podiatric E/M visits using distinct coding. Commenters stated that, by creating separate coding and payment to describe these types of visits, CMS was singling out podiatrists and devaluing podiatric physicians' status among their peer physicians. Some commenters questioned the legality of our proposal since it would effectively pay physicians of different specialties different amounts for services that CPT considers to be the same. Furthermore, commenters stated that the proposed rates for podiatric E/M visits did not reflect the resource costs associated with providing podiatric care. Commenters also objected to the use of the ophthalmology visit codes as a precedent, stating that the significant practice expense associated with ophthalmologic visits was the impetus for separate coding for those services.

Response: Based on our consideration of the information presented by commenters, we are persuaded that there could be a perceived devaluation of the breadth and value of care associated with podiatric visits by use of separate coding for these visits. Given these potential negative consequences, we are not finalizing the proposal to adopt separate coding for podiatric E/M visits. However, as our discussion in the preceding sections reflects, we do not agree with the commenters that all office/outpatient visits furnished by physicians are only distinguishable by visit levels under the current CPT definitions. Instead, we believe that, like procedural services, visit services and their associated relative resource costs can vary greatly by the kind of care that is provided by particular physicians. We also believe that physician specialties can often reflect different approaches to medical care, and that the nomenclature used to describe and define various clinical specialties is useful for purposes of distinguishing among the types of services, including visits, furnished by physicians using these different approaches.

We also acknowledge that our proposal should have clearly articulated that we were not proposing to prohibit podiatrists from reporting the E/M office/outpatient visit codes under circumstances where those codes more accurately described visits with particular patients or, more broadly, visits generally furnished by particular podiatrists.

We also would like to note that our analysis of claims data indicates that the vast majority of podiatric visits are reported as level 2 and 3 visits. We believe that these claims data are an important piece of evidence regarding the relative resource costs of office/outpatient visits that are podiatric in nature. Therefore, we do not agree with the commenters that stated that our proposal did not reflect resource-based valuation, since we consider Medicare claims data to be one of the best sources of data regarding the resources involved in furnishing PFS services.

After considering the comments regarding this proposal, we are not finalizing our proposal to create separate coding for podiatric E/M services and establish payment rates for podiatric E/M visits based on historical billing patterns. We acknowledge the commenters' concerns that creating specific coding as we proposed could suggest a devaluation of services furnished by podiatrists. Therefore, we are not finalizing creation of specific coding and payment values for podiatric E/M visits. For CY 2021, podiatric E/M visits would be reported and paid using the E/M coding and payment structure applicable to other E/M office/outpatient visits.

(d) Adjustment to the PE/HR Calculation

As we explain in section II.B. of this final rule, Determination of Practice Expense (PE) Relative Value Units (RVUs), we generally allocate indirect costs for each code on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. Indirect expenses include administrative labor, office expense, and all other PEs that are not directly attributable to a particular service for a particular patient. Generally, the proportion of indirect PE allocated to a service is determined by calculating a PE/HR based upon the mix of specialties that bill for a service.

As described earlier, E/M visits comprise a significant portion of allowable charges under the PFS and are used broadly across specialties such that our proposed changes can greatly impact the change in payment at the specialty level and at the practitioner level. Our proposals sought to simplify payment for E/M visit levels 2 through 5, and to additionally take into consideration that there are inherent differences in primary care-focused E/M services and in more complex E/M services such that those visits involve greater relative resources, while seeking to maintain overall payment stability across specialties. However, establishing a single PFS rate for new and established patient E/M levels 2 through 5 would have a large and unintended effect on many specialties due to the way that indirect PE is allocated based on the mixture of specialties that furnish a service. The single payment rates proposed for E/M levels 2 through 5 could not reflect the indirect PE previously allocated differentially across those 8 codes. Historically, a broad blend of specialties and associated PE/HR has been used in the allocation of indirect PE and MP RVUs to E/M services to determine payment rates for these services. As this proposal would have significantly altered the PE/HR allocation for the office/outpatient E/M codes and any previous opportunities for the public to comment on the data would not have applied to these kinds of E/M services, we did not believe it was in the public interest to allow the allocation of indirect PE to have such an outsized impact on the payment rates for this proposal. Due to the magnitude of the proposed coding and payment changes for E/M visits, it was unclear how the distribution of specialties across E/M services would change. We were concerned that such changes could produce anomalous results for indirect PE allocations since we did not yet know the extent to which specialties would utilize the proposed simplified E/M codes and proposed G-codes. In the past, when utilization data are not available or do not accurately reflect the expected specialty mix of a new service, we have proposed to crosswalk the PE/HR value from another specialty (76 FR 73036). As such, we proposed to create a single PE/HR value for E/M visits (including all of the proposed HCPCS G-codes discussed above) of approximately $136, based on an average of the PE/HR across all specialties that bill these E/M codes, weighted by the volume of those specialties' allowed E/M services. We believed that this was consistent with

the methodology used to develop the inputs for the proposed simplified E/M payment for the levels 2 through 5 E/M visit codes, and that, for purposes of consistency, the new PE/HR should be applied across the additional E/M codes. We believed a new PE/HR value would more accurately reflect the mix of specialties billing both the generic E/M code set and the add-on codes. If we finalized this proposal, we would have considered revisiting the PE/HR after several years of claims data become available.

The following is a summary of the comments we received on this proposal.

Comment: Many commenters noted that the application of a single PE/HR value to E/M visit codes had significant, if unintended, consequences for the allocation of indirect PE across the PFS. Commenters also stated that CMS did not provide enough information as to how we arrived at the PE/HR value, which resulted in difficulty among external stakeholders in modeling the proposal.

Response: We appreciate commenters highlighting the broad ramifications of this proposal.

After consideration of these comments, we will not be finalizing a separate PE/HR for office/outpatient E/M visits.

(e) HCPCS G-Code for Extended Visit Services

Time is often an important determining factor in the level of care, which we consider in our proposal described earlier that physicians and other practitioners can use time as the basis for documenting and billing the appropriate level of E/M visit for purposes of Medicare payment. Currently there is inadequate coding to describe services where the primary resource of a service is physician time. CPT codes 99354 (Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; first hour (List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service)) and 99355 (Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (List separately in addition to code for prolonged service)) describe additional time spent face-to-face with a patient and may be billed when the applicable amount of time exceeds the typical service time of the primary procedure.

Stakeholders have informed CMS that the ''first hour'' time threshold in the descriptor for CPT code 99354 is difficult to meet and is an impediment to billing these codes (81 FR 80228). In response to stakeholder feedback and as part of our proposal to implement a single payment rate for E/M visit levels 2 through 5 while maintaining payment accuracy across the specialties, we proposed to create a new HCPCS code GPRO1 (Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; 30 minutes (List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service)). Given that the physician time of HCPCS code GPRO1 is half of the physician time assigned to CPT code 99354, we proposed a work RVU of 1.17, which is half the work RVU of CPT code 99354.

Comment: Many commenters, including the AMA, were supportive of the creation of this code in isolation from the rest of the E/M coding and payment proposals. Other commenters stated that the code was unnecessary, that current coding was sufficient to account for additional time spent with patients, and that it was unrealistic to expect that most physicians would be able to meet the time threshold in enough volume to offset the negative impacts of the single payment rate for E/M office/outpatient new and established patient visit levels 2 through 5. Some commenters suggested more documentation would be necessary to bill this new code. Many commenters also stated that referring to this code as ''prolonged services'' was inconsistent with coding conventions and CPT definitions, as the CPT Editorial Panel defined prolonged services as an unusual amount of time spent beyond the typical time and these commenters understood from the proposal that the code was intended to be reported more frequently. Many commenters stated that it would be difficult to assess how the code might be used without more specific guidelines regarding how time would be counted, particularly with regard to how many minutes would be assumed to be associated with the companion visit code and whether or not we adopt the usual CPT coding convention for appropriate reporting of the time-based code when over half the number of minutes (16 in this case) have been spent. Several commenters suggested that 16 minutes beyond the time associated with the proposed single payment rate (31 minutes as described by many of these commenters) would mean that the code could only be reported after 47 minutes spent with an established patient. These commenters suggested that that threshold would likely result in the code being used rarely.

Response: We agree with commenters that current coding describing prolonged services is not sufficient to capture additional time spent with patients, especially in the context of creating a single payment rate for office/outpatient E/M levels 2 through 4. We believe that time is a critical resource cost for physicians and other practitioners, and the time spent with patients is a great benefit to Medicare beneficiaries. We also note that we are required by statute to consider time, along with intensity, in establishing the work relative value units that determine PFS payments. We are therefore finalizing for 2021 separate payment for HCPCS code GPRO1, and are finalizing the input values as proposed.

We appreciate commenters' concerns regarding the current definitions and use of ''prolonged'' as applying to unusually long visits. We believe that time spent with patients ought to vary based on the particular needs of the patient and that variations in time spent face-to-face with the patient can be critical in defining differences between the services being furnished. Consequently, we agree that for many practitioners, times that extend beyond what we, or the CPT Editorial Panel, consider to be typical under the current visit code descriptors and definitions, might, in actual practice, be routine. We also note that many services, such as psychotherapy, are currently defined and paid based on the duration of the service.

However, since commenters have suggested that the term ''prolonged'' has been established in coding convention as applying only to unusually long visits as opposed to use in describing routine variations in the amount of time spent during visits with patients, we believe using an alternative term, like ''extended visit'' may serve to underscore our expectation that the length of some visits might exceed the typical length, but would not be unusual for certain practices or patients.

We also note that, for audit purposes, we would expect the medical record to reflect that the billing practitioner actually spent the amount of time with the patient described by the code and that the visit itself, in its entirety, was medically necessary; but we would not

expect additional documentation to demonstrate that the difference in time between the visit code and the extended visit code was, in isolation of the visit, medically necessary.

For CY 2021, we are finalizing a coding and payment policy to account for the additional resources required when practitioners need to spend extended time with their patients during particular E/M office/outpatient level 2 through 4 visits, regardless of the kind of care the practitioner is furnishing or whether or not the medical complexity of the visit is the determining factor for the length of visit. After considering the comments, we believe that 30 additional minutes (which, in accordance with CPT coding conventions for timed codes, can be reported after 15 additional minutes is spent with the patient) is an appropriate interval of time after which to reflect the additional resource costs associated with patient visits that require more time than is typical for the visit. After considering the questions and concerns expressed by commenters about how the new add-on code would be used, and in particular, the number of minutes that would serve as the basis for counting time toward an extended visit (for example, whether we would look to the typical time for the companion E/M code level and use the CPT coding convention for time-based codes), we acknowledge that it would not be workable to use the same conventions as are used for the prolonged service codes.

Under the current conventions used in reporting the existing prolonged service codes, the prolonged codes are defined by a set number of additional minutes beyond time associated with individual companion visit codes. For example, the initial prolonged services code describes 60 minutes of prolonged time beyond the time associated with the individual companion visit code. The current level 5 existing patient code is described by CPT as typically requiring 40 minutes with the patient, so that when reporting 99215 with the prolonged service code, the time being described is a total of 100 minutes (40 minutes for the level 5 code and 60 minutes for the initial prolonged code). Under applicable coding conventions, the code is reportable, when at least half the number of described minutes for the prolonged code is spent. This means that the initial prolonged service code can be reported with a level 5 existing patient code after 70 minutes (40 minutes for the full time associated with the level 5 visit and 30 minutes for half the number of minutes described by the initial prolonged service code).

We recognize that to implement use of either new or even the existing prolonged services code in the context of using a single payment rate for codes of varying levels, we would need to be clear about what time should be used for the companion visit codes. Currently, practitioners rely on the CPT ''typical'' times to determine the time for the visit codes of varying levels. This means that the thresholds for visit time required before the prolonged services can be reported are higher when higher level visits are reported in comparison to lower level visits. Under current payment rates, this situation is offset to some degree by the higher overall payment in circumstances where the higher level visit code is reported.

Because we are finalizing a single payment rate for levels 2–4, however, use of the ''typical'' CPT times as the basis for reporting add-on codes that describe additional time would mean that lower level visits that take more time would be paid at higher rates than higher visit rates that take the same amount of time. We believe that because we are paying a single rate for these services (as each of the codes describe a single ''typical'' for purposes of payment), we should also use a single number of minutes for purposes of reporting time-based add-on codes: The weighted average of the ''typical'' times associated with each of the codes that comprise the single payment rate.

One approach to implementing this would be to revise our billing rules to instruct practitioners to use the weighted average of the ''typical'' times associated with each of the codes that comprise the single payment rate, instead of the ''typical'' CPT times associated with the individual billed codes. We could apply this definition broadly to specify use of the weighted average typical times for level 2–4 codes regardless of whether or not they are being reported with time-based add-on codes, but we do not want to prevent practitioners from appropriately reporting visits based on the time defined as typical under the CPT code descriptors for office/outpatient E/M visits, especially since we are adopting a policy to allow clinicians to use time as the basis for documentation and code selection. Alternatively, we could require practitioners to use the weighted average of the ''typical'' times associated with each of the codes that comprise the single payment rate only in cases where time-based add-on codes are also being reported. However, we believe using two separate rules, especially one that deviates from the typical times established for the different visit levels that will continue to be routinely reported by a wide range of practitioners, would be likely to cause confusion.

After consideration of these issues and considering the alternatives, we are finalizing a code descriptor for the extended visit code that describes a single range of minutes that applies to the overall duration of face-to-face time during the visit, without regard to which level 2, 3, or 4 E/M office/outpatient visit was reported. This range is 34 to 69 minutes, so that the add-on code for extended visits would be appropriately reported in any case where a medically necessary E/M office/outpatient visit, reported using levels 2 through 4, required between 34 and 69 minutes (for established patients) and between 38 and 89 minutes (for new patients) of face-to-face time with the billing practitioner. We calculated the lower end of the range by summing the weighted average of intraservice times for the component codes that make up the single payment rate for level 2 through 4 visits (23 minutes for new and 19 minutes for established) and the additional amount of time required to bill the proposed add-on code (15 minutes under coding convention for prolonged services). The upper range of the use of the extended visit code is 69 minutes for established patients and 89 minutes for new patients.

We note that to report the current prolonged codes or the new extended services code, practitioners need to note that the requisite number of minutes were spent with the patient. We also note that we are finalizing the policy to allow practitioners the choice to use time as the basis for code selection for level 2 through 5 all office/outpatient E/M codes beginning in 2021 regardless of whether or not counseling and/or coordination of care accounts for more than 50 percent of the face-to-face physician/patient encounter. Under the new policy, then, any visits that exceed the length of the time ranges of the level 2 through 4 visit codes plus the extended visit code, could be reported using the level 5 visit code and the existing prolonged services code. Table 24A illustrates these rules:

TABLE 24A—MINUTES SPENT ON EXTENDED OUTPATIENT VISITS

[Established and new patients]

Established patient			New patient		
Level	Minutes spent	Codes reported	Level	Minutes spent	Codes reported
1	N/A		1	N/A	
2 ..... 3 ..... 4	34–69	99212/3/4+extended services G-code	2 ..... 3 ..... 4	38–89	99203/4/5+extended services G-code.
5	70+	99215+99354	5	90+	99205+99354.

The new extended services code will be described as GPRO1 (Extended time for evaluation and management service(s) in the office or other outpatient setting, when the visit requires direct patient contact of 34–69 total face-to-face minutes overall for an existing patient or 38–89 minutes for a new patient (List separately in addition to code for level 2 through 4 office or other outpatient Evaluation and Management service)). We again note that we are finalizing payment and coding changes to be implemented for E/M office/outpatient visits for CY 2021. We will consider any changes that are made to CPT coding, including for prolonged services, and recommendations regarding appropriate valuation of new or revised codes, through our annual rulemaking process.

In order to estimate the potential impact of the proposed changes in the proposed rule, we modeled the results of several options and examined the estimated resulting impacts in overall Medicare allowed charges by physician specialty. Because we are not finalizing many of the changes for CY 2019 as proposed, we believe the inclusion of those same discussions in this final rule is unnecessary and could potentially be confusing. We point readers to the CY 2019 PFS proposed rule, (83 FR 35844 through 35847) for discussion of the analyses relevant to the proposals. For analysis regarding the potential impacts of the alternatives considered in development of this final rule, we direct readers to the section VII. of this final rule, Regulatory Impact Analysis, in addition to the discussion that follows.

To compare the overall payment impact for the changes in payment for visit services between the current policy as of 2018 and the policies we are finalizing starting in 2021, we provide a narrative example in the paragraph below and Table 24B. In CY 2018, a physician would bill a level 4 E/M visit and document using the existing documentation framework for a level 4 E/M visit. The payment rate would be approximately $109 in the office setting. In CY 2021, the physician would bill the same visit code for a level 4 E/M visit, with the option to document the visit according to the minimum documentation requirements for a level 2 E/M visit if they choose to document based on MDM, or the 1995 or 1997 guidelines, or to document on the basis of time. The physician might also bill either of the proposed add-on codes (HCPCS codes GPC1X or GCG0X) depending on the type of patient care furnished, and could bill the extended services code if she met the time threshold for this code. The combined payment rate for the E/M visit code, plus the extended services code, and either HCPCS code GPC1X or GCG0X would be approximately $170.

TABLE 24B: Comparison of 2018 and 2021 Estimated National Payment Amounts for Visits

	Complexity Level under CPT	Visit Code	Visit Code	Visit Code With Either Primary or specialized care add-on code*	Visit Code with New Extended Services Code
New Patient	Level 2	$76	$130	$143	$197
	Level 3	$110			
	Level 4	$167			
	Level 5	$211	$212		
Established Patient	Level 2	$45	$90	$103	$157
	Level 3	$74			
	Level 4	$109			
	Level 5	$148	$149		

*In cases where one could bill both the primary and specialized care add-on, there would be an additional $13.

(f) Alternatives Considered

We considered a number of other options for simplifying coding and payment for E/M services to align with the proposed reduction in documentation requirements and to better account for the resources associated with inherent complexity, visit complexity, and visits furnished on the same day as a 0-day global procedure. As we are finalizing a policy very similar to one of the alternatives we considered for the proposed rule, we believe it would be confusing to include a detailed discussion of that policy as an alternative considered. We therefore direct interested readers to the CY 2019 PFS proposed rule (83 FR 35847).

Section 101(f) of the MACRA added a new subsection (r) under section 1848 of the Act entitled Collaborating with the Physician, Practitioner, and Other Stakeholder Communities to Improve Resource Use Measurement. Section 1848(r) of the Act requires the establishment and use of classification code sets: Care episode and patient condition groups and codes; and patient relationship categories and codes. As described in the CY 2018 PFS final rule, we finalized use of Level II HCPCS Modifiers as the patient relationship codes and finalized that Medicare claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018, should include the applicable patient relationship codes, as well as the NPI of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner). We noted that for CY 2018, reporting of the patient relationship modifiers would be voluntary and the use and selection of the modifiers would not be a condition of payment (82 FR 53234). The patient relationship codes are as follows: X1: Continuous/broad; X2: Continuous/focused; X3: Episodic/focused; X4: Episodic/broad; and X5: Only as ordered by another physician. These codes are to be used to help define and distinguish the relationship and responsibility of a clinician with a patient at the time of furnishing an item or service, facilitate the attribution of patients and episodes to one or more clinicians, and to allow clinicians to self-identify their patient relationships.

We considered proposing the use of the care episode and patient relationship codes to adjust payment for E/M visits to the extent that these codes are indicative of differentiated resources provided in E/M visits, and we considered using these codes as an alternative to the proposed use of G-codes to reflect visit complexity inherent to evaluation and management in primary care and certain other specialist services, as a way to more accurately reflect the resource costs associated with furnishing different kinds of E/M visits. We solicited comment on this alternative. We were particularly interested in whether the modifiers would accurately reflect the differences between resources for E/M visits across specialties and would therefore be useful to adjust payment differentially for the different types of E/M visits that we previously identified. The following is a summary of the comments we received on these items.

Comment: AAFP urged CMS not to use the patient relationship codes for the purposes of making differential payment, stating that these modifiers were never intended to adjust payment or reflect visit complexity, only to denote the relationship of the beneficiary and practitioner at any given encounter. One commenter stated that using patient relationship codes to adjust payment was an intriguing idea that should be researched further.

Response: We thank commenters for their input and will consider whether to adopt these codes for use to adjust payment at a later date through notice and comment rulemaking. We note, however, that we believe the use of the continuous care patient relationship codes stands as a good example of evidence in the claims record to support use of the primary care inherent complexity add-on code, as discussed previously.

In Table 24C, we estimate the specialty level impacts of the E/M payment and coding policies we are finalizing for 2021, calculated as if they were implemented for CY 2019.

TABLE 24C—ESTIMATED SPECIALTY LEVEL IMPACTS OF FINAL E/M PAYMENT AND CODING POLICIES IF IMPLEMENTED FOR 2019

(A) Specialty	(B) Allowed charges (mil)	(C) Impact of work RVU changes (%)	(D) Impact of PE RVU changes (%)	(E) Impact of MP RVU changes (%)	(F) Combined impact (%)
Allergy/Immunology	$239	0	0	0	0
Anesthesiology	1,981	−1	0	0	−2
Audiologist	68	−1	1	0	0
Cardiac Surgery	294	−1	−1	0	−2
Cardiology	6,618	−1	−1	0	−2
Chiropractor	754	−1	0	0	−1
Clinical Psychologist	776	−1	1	0	0
Clinical Social Worker	728	−2	2	0	0
Colon And Rectal Surgery	166	0	1	0	0
Critical Care	342	−2	−1	0	−3
Dermatology	3,486	1	3	0	4
Diagnostic Testing Facility	733	0	−5	0	−5
Emergency Medicine	3,121	−2	−1	0	−2
Endocrinology	482	−1	−1	0	−2
Family Practice	6,208	1	1	0	2
Gastroenterology	1,757	−2	−1	0	−3
General Practice	429	2	1	0	3
General Surgery	2,093	0	0	0	−1
Geriatrics	197	−1	−1	0	−1
Hand Surgery	214	1	1	0	3
Hematology/Oncology	1,741	0	−1	0	0
Independent Laboratory	646	−1	3	0	3
Infectious Disease	649	−1	−1	0	−1
Internal Medicine	10,767	0	0	0	0

TABLE 24C—ESTIMATED SPECIALTY LEVEL IMPACTS OF FINAL E/M PAYMENT AND CODING POLICIES IF IMPLEMENTED FOR 2019—Continued

(A) Specialty	(B) Allowed charges (mil)	(C) Impact of work RVU changes (%)	(D) Impact of PE RVU changes (%)	(E) Impact of MP RVU changes (%)	(F) Combined impact (%)
Interventional Pain Mgmt	868	1	2	0	3
Interventional Radiology	386	0	−2	0	−2
Multispecialty Clinic/Other Phys	149	−1	−1	0	−2
Nephrology	2,190	−1	−1	0	−2
Neurology	1,529	−1	0	0	−1
Neurosurgery	804	−1	−1	0	−1
Nuclear Medicine	50	−1	−1	0	−3
Nurse Anes/Anes Asst	1,242	−2	0	0	−2
Nurse Practitioner	4,065	2	1	0	3
Obstetrics/Gynecology	638	2	2	0	5
Ophthalmology	5,448	−1	−2	0	−3
Optometry	1,309	0	−1	0	−1
Oral/Maxillofacial Surgery	68	0	0	0	1
Orthopedic Surgery	3,743	0	1	0	1
Other	31	−1	3	0	2
Otolarngology	1,210	3	3	0	5
Pathology	1,165	−1	−1	0	−2
Pediatrics	61	1	0	0	1
Physical Medicine	1,107	−1	0	0	−2
Physical/Occupational Therapy	3,950	−1	−2	0	−3
Physician Assistant	2,457	2	1	0	4
Plastic Surgery	377	0	0	0	1
Podiatry	1,974	4	6	0	10
Portable X-Ray Supplier	99	0	0	0	0
Psychiatry	1,187	3	2	0	5
Pulmonary Disease	1,715	−1	−1	0	−2
Radiation Oncology And Radiation Therapy Centers	1,766	−1	−1	0	−1
Radiology	4,911	−1	−1	0	−2
Rheumatology	541	0	−1	0	−1
Thoracic Surgery	358	−1	−1	0	−2
Urology	1,738	2	3	0	4
Vascular Surgery	1,148	0	−2	0	−2
Total	92,771	0	0	0	0

Table 24C illustrates the estimated specialty level impacts associated with implementing our finalized policies for E/M coding and payment in CY 2019, rather than delaying until CY 2021. Table 24C shows the estimated impacts of adopting single payment rates for new and established patient E/M office/outpatient visit levels 2 through 4 (with the rates determined using input values that reflect the 5 year weighted average of current inputs for codes describing those visit levels), keeping separate rates for new and established patient E/M visit level 5 (with the rates determined using the current input values for level 5 visits), and adopting add-on codes with equal rates to adjust for the inherent visit complexity of primary care and non-procedural specialty care (with the rates determined using the input values from the proposed rule for the non-procedural specialty care complexity code). Under our finalized policies, specialties who disproportionately report lower level visits, such as podiatry, and specialties that report office/outpatient visits in conjunction with minor procedures, such as dermatology, would see the significant increases. Specialties that predominantly furnish higher level visits would have their payment decreases significantly mitigated by the maintenance of the level 5 visit and the add-on codes for inherent visit complexity for primary and non-procedural specialty care. Specialties that do not furnish office/outpatient visits generally would see modest reductions in overall payment.

We note that because our original proposal was developed more generally to maintain overall RVUs within the range of codes describing office/outpatient E/M visits, but, in response to public comment, we are not finalizing several elements of those proposals including, and especially, the multiple procedure payment reduction relating to global services billed with same day E/M services, the overall number of RVUs allocated to office/outpatient services would be increased relative to other PFS services. Under our established methodology and consistent with the governing statute, we usually apply a budget neutrality adjustment in the PFS conversion factor to account for the changes in overall RVUs. This adjustment would apply to all PFS services, and we are not finalizing any deviation from that approach for 2021. However, we also note that in some cases, we have proposed and finalized inputs for particular services that are designed to maintain the overall RVUs for those services despite changes in coding. For more detailed information on this approach to addressing valuation for families of services, we direct readers to the CY 2012 PFS final rule with comment period (76 FR 73105). We also note that while it has been our standard practice to avoid scaling the full set of work RVUs to maintain budget neutrality, we could also consider that alternative given the significance of office/outpatient visit codes in PFS relativity. Were we to consider either of these alternative

approaches for 2021, we would address them through future rulemaking.

g. Emergency Department and Other E/M Visit Settings

As we mentioned above, the E/M visit code set is comprised of individual subsets of codes that are specific to various clinical settings including office/outpatient, observation, hospital inpatient, emergency department, critical care, nursing facility, domiciliary or rest home, and home services. Some of these code subsets have three E/M levels of care, while others have five. Some of these E/M code subsets distinguish among levels based heavily on time, while others do not. Recent public comments have noted that some E/M code subsets intersect more heavily than others with hospital conditions of participation (CoP). For example, the American Psychiatric Association (APA) submitted a letter to CMS indicating that Medicare requires specific documentation in the medical record as part of the CoPs for inpatient psychiatric facilities. The APA believed that the required initial psychiatric evaluation for inpatients currently closely follows the E/M criteria for CPT codes 99221–99223, which are the codes that would be used to bill for these services. The APA stated that any changes in these E/M codes, without corresponding changes in the CoPs, could lead to the unintended consequence of adding to the burden of documentation by essentially requiring two different sets of data or areas of focus to be included, or two different documentation formats being required.

Regarding emergency department visits (CPT codes 99281–99285), we received more recent feedback through our coordinated efforts with ONC this year, emphasizing that these codes may benefit from a coding or payment compression into fewer levels of codes, or that documentation rules may need to be reduced or altered. However, in public comments to the CY 2018 PFS proposed rule, commenters noted several issues unique to the emergency department setting that we believe require further consideration. For example, commenters stated that intensity, and not time, is the main determinant of code level in emergency departments. They requested that CMS use caution in changing required elements for documentation so that medical information used for legal purposes (for example, meeting the prudent layperson standard) is not lost. They urged caution and requested that CMS not immediately implement any major changes. They recommended refocusing documentation on presenting conditions and medical decision-making. Some commenters were supportive of leaving it largely to the discretion of individual practitioners to determine the degree to which they should perform and document the history and physical exam in the emergency department setting. Other commenters suggested that CMS encourage use of standardized guidelines and minimum documentation requirements to facilitate post-treatment evaluation, as well as analysis of records for various clinical, legal, operational and other purposes. The commenters discussed the importance of extensive histories and exams in emergency departments, where usually there is no established relationship with the patient and differential diagnosis is critical to rule out many life-threatening conditions. They were cognizant of the need for a clear record of services rendered and the medical necessity for each service, procedure, diagnostic test, and MDM performed for every patient encounter.

In addition, although the RUC is in the process of revaluing this code set, some commenters stated that the main issue is not that the emergency department visit codes themselves are undervalued. Rather, these commenters noted that a greater percentage of emergency department visits are at a higher acuity level, yet payers often do not pay at a higher level of care and the visit is often inappropriately down-coded based on retrospective review. These commenters noted that the documentation needed to support a higher level of care is too burdensome or subjective. In addition, it seems that policy proposals regarding emergency department visits billed by physicians might best be coordinated with parallel changes to payment policy for facility billing of these codes, which would require more time and analyses.

Accordingly, we did not propose any changes to the emergency department E/M code set or to the E/M code sets for settings of care other than office-based and outpatient settings at this time. However, we solicited public comment on whether we should make any changes to it in future years, whether by way of documentation, coding, and/or payment and, if so, what the changes should be.

Consistent with public feedback to date, we are taking a step-wise approach and limiting our policy proposals this year to the office/outpatient E/M code set (and the limited proposal above regarding documentation of medical necessity for home visits in lieu of office visits). We may consider expanding our efforts more broadly to additional sections of the E/M visit code set in future years, and solicited public comment broadly on how we might proceed in this regard.

We received a few comments on this solicitation. We thank the commenters for their feedback and will take it into account for future rulemaking.

(h) Implementation Date

We proposed that our proposed E/M visit policies would be effective January 1, 2019. However, we were sensitive to commenters' suggestions that we should consider a multi-year process and proceed cautiously, allowing adequate time to educate practitioners and their staff; and to transition clinical workflows, EHR templates, institutional processes and policies (such as those for provider-based practitioners), and other aspects of practitioner work that would be impacted by these policy changes. We emphasized that our proposed documentation changes for office/outpatient E/M visits would be optional, and practitioners could choose to continue to document these visits using the current framework and rules, which may reduce the need for a delayed implementation. Nevertheless, practitioners who choose a new documentation framework may need time to deploy it. A delayed implementation date for our documentation proposals would also allow the AMA time to develop changes to the CPT coding definitions and guidance prior to our implementation, such as changes to MDM or code definitions that we could then consider for adoption. It would also allow other payers time to react and potentially adjust their policies. Accordingly, we solicited comment on whether a delayed implementation date, such as January 1, 2020, would be appropriate for our proposals.

Comment: With the exception of several documentation proposals, most of the commenters urged us not to finalize the E/M visit proposals, or to delay their implementation by at least one year. With the exception of our proposals regarding home E/M visits and reducing redundant recording of data, most commenters recommended that CMS engage in further work with the AMA and other stakeholders in the coming months to develop alternative approaches. Many commenters noted that our proposals regarding home E/M visits and reducing redundant recording of data would not impact payment or require extensive training or other extended preparatory time. The commenters largely recommended that CMS finalize these proposals for 2019,

but defer other documentation, coding and payment reforms to future years after obtaining additional stakeholder input. Some commenters did recommend that CMS finalize the proposed policy to allow choice among documentation methodologies while working with stakeholders to refine any coding and payment changes. A few commenters were supportive of a minimum level 2 documentation standard and intimated that this could be accomplished without changes to coding or payment, but other commenters opposed this approach.

Many stakeholders, including some commercial insurers and EHR-related associations, commented that if CMS were to finalize its proposals, the industry would need more time to prepare and CMS should delay implementation a year or more. Some commenters noted that CMS should consider not setting a date for implementation until the necessary structure is in place. Most commenters, including some insurers, urged CMS to work with the AMA or other stakeholders on alternative policies. For example, some insurers were concerned that the proposals would not allow them to understand the true complexity of care being delivered and recommended that documentation requirements should continue to be linked to complexity and, if the proposal were finalized, CMS would need to monitor various program integrity issues. They were concerned that the collapsed payment rate for level 2 through 5 E/M visits would disincentivize treatment of complex patients. Some health plans expressed concern that medical record data used to inform their payments and risk adjustment and HEDIS scores might be impacted. In response to our proposed rule, several organizations stated they are forming workgroups to conduct data analysis and develop policy alternatives, including the AMA and the Cognitive Care Alliance. The American Health Insurance Plans believed documentation requirements should continue to be linked to complexity.

Commenters were concerned there would not be enough time for developers and clinicians to make changes, leading to confusion in the market and disparate systems with other payers, in addition to other concerns about the coding and payment proposals discussed further below. The commenters were concerned about not having enough time to develop differing documentation based on payer status, and said that the burden on the clinician to determine which payer and which documentation method should not be underestimated.

Response: After consideration of public comments, we are not finalizing aspects of our proposal that would have reduced payment when E/M office/outpatient visits are furnished on the same day as certain procedures, established separate podiatric E/M visit codes, or standardized the allocation of PE RVUs for E/M visit codes. After considering the comments, for 2019 we are finalizing several of our documentation proposals that will provide some significant and immediate burden reduction but are unrelated to changes to payment and coding. Specifically, we are finalizing the proposals regarding home visits and redundant data recording (discussed above), as proposed and effective January 1, 2019. We are delaying implementation of our other final policies relating to payment for E/M visits to January 1, 2021.

J. Teaching Physician Documentation Requirements for Evaluation and Management Services

1. Background

Per 42 CFR part 415, subpart D, Medicare Part B makes payment under the PFS for teaching physician services when certain conditions are met, including that medical record documentation must reflect the teaching physician's participation in the review and direction of services performed by residents in teaching settings. Under § 415.172(b), for certain procedural services, the participation of the teaching physician may be demonstrated by the notes in the medical records made by a physician, resident, or nurse; and for E/M visits, the teaching physician is required to personally document their participation in the medical record. We received stakeholder feedback suggesting that documentation requirements for E/M services furnished by teaching physicians are burdensome and duplicative of notations that may have previously been included in the medical records by residents or other members of the medical team.

2. Implementation

We proposed to revise our regulations to eliminate potentially duplicative requirements for notations that may have previously been included in the medical records by residents or other members of the medical team. These modifications are intended to align and simplify teaching physician E/M service documentation requirements. We believed these changes would reduce burden and duplication of effort for teaching physicians. We proposed to amend § 415.172(b) to provide that, except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document that the teaching physician was present at the time the service is furnished. Additionally, the revised paragraph would specify that the presence of the teaching physician during procedures and E/M services may be demonstrated by the notes in the medical records made by a physician, resident, or nurse. We also proposed to amend § 415.174, by deleting paragraph (a)(3)(v) which requires the teaching physician to document the extent of their participation in the review and direction of the services furnished to each beneficiary. We proposed to add new paragraph (a)(6) to § 415.174 to provide that the medical record must document the extent of the teaching physician's participation in the review and direction of services furnished to each beneficiary, and that the extent of the teaching physician's participation may be demonstrated by the notes in the medical records made by a physician, resident, or nurse.

Comment: Many commenters supported the proposed regulatory changes without modifications.

Response: We appreciate the commenters' support of our proposals.

Comment: Some commenters disagreed with the proposed changes and indicated teaching physicians should continue to be personally responsible for documenting their physical presence and for verification with patients of all medical team members' documentation as it relates to the patient encounters. The commenters were concerned that the proposed changes would shift the documentation burden and responsibility from the teaching physician to the resident or nurse who has a limited number of hours of work. One commenter stated that the nurse would not be an inherent party to the teaching physician's or resident's involvement in an E/M service.

Response: While we appreciate the commenters' concerns, the purpose of these revisions to the regulations is to eliminate potentially duplicative requirements for notations that may have previously been included in the medical records by residents or other members of the medical team. The teaching physician continues to be

responsible for reviewing and verifying the accuracy of notations previously included by residents and members of the medical team, along with further documenting the medical record if the notations previously provided did not accurately demonstrate the teaching physician's involvement in an E/M service. After consideration of the comments received, we are finalizing the proposed changes to §§ 415.172(b) and 415.174 without modification.

K. GPCI Comment Solicitation

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years. Section 1848(e)(1)(D) of the Act requires us to establish the GPCIs using the most recent data available. The last GPCI update was implemented in CY 2017; therefore, we are required to review and make any necessary revisions to the GPCIs for CY 2020. Please refer to the CY 2017 PFS final rule with comment period for a discussion of the last GPCI update (81 FR 80261 through 80270). Some commenters have continued to express concerns regarding some of the data sources used in developing the indices for PFS geographic adjustment purposes, specifically that we use residential rent data as a proxy for commercial rent in the rent index component of the PE GPCI—that is, the data that are used to develop the office rent component of the PE GPCI. We will continue our efforts to identify a nationally representative commercial rent data source that could be made available to CMS. In support of that effort, we were particularly interested in, and solicited comments regarding potential sources of commercial rent data for potential use in the next GPCI update for CY 2020.

We received a few comments in response to the comment solicitation, and we appreciate the commenters' feedback and input. We will consider the suggestions and information received for future rulemaking, and in particular for the CY 2020 statutorily required update to the GPCIs.

L. Therapy Services

1. Repeal of the Therapy Caps and Limitation To Ensure Appropriate Therapy

Section 50202 of the Bipartisan Budget Act of 2018 amended section 1833(g) of the Act, effective January 1, 2018, to repeal the application of the Medicare outpatient therapy caps and the therapy cap exceptions process while retaining and adding limitations to ensure therapy services are furnished when appropriate. Section 50202 also adds section 1833(g)(7)(A) of the Act which requires that after expenses incurred for the beneficiary's outpatient therapy services for the year have exceeded one or both of the previous therapy cap amounts, all therapy suppliers and providers must continue to use an appropriate modifier such as the KX modifier on claims for subsequent services in order for Medicare to pay for the services. We implemented this provision by continuing to use the existing KX modifier. By applying the KX modifier to the claim, the therapist or therapy provider is confirming that the services are medically necessary as justified by appropriate documentation in the medical record. Just as with the incurred expenses for the prior therapy cap amounts, there is one amount for physical therapy (PT) and speech language pathology (SLP) services combined and a separate amount for occupational therapy (OT) services. These KX modifier threshold amounts are indexed annually by the Medicare Economic Index (MEI). For CY 2018, the KX modifier threshold amount was $2,010 for PT and SLP services combined, and $2,010 for OT. After the beneficiary's incurred expenditures for outpatient therapy services exceed the KX modifier threshold amount for the year, claims for outpatient therapy services without the KX modifier are denied.

Along with the KX modifier thresholds, section 50202 also adds section 1833(g)(7)(B) of the Act that retains the targeted medical review (MR) process (first established through section 202 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)), but at a lower threshold amount of $3,000. For CY 2018 (and each successive calendar year until 2028, at which time it is indexed annually by the MEI), the MR threshold is $3,000 for PT and SLP services and $3,000 for OT services. The targeted MR process means that not all claims exceeding the MR threshold amount are subject to review as they once were.

Section 1833(g)(8) of the Act, as re-designated by section 50202 of the Bipartisan Budget Act of 2018, retains the provider liability procedures which first became effective January 1, 2013, extending limitation of liability protections to beneficiaries who receive outpatient therapy services, when services are denied for certain reasons, including failure to include a necessary KX modifier.

2. Payment for Outpatient PT and OT Services Furnished by Therapy Assistants

Section 53107 of the Bipartisan Budget Act of 2018 (BBA of 2018) amended the Act to add a new subsection 1834(v) that addresses payment for outpatient therapy services for which payment is made under section 1848 or section 1834(k) of the Act that are furnished on or after January 1, 2022, in whole or in part by a therapy assistant (as defined by the Secretary). The new section 1834(v)(1) of the Act provides for payment of those services at 85 percent of the otherwise applicable Part B payment amount for the service. In accordance with section 1834(v)(1) of the Act, the reduced payment amount for such outpatient therapy services is applicable when payment is made directly under the PFS as specified in section 1848 of the Act, for example when payment is made to therapists in private practice (TPPs); and when payment is made based on the PFS as specified in section 1834(k)(3) of the Act, for example, when payment is made for outpatient therapy services identified in sections 1833(a)(8) and (9) of the Act, including payment to providers that submit institutional claims for therapy services such as outpatient hospitals, rehabilitation agencies, skilled nursing facilities, home health agencies and comprehensive outpatient rehabilitation facilities (CORFs). The reduced payment rate under section 1834(v)(1) of the Act for outpatient therapy services when furnished in whole or in part by a therapy assistant is not applicable to outpatient therapy services furnished by critical access hospitals for which payment is made as specified in section 1834(g) of the Act.

To implement this payment reduction, section 1834(v)(2)(A) of the Act requires us to establish a new modifier, in a form and manner specified by the Secretary, by January 1, 2019 to indicate, in the case of an outpatient therapy service furnished in whole or in part by a therapy assistant, that the service was furnished by a therapy assistant. Although we generally consider all genres of outpatient therapy services together (PT/OT/SLP), we did not believe there are therapy assistants in the case of SLP services, so we proposed to apply the new modifier only to services furnished in whole or in part by a physical therapist assistant (PTA) or an occupational therapy assistant (OTA). Section 1834(v)(2)(B) of the Act requires that each request for payment or bill submitted for an outpatient PT or OT

service furnished in whole or in part by a therapy assistant on or after January 1, 2020, must include the established modifier. As such, the modifier will be required to be reported on claims for outpatient PT and OT services with dates of service on and after January 1, 2020, when the service is furnished in whole or in part by a therapy assistant, regardless of whether the reduced payment under section 1834(v)(1) of the Act is applicable. However, the required payment reductions do not apply for these services until January 1, 2022, as required by section 1834(v)(1) of the Act.

To implement this provision, we proposed to establish two new modifiers to separately identify PT and OT services that are furnished in whole or in part by PTAs and OTAs, respectively. We proposed to establish two modifiers because the incurred expenses for PT and OT services are tracked and accrued separately in order to apply the two different KX modifier threshold amounts as specified by section 1833(g)(2) of the Act; and the use of the two proposed modifiers would facilitate appropriate tracking and accrual of services furnished in whole or in part by PTAs and OTAs. We additionally proposed that these two new therapy modifiers would be added to the existing three therapy modifiers—GP, GO, and GN—that are currently used to identify all therapy services delivered under a PT, OT or SLP plan of care, respectively. The addition of the two new modifiers as therapy modifiers would bring the total to five therapy modifiers, with four therapy modifiers used to report and track PT and OT services, instead of two. The GP, GO, and GN modifiers have existed since 1998 to track outpatient therapy services that were subject to the therapy caps. Although the therapy caps were repealed through amendments made to section 1833(g) of the Act by section 50202 of the Bipartisan Budget Act of 2018, as discussed in the above section, the statute continues to require that we track and accrue incurred expenses for all PT, OT, and SLP services, including those above the specified per beneficiary amounts for medically necessary therapy services for each calendar year; one amount for PT and SLP services combined, and another for OT services.

For purposes of implementing section 1834(v) of the Act through rulemaking as required under section 1834(v)(2)(C) of the Act, we proposed to define therapy assistant as an individual who meets the personnel qualifications set forth at § 484.4 of our regulations for a PTA and OTA. We proposed that the two new therapy modifiers would be used to identify services furnished in whole or in part by a PTA or an OTA; and, that these new therapy modifiers would be used instead of the GP and GO modifiers that are currently used to report PT and OT services delivered under the respective plan of care whenever the service is furnished in whole or in part by a PTA or OTA.

Effective for dates of service on and after January 1, 2020, the new therapy modifiers that identify services furnished in whole or in part by a PTA or OTA would be required to be used on all therapy claims instead of the existing modifiers GP and GO, respectively. As a result, in order to implement the provisions of the new subsection 1834(v) of the Act and carry out the continuing provisions of section 1833(g) of the Act as amended, we proposed that, beginning in CY 2020, five therapy modifiers be used to track outpatient therapy services instead of the current three. These five therapy modifiers would include two new therapy modifiers to identify PT and OT services furnished by PTAs and OTAs, respectively, and three existing therapy modifiers—GP, GO and GN—that will be used when PT, OT, and SLP services, respectively, are fully furnished by therapists or when fully furnished by or incident to physicians and NPPs.

The creation of therapy modifiers specific to PT or OT services delivered under a plan of care and furnished in whole or in part by a PTA or OTA would necessitate that we make changes to the descriptors of the existing GP and GO modifiers to clarify which qualified professionals, for example, therapist, physician, or NPP, can furnish the PT and OT services identified by these modifiers, and to differentiate them from the therapy modifiers specific to the services of PTAs and OTAs. We also proposed to revise the GN modifier descriptor to conform to the changes to the GP and GO modifiers by clarifying the qualified professionals that furnish SLP therapy services.

We proposed to define the two new therapy modifiers for services furnished in whole or in part by therapy assistants and to revise the existing therapy modifier descriptors as follows:

- New PT Assistant services modifier (to be used instead of the GP modifier currently reported when a PTA furnishes services in whole or in part): Services furnished in whole or in part by a physical therapist assistant under an outpatient physical therapy plan of care;
- New OT Assistant services modifier (to be used instead of the GO modifier currently reported when an OTA furnishes services in whole or in part): Services furnished in whole or in part by occupational therapy assistant under an outpatient occupational therapy plan of care.

We proposed that the existing GP modifier, ''Services delivered under an outpatient physical therapy plan of care'' would be revised to read as follows:

- *Revised GP modifier:* Services fully furnished by a physical therapist or by or incident to the services of another qualified clinician—that is, physician, nurse practitioner, certified clinical nurse specialist, or physician assistant—under an outpatient physical therapy plan of care.

We proposed that the existing GO modifier, ''Services delivered under an outpatient occupational therapy plan of care'' would be revised to read as follows:

- *Revised GO modifier:* Services fully furnished by an occupational therapist or by or incident to the services of another qualified clinician—that is, physician, nurse practitioner, certified clinical nurse specialist, or physician assistant—under an outpatient occupational therapy plan of care.

We proposed that the existing GN modifier, ''Services delivered under an outpatient speech-language pathology plan of care'' would be revised to be consistent with the revisions to the GP and GO modifiers to read as follows:

- *Revised GN modifier:* Services fully furnished by a speech-language pathologist or by or incident to the services of another qualified clinician—that is, physician, nurse practitioner, certified clinical nurse specialist, or physician assistant—under an outpatient speech-language pathology plan of care.

As finalized in CY 2005 PFS final rule with comment period (69 FR 66351 through 66354), and as required as a condition of payment under our regulations at §§ 410.59(a)(3)(iii), 410.60(a)(3)(iii), and 410.62(a)(3)(iii), the person furnishing outpatient therapy services incident to the physician, PA, NP or CNS service must meet the therapist personnel qualification and standards at § 484.4, except for licensure per section 1862(a)(20) of the Act. As such, we noted that only a therapist, not a therapy assistant, can furnish outpatient therapy services incident to the services of a physician or a non-physician practitioner (NPP), so the new PT- and OT-Assistant therapy modifiers cannot be used on the line of service when the rendering practitioner identified on the claim is a physician or an NPP. For therapy services billed by physicians or NPPs, whether furnished

personally or incident to their professional services, the GP or GO modifier is required for those PT or OT services furnished under an outpatient therapy plan.

We proposed that all services that are furnished in whole or in part by a PTA or OTA are subject to the use of the new therapy modifiers. A new therapy modifier would be required to be used whenever a PTA or OTA furnishes all or part of any covered outpatient therapy service. However, we did not believe the provisions of section 1834(v) of the Act were intended to apply when a PTA or OTA performs portions of the service such as administrative tasks that are not related to their qualifications as a PTA or OTA. Rather, we believed the provisions of section 1834(v) of the Act were meant to apply when a PTA or OTA is involved in providing some or all of the therapeutic portions of an outpatient therapy service. We proposed to define ''in part,'' for purposes of the proposed new modifiers, to mean any minute of the outpatient therapy service that is therapeutic in nature, and that is provided by the PTA or OTA when acting as an extension of the therapist. Therefore, a service furnished in part by a therapy assistant would not include a service for which the PTA or OTA furnished only non-therapeutic services that others without the PTA's or OTA's training can do, such as scheduling the next appointment, greeting and gowning the patient, and preparing or cleaning the room. We remind therapists and therapy providers that we do not recognize PTAs and OTAs to wholly furnish PT and OT evaluations and reevaluations, that is, CPT codes 97161 through 97164 for PT and CPT codes 97165 through 97168 for OT, but to the extent that they do furnish part of an evaluative service, the appropriate therapy modifier must be used on the claim to signal that the service was furnished in part by the PTA or OTA, and the payment reduction should be applied once it goes into effect. We continue to believe that the clinical judgment and decision making involved in furnishing an evaluation or re-evaluation is similar to that involved with establishing the therapy plan that can only be established by a therapist, physician, or NPP (NP, CNS, or PA) as specified in § 410.61 of our regulations. In addition, PTAs and OTAs are not recognized separately in the statute to enroll as practitioners for purposes of independently billing for their services under the Medicare program. For these reasons, Pub. 100–02, Medicare Benefits Policy Manual, Chapter 15, sections 230.1 and 230.2 state that PTAs and OTAs may not provide evaluative or assessment services, make clinical judgments or decisions; develop, manage, or furnish skilled maintenance program services; or take responsibility for the service. Although we expect that the therapist will continue to furnish the majority of an evaluative procedure service, section 1834(v)(1) of the Act requires that the adjusted payment amount (85 percent of the otherwise applicable Part B payment amount) be applied when a therapy assistant furnishes a therapy service in part, including part of an evaluative service.

Additionally, we would like to clarify that the requirements for evaluations, including those for documentation, are separate and distinct from those for plans of care (plans). The plan is a statutory requirement under section 1861(p) of the Act for outpatient PT services (and through sections 1861(g) and 1861(ll)(2) of the Act for outpatient OT and SLP services, respectively) and may only be established by a therapist or physician. Through § 410.61(b)(5), NPs, CNSs, and PAs are also permitted to establish the plan. This means that if the evaluative procedure is furnished in part by an assistant, the new therapy modifiers that distinguish services furnished by PTAs or OTAs must be applied to the claim; however, the plan, which is not separately reported or paid, must be established by the supervising therapist who furnished part of the evaluation services as specified at § 410.61(b). When an evaluative therapy service is billed by a physician or an NPP as the rendering provider, either the physician/NPP or the therapist furnishing the service incident to the services of the physician or NPP, may establish the therapy plan in accordance with § 410.61(b). All regulatory and subregulatory plan requirements continue to apply.

To implement the new statutory provision at section 1834(v)(2)(A) of the Act, we proposed to establish two new therapy modifiers to identify the services furnished in whole or in part by PTAs and OTAs. As required under section 1834(v)(2)(B) of the Act, claims from all providers of PT and OT services furnished on and after January 1, 2020, will be required to include these new PT- and OT-Assistant therapy modifiers for services furnished in whole or in part by a PTA or OTA. We proposed that these therapy modifiers would be required, when applicable, in place of the GP and GO modifiers currently used to identify all PT and OT services furnished under an outpatient plan of care, including the services furnished by PTAs and OTAs. To test our systems ahead of the required implementation date of January 1, 2020, we anticipated allowing voluntary reporting of the new modifiers at some point during CY 2019, which we would announce to our contractors, therapists and therapy providers through a Change Request, as part of our usual change management process.

We solicited comments on these proposals.

The following is a summary of the comments we received on these proposals.

Comment: Some commenters opposed paying differently for the services furnished in whole or in part by OTAs and PTAs while other commenters supported the payment differential, with a few comparing it to the 85 percent payment rate for certain NPPs.

Response: While we appreciate hearing various commenters' views, the new statutory provision at section 1834(v) of the Act added by section 53107 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018) requires CMS to implement through notice and comment rulemaking a reduced rate for the services furnished on or after January 1, 2022, in whole or in part by therapy assistants at 85 percent of the otherwise applicable Part B payment amount for the service. Section 1834(v) of the Act further requires that we establish a modifier to identify services furnished in whole or in part by a therapy assistant by January 1, 2019, and that claims for outpatient therapy services furnished in whole or in part by therapy assistant on or after January 1, 2020, must include the modifier. As such, we are following statutory directives to implement section 1834(v) of the Act.

Comment: Some commenters supported our proposal to establish two modifiers, instead of one, to separately identify PT and OT services that are furnished in whole or in part by PTAs and OTAs, respectively. Several commenters expressed support for our proposal defining therapy assistant as an individual who meets the personnel qualifications set forth in § 484.4 of our regulations for PTAs and OTAs.

Response: We thank the many commenters who supported our proposals to (a) establish two new modifiers instead of one to separately define therapy assistant services furnished by PTAs and OTAs, and (b) to define the PTA and OTA as individuals who meet the personnel qualifications set forth in regulations at 42 CFR part 484. Although we stated that these personnel qualifications were located at § 484.4, we note that, effective January 13, 2018, the personnel qualifications for PTAs and OTAs were moved from

§ 484.4 and redesignated without changes at §§ 484.115(g) and (i), respectively (82 FR 4504, January 13, 2017).

Comment: Most commenters did not choose to comment specifically about our proposal to establish the two new modifiers as therapy modifiers for services furnished by PTAs and OTAs that are to be used instead of the current GP and GO modifiers used to capture the these services. However, several commenters opposed the structure we proposed for the modifiers that would be required on therapy claims when services are furnished by PTAs and OTAs which would change from the current two therapy modifiers, GP and GO, to identify all therapy services delivered under an outpatient PT or OT plan of care, to four therapy modifiers. Instead, they urged us to adopt new modifiers that would be used in tandem with, rather than replace, the respective existing GP and GO therapy modifiers on the same claim line of service to identify services delivered in whole or in part by PTAs and OTAs. The commenters stated that their suggested approach would mitigate administrative burden for all PT and OT professionals, as well as therapy assistants. Specifically, commenters stated that their therapists and therapy assistants use the same chargemasters, and their charge systems are hardcoded to default to either the PT or OT therapy modifier (GP or GO) that are now required on these claims, which saves both the therapists and therapy assistants from having to add the GP or GO therapy modifier to each claim line for the services they furnish. According to the commenters, under our proposal, both therapists and assistants would have to add one of the four modifiers for PT and OT services to the claim line and they would no longer be able to default their charge systems to report the GP or GO modifiers. This would mean that new PTA- and OTA-specific systems would need to be duplicated, creating undue chargemaster confusion and adding training and education burden to both therapists and therapy assistants for reporting one the four therapy modifiers. The commenters stated that adopting their proposal to add the new therapy assistant modifiers to the same claim line of service alongside the existing GP and GO modifiers eliminates the administrative burden on therapists since only therapy assistants would be required to use the new modifiers, and charge systems could remain hardcoded to default to the GP or GO modifiers as they are now to include all PT and OT services.

Response: We appreciate the commenters' concerns and agree that their suggested approach to use the new modifiers for services furnished in whole or in part by PTAs and OTAs on the same line of service as the existing GP and GO therapy modifiers, instead of replacing them, has merit, since it preserves the current use of the GP and GO therapy modifiers to identify outpatient therapy services furnished by both therapists and therapy assistants under a PT or OT plan of care. We also agree that adding the new therapy assistant modifiers to the same claim line of service alongside the existing GP and GO modifiers will prevent undue burden for physical therapists and occupational therapists, as only PTAs and OTAs will add the new modifiers to the claim line of service.

After considering the comments on the establishment and use of the new modifiers, the statutory changes, and our other payment policies for therapy services, we are not finalizing the new modifiers for therapy assistant services as therapy modifiers as proposed. Instead, we will use the two new modifiers for therapy assistant services as a type of payment modifier that will be used alongside of, instead of replacing, the GP and GO therapy modifiers, to identify the services furnished in whole or in part by PTAs or OTAs that will be tied to the reduced payment for the respective PT or OT discipline in CY 2022. By using the new modifiers for therapy assistants as payment modifiers, rather than therapy modifiers, services furnished by PTAs and OTAs will continue to be captured by the GP and GO therapy modifiers, as they are now, when delivered under the an outpatient PT or OT plan of care, respectively. We considered the commenters' requests not to use the two new modifiers for services furnished by PTAs and OTAs as therapy modifiers in addition to the current two therapy modifiers, GP and GO, respectively. We took into account their concerns about the reporting burden for both therapists and therapy assistants that would result if we were to double the number of therapy modifiers used to report the services delivered under PT and OT plans of care. We also considered the unintended consequences that could result from changing the long-standing nature of our three existing discipline-specific therapy modifiers used to report all services delivered under an outpatient plan of care for PT, OT, and SLP services. These consequences could be significant, especially since the existing modifiers are used by many other government payers and private insurers. Additionally, our claims processing systems have numerous edits tied to the therapy modifiers because these modifiers are used to track and accrue incurred costs of therapy services furnished under the outpatient therapy benefit by therapists and their assistants, as well as those services that physicians and NPPs furnish and bill as therapy services. Consequently, we agree with commenters that it is preferable to use the two new modifiers as payment modifiers to identify the services furnished in whole or in part by therapy assistants, instead of changing the overall configuration of our therapy modifiers established through CY 1998 rulemaking and designed to track services to the then therapy cap amounts for outpatient therapy services furnished under PT, OT, and SLP plans of care.

This approach—using payment modifiers rather than therapy modifiers—necessitates revisions to the descriptors we proposed for the new therapy assistant modifiers. As therapy modifiers, the new modifiers were proposed to define the PTA or OTA services delivered under an outpatient PT or OT plan of care, respectively. Modifying our proposal to instead use the two new modifiers as payment modifiers, we are removing references to the services being delivered under an outpatient PT or OT plan of care because the plan is specific to the GP and GO therapy modifiers. We also retained the terminology of ''in whole or in part'' as part of the definition of these therapy assistant payment modifiers, as specified at section 1834(v) of the Act, and clarified the therapy assistants' services are included as part of the corresponding PT or OT discipline. As a result, we are finalizing the two new payment modifiers to identify services furnished in whole or in part by a PTA and OTA, modifiers CQ and CO (C, capital letter O), respectively as follows.

- *PTA Modifier CQ:* Outpatient physical therapy services furnished in whole or in part by a physical therapist assistant.
- *OTA Modifier CO:* Outpatient occupational therapy services furnished in whole or in part by an occupational therapy assistant.

Because we are establishing the two new modifiers for the services furnished in whole or in part by a PTA or OTA as payment modifiers instead of as therapy modifiers, it is no longer necessary to revise the existing GP, GO, and GN therapy modifiers as we initially proposed to differentiate which professionals may furnish services using the GP, GO, and GN therapy modifiers in the absence of therapy modifiers used

specifically to identify services furnished in whole or in part by PTAs and OTAs. As a result, we are not finalizing our proposal to change the descriptors for the current therapy modifiers: GP, GO and GN—their descriptors and their use remains unchanged, as follows:

- GP—services delivered under an outpatient physical therapy plan of care.
- GO—services delivered under an outpatient occupational therapy plan of care.
- GN—services delivered under an outpatient speech-language pathology plan of care.

As part of the proposed rule, we noted that therapy assistants are precluded from furnishing outpatient therapy services incident to the services of a physician or NPP, and as such, the new PTA and OTA modifiers cannot be used on the line of service of the professional claim when the rendering NPI identified on the claim is a physician or an NPP. This is because PTAs and OTAs don't meet the qualifications of a physical or occupational therapist that is set forth as conditions of payment in the regulatory provisions at §§ 410.59(a)(3)(iii) and 410.60(a)(3)(iii). We are clarifying that this payment policy applies similarly when the CQ and CO modifiers are used as payment modifiers. We plan to revise our manual provisions at Pub. 100–02, Medicare Benefit Policy Manual, Chapter 15, section 230, as appropriate, to reference the new CQ and CO modifiers that will be used to identify services furnished in whole or in part by a PTA or OTA starting in CY 2020.

Comment: Several commenters referenced therapist and therapy assistant shortages, and stated that this discounted payment rate for services furnished in whole or in part by therapy assistants will increase financial hardships to retain therapists and therapy assistants. Commenters requested that CMS exempt therapy services furnished in rural areas, health professional shortage areas (HPSAs), and medically underserved areas (MUAs) from application of the reduced payment rate when a therapy assistant is involved.

Response: We understand the commenters' concerns. Given the parameters of the statute at section 1834(v) of the Act, we do not have authority to exempt services furnished in whole or in part by therapy assistants from application of the reduced payment rate when furnished in rural areas, HPSAs, and MUAs. As we do for other services, we will monitor for potential access issues and consider how to address them should they arise. We do not currently have information on the geographic distribution or quantity of services furnished in whole or in part by PTAs and OTAs, and look forward to reviewing this information as it becomes available after January 1, 2020, when the new therapy assistant modifiers are required to be reported on claims.

Comment: Many commenters expressed concerns about different aspects of our proposed interpretation of the statutory reference to services furnished ''in whole or in part'' by PTAs and OTAs. Commenters also expressed concern about our proposal to define ''in part'' to mean any minute of therapeutic services delivered by a PTA or OTA. Several commenters raised concerns about the reduced payment associated with the future use of the new modifiers to describe services furnished in whole or in part by PTAs and OTAs, and asked us to consider the practical day-to-day implications of using these modifiers. These commenters stated that requiring the new modifiers to be applied when any minute of outpatient therapy is delivered by the PTA or OTA has serious implications for beneficiary access to care.

Some commenters stated that documenting in the medical record the therapy services that are delivered in part by a therapy assistant will be burdensome for those services not fully or wholly furnished by an OTA or PTA, and some suggested that the reduced payment rates should only apply when the PTA or OTA furnishes the entire service.

Many commenters objected to our definition of ''in part'' and offered several alternatives. Some commenters suggested that we should not define when a PTA or OTA furnishes a service in whole or in part, but instead consider whether a therapist furnishes a service in whole or in part, stating that the PTA/OTA modifiers should not apply in cases where the therapist, not the assistant, furnishes the majority of the service.

Several commenters were concerned that applying the modifier when any minute of outpatient therapy is delivered by a therapy assistant has serious implications for beneficiary access to care and asked us to not finalize the definition of ''in part'' until CY 2020 rulemaking, when the new modifiers for services of therapy assistants are required on claims. The commenters stated that this delay would allow CMS additional time to engage in an extensive discussion with various external stakeholders in order to consider their input before CY 2020 rulemaking. Instead of waiting to define ''in part'' during CY 2020 rulemaking, one commenter suggested that we adopt a blended fee schedule rate for services furnished for more than 50 percent of the time by a therapist, including the services of both the 15-minute timed codes or untimed service-based codes, meaning that the rate paid would be 92.5 percent, halfway between 85 and 100 percent. Other commenters stated that the modifiers to identify services of PTAs and OTAs should not apply when the therapist fully furnished the services and the assistant merely lent a second pair of hands during the treatment for example, for safety reasons, such as where the patient is morbidly obese or has flaccid limb(s) and the completion of such services require more than one therapy professional.

Many commenters raised concerns about the application of our definition of ''in part'' when therapists and therapy assistants work together collaboratively. Some commenters raised concerns about applying the modifier for therapy assistant services when therapists and their assistants work interchangeably without a clear line between when the physical therapist might stop delivering treatment and the therapy assistant resumes treatment, and when the assistant acts as a second pair of hands to the therapist. Some commenters stated that when a therapist and assistant work together in a team-based approach, regardless of the amount of time the PTA or OTA contributes, that the new modifiers identifying services for application of the discounted payment rate should not apply. Some of these commenters requested that we exclude the use of new modifiers for therapy evaluations and re-evaluations because a therapy assistant is not permitted to fully furnish these services and these services require the therapist's clinical skill, judgment, and decision-making throughout. Others commenters requested that the modifiers should not apply for group therapy services, which are often provided collaboratively between the assistant and therapist because it is not fair to affix the discounted payment modifier to every patient in the group when a PTA or OTA furnishes one minute of the group service. Some commenters suggested we apply an 8-minute rule to the codes defined by 15-minute increments, stating that the modifiers should apply only when the PTA/OTA furnishes at least 8 minutes of the service, while other commenters asked us not to apply the assistant modifiers when these intervention services are furnished collaboratively by the therapist and

assistant. Several commenters recommended that CMS allow for reporting of the same code on the same day for the same beneficiary on two different claim lines to distinguish between those code units furnished by a therapist and those furnished by a therapy assistant in reference to the 15-minute timed intervention codes and the group therapy code (CPT code 97150).

Response: We acknowledge the views of the many commenters regarding our proposed interpretation of the statutory reference to therapy services furnished in whole or ''in part'' by PTAs and OTAs as part of the requirement that we establish a modifier to identify such services on claims beginning January 1, 2020, and apply a discounted payment rate to those services beginning January 1, 2022. We offer clarification on some of the commenters' concerns and alternatives, as follows. We do not agree that the statutory provision at section 1834(v) of the Act, which specifies a discounted payment rate for services furnished ''in whole or in part'' by a therapy assistant, could be interpreted to apply only when the therapy assistant furnishes the entire service. We also clarify that the modifiers would not apply to those services that are exclusively furnished by therapists without the assistance of PTAs or OTAs. However, the extent to which the modifiers apply to clinical scenarios in which the therapist and therapy assistant work together to furnish services collaboratively may be dependent on whether the therapy assistant's services are furnished in the absence of the therapist, whose time could then no longer be attributed to that patient. We do not agree that services in which the therapist and therapy assistant work collaboratively or in tandem are necessarily services that are not furnished ''in part'' by a therapy assistant. Rather, when a therapist and therapy assistant work together in furnishing a therapy service, we would generally view that service as being furnished in part by a therapy assistant, especially when the therapist is absent for a portion of the service, as explained above. We recognize there are other clinical scenarios and types of services where it is less obvious whether the service should be considered furnished ''in part'' by a therapy assistant when a therapist and therapy assistant work collaboratively together to treat one patient, and we anticipate addressing applicability of the modifiers in additional clinical scenarios through further rulemaking for CY 2020. We also clarify that the statutory provision at section 1834(v) of the Act requiring the reduced payment at 85 percent for services furnished in whole or in part by a therapy assistant beginning in CY 2022, does not permit us to make payment at 92.5 percent, as suggested by some commenters. We also note the concerns of the few commenters requesting that we allow the same procedure code for the same patient on the same day to appear on multiple claim lines, some of which might include the new modifier for therapy assistant services and others of which would not. CMS claims processing systems already allow, when not constrained by other policies such as Medically Unlikely Edits (MUEs), the same procedure code to be reported on two different claim lines as long as there is a different modifier used to uniquely identify the service and prevent the service from being considered a duplicate. For example, if a therapy assistant furnished one unit (15 minutes) and the therapist furnished 2 units (30 minutes) of the same procedure code that is defined to be billable in 15-minute increments, one unit of the procedure code would be billed on the claim line with the modifier for the therapy assistant's services and two units of the procedure code would be billed on another claim line without the assistant modifier.

We do not agree with the commenters' suggestion that we define ''in part'' to mean a therapy service for which a PTA or OTA furnishes 50 percent or a majority of the service, or an otherwise substantial part of the service. The discounted payment rate specified under section 1834(v)(1) of the Act is required to be applied for services furnished ''in whole or in part'' by a therapy assistant. We do not believe ''in whole or in part'' means that the discounted payment rate would apply only to services for which 50 percent or more of the service was furnished by a therapy assistant.

In our review of section 1834(v)(1) of the Act, we believe that the phrase ''in part'' could be read to mean that if a therapy assistant participates only in a very small (so insubstantial as to not be meaningful) portion of the service, the discounted payment rate would not apply. In the proposed rule, we proposed that ''in part'' would not include the non-therapeutic portions of a service that could be performed by others without the training of PTAs or OTAs. Along those same lines, after further consideration of the public comments explaining the fluid nature of clinical practice between therapists and therapy assistants and the complexity of identifying and documenting when a service is furnished in part by a therapy assistant, we believe it would be appropriate to define a therapy assistant's participation in furnishing a therapy service ''in part'' to mean that the therapy assistant furnished more than a de minimis portion of the therapy service. Specifically, we believe it would be appropriate to specify that a therapy assistant is considered to furnish a therapy service ''in part'' when they perform more than 10 percent of the service. If, instead of specifying as we proposed that the modifiers are applicable when any minute of a therapeutic service is furnished by a PTA or OTA, we specified that the modifiers apply when more than 10 percent of a service is furnished by the therapy assistant, 1.5 minutes of a 15-minute unit could be furnished by the PTA or OTA without being subject to the discounted payment rate. If this 10 percent de minimis standard is applied to an untimed service, for example to a therapy evaluation for which the typical time is 45 minutes, the PTA or OTA could furnish up to 4.5 minutes of the service before the modifier and discounted payment rate would apply. We anticipate addressing applicability of the ten percent de minimis standard for other clinical scenarios in further rulemaking for CY 2020.

After consideration of the public comments, the following reflects a full summary of our finalized policies.

We are finalizing the establishment of two modifiers, one to identify services furnished in whole or in part by PTAs and the other to identify services furnished in whole or in part by OTAs. We are also finalizing our proposal to define PTAs and OTAs as those individuals meeting the personnel qualifications set forth in part 484.

Instead of finalizing the new modifiers to identify services furnished by PTAs and OTAs as therapy modifiers, we are adopting a final policy to use these new modifiers as a payment modifier that will be appended on the same line of service with the respective PT or OT therapy modifier. This modified approach necessitates revisions to the proposed descriptors of the new CQ and CO modifiers, and allows us to proceed without making the proposed revisions to the current descriptors for the three therapy modifiers—GP, GO and GN. We are finalizing the new payment modifiers as follows.

- *CQ Modifier:* Outpatient physical therapy services furnished in whole or in part by a physical therapist assistant.
- *CO Modifier:* Outpatient occupational therapy services furnished

in whole or in part by an occupational therapy assistant.

We are not revising the three therapy modifiers as we had proposed. Instead, they will continue in effect, unmodified, as follows:

- GP—services delivered under an outpatient physical therapy plan of care.
- GO—services delivered under an outpatient occupational therapy plan of care.
- GN—services delivered under an outpatient speech-language pathology plan of care.

Instead of finalizing our proposed definition of a service that is furnished in whole or in part by a PTA or OTA as a service for which any minute of a therapeutic service is furnished by a PTA or OTA, we are finalizing a de minimis standard under which a service is furnished in whole or in part by a PTA or OTA when more than 10 percent of the service is furnished by the PTA or OTA. We anticipate addressing application of the therapy assistant modifiers and the 10 percent standard more specifically, including their application for different scenarios and types of services, in rulemaking for CY 2020.

3. Functional Reporting Modifications

Since January 1, 2013, all providers of outpatient therapy services, including PT, OT, and SLP services, have been required to include functional status information on claims for therapy services. In response to the Request for Information (RFI) on CMS Flexibilities and Efficiencies that was issued in the CY 2018 PFS proposed rule (82 FR 34172 through 34173), we received comments requesting burden reduction related to the functional reporting requirements that were adopted to implement section 3005(g) of the Middle Class Tax Relief and Jobs Creation Act (MCTRJCA) of 2012 (Pub. L. 112–96, January 1, 2013). More information about these requirements can be found in the CY 2019 PFS proposed rule (83 FR 35852).

We proposed to discontinue the functional reporting requirements for services furnished on or after January 1, 2019. Specifically, we proposed to amend our regulations by removing the following: (1) Conditions of payment at §§ 410.59(a)(4), 410.60(a)(4), 410.62(a)(4), and 410.105(d) that require claims for OT, PT, SLP, and Comprehensive Outpatient Rehabilitation Facility (CORF) PT, OT, and SLP services, respectively, to contain prescribed information on patient functional limitations; and, (2) the functional reporting-related phrase that requires the plan's goals to be consistent with functional information on the claim at § 410.61(c) for outpatient PT, OT, and SLP services and at § 410.105(c)(1)(ii) for the PT, OT, and SLP services in CORFs. In addition, we would (1) remove the functional reporting subregulatory requirements implemented primarily through Change Request 8005 last issued on December 21, 2012, via Transmittal 2622, (2) eliminate the functional reporting standard systems edits we have applied to claims, and (3) remove the functional reporting requirement provisions in our internet Only Manual (IOM) provisions including the Medicare Claims Processing Manual, Chapter 5 and the functional reporting requirements in Chapters 12 and 15 of the Medicare Benefits Policy Manual.

Our proposal would end the requirements for the reporting and documentation of functional limitation G-codes (HCPCS codes G8978 through G8999 and G9158 through G9186) and severity modifiers (in the range CH through CN) for outpatient therapy claims with dates of service on and after January 1, 2019. Accordingly, with the conclusion of our functional reporting system for dates of service after December 31, 2018, we proposed to delete the applicable non-payable HCPCS G-codes specifically developed to implement that system through the CY 2013 PFS final rule with comment period (77 FR 68598 through 68978).

We sought comment on these proposals. The following is a summary of the comments we received on these proposals.

Comment: Many commenters supported the proposal to eliminate the functional reporting requirements for outpatient therapy services and urged us to end these requirements for reporting and documenting the G-codes and severity modifiers on claims for PT, OT, and SLP services beginning January 1, 2019. Many commenters agreed that these requirements are overly complex and burdensome for therapy providers.

Response: We appreciate the commenters' support of our proposal to end the reporting and documentation requirements effective January 1, 2019.

Comment: Some commenters disagreed with our proposal to end the functional reporting and documentation requirements beginning in CY 2019. One commenter who liked our functional reporting system suggested that we retain a reduced version of it. Two other commenters supported our requirement for assessment tools or outcome measures to be used to quantify the severity of dysfunction or disability. One commenter representing a software developer supported the flexibility in our rules permitting professional judgment of therapists to select from a composite outcome measure a single functional measure that reflects a more accurate disability rating. Another commenter representing a large private payer asked us to retain our functional reporting requirements because they believe that information about functional status of therapy patients remains an essential source of information for health plan care management activities such as health plan care coordination programs and to accurately complete risk adjustment requirements. This commenter also noted that the end of Medicare functional reporting requirements may cause therapists to stop documenting information about their patients' functional status, and this, along with the repeal of the therapy caps, could instead prompt therapists to furnish non-covered long-term custodial care services that are not medically necessary.

Response: We appreciate the commenters' support for the claims-based functional reporting system requirements currently in place including the use by the private payer of the functional status information reported on claims for health plan care management activities. While we acknowledge that functional status will no longer be required to be reported on Medicare claims and, thus, will not be available for use on claims for health plan care management activities, we do not share the commenter's concern though that the lack of a functional reporting requirement to document the non-payable HCPCS codes and related severity modifiers or the repeal of the therapy caps will cause therapists to begin furnishing therapy services that do not meet the statutory requirement for reasonable and necessary services or keep them from documenting other information required about patients' physical status in medical records. The documentation requirements specified in Pub. 100–02, Medicare Benefit Policy Manual, Chapter 15, section 220.3 titled Documentation Requirements for Therapy Services, in subsection C. for Evaluation/Re-Evaluation and Plan of Care, which were established prior to the MCTRJCA provisions' mandate, would remain in place. These documentation instructions continue to require that therapists document in the beneficiary's medical record, either in the evaluation or in the plan of care containing the evaluation, objective, measurable beneficiary physical function. In order to meet these requirements, therapists may use one of

four measurement instruments, including National Outcomes Measurement System (NOMS) by the American Speech-Language Hearing Association, Activity Measure—Post Acute Care (AM–PAC), Patient Inquiry by Focus On Therapeutic Outcomes, Inc. (FOTO), or OPTIMAL by Cedaron through the American Physical Therapy Association; or, when one of these tools is not used, they may use (a) functional assessment individual item and summary scores from commercially available therapy outcomes instruments, (b) functional assessment scores from tests and measurements validated in the professional literature that are appropriate for the condition/function being measured; or (c) other measurable progress towards identified goals for functioning in the home environment at the conclusion of the therapy episode of care. For these reasons, we believe therapists will continue to use the measurement tools they have used in the past to identify measureable physical functional status even after we discontinue the claims-based functional reporting requirements.

After consideration of the public comments, we are finalizing our proposed changes to discontinue the functional reporting requirements for outpatient therapy services furnished on or after January 1, 2019. Specifically, we are removing the following regulatory requirements: (1) Conditions of payment at §§ 410.59(a)(4), 410.60(a)(4), 410.62(a)(4), and 410.105(d) that require claims for OT, PT, SLP, and Comprehensive Outpatient Rehabilitation Facility (CORF) PT, OT, and SLP services, respectively, to contain prescribed information on patient functional limitations; and, (2) the functional reporting-related phrase that requires the plan's goals to be consistent with functional information on the claim at § 410.61(c) for outpatient PT, OT, and SLP services and at § 410.105(c)(1)(ii) for the PT, OT, and SLP services in CORFs.

In addition to amending these regulations, we are ending the requirements for the reporting and documentation of functional limitation G-codes (HCPCS codes G8978 through G8999 and G9158 through G9186) and severity modifiers (in the range CH through CN) for outpatient therapy claims with dates of service on and after January 1, 2019.

Instead of deleting the HCPCS G-codes effective for CY 2019 as proposed, we are finalizing a modification of that proposal to retain the set of 42 non-payable HCPCS G-codes until CY 2020 as this will allow time for therapy providers and other private insurers who currently use these HCPCS G-codes for purposes of functional reporting to update their billing systems and policies. This will avoid a situation where claims that inadvertently contain any of these G-codes during CY 2019 can be processed, and are not unnecessarily returned or rejected. The retention of HCPCS G-codes through CY 2019 will also allow physical and occupational therapists to report six of these non-payable HCPCS G-codes and the measures developed from them for purposes of meeting the MIPS program requirements which are found in section III.I.3. of this final rule.

We also intend to revise our manuals regarding the application of the functional reporting requirements in our IOM, Pub. 100–02, Medicare Benefits Policy Manual, Chapters 12 and 15, and Pub. 100–04, Medicare Claims Processing Manual, Chapter 5.

4. Therapy KX Threshold Amounts

As noted above in this section, the KX modifier thresholds were established through section 50202 of the Bipartisan Budget Act of 2018. These KX modifier thresholds were formerly referred to as therapy caps and are a permanent provision of the law, meaning that the statute does not specify an end date. These per-beneficiary amounts under section 1833(g) of the Act (as amended by section 4541 of the Balanced Budget Act of 1997) (Pub. L. 105–33, August 5, 1997) are updated each year based on the MEI. Specifically, these amounts are calculated by updating the previous year's amount by the MEI for the upcoming calendar year and rounding to the nearest $10.00. Increasing the CY 2018 KX modifier threshold amount of $2,010 by the CY 2019 MEI of 1.5 percent and rounding to the nearest $10.00 results in a CY 2019 KX threshold amount of $2,040 for PT and SLP services combined and $2,040 for OT services.

Along with the KX modifier thresholds, section 50202 of the Bipartisan Budget Act of 2018 also added section 1833(g)(7)(B) of the Act which retains the targeted medical review process, but at a lower threshold amount of $3,000 (until CY 2028) as detailed previously in this section. For CY 2018, the MR threshold is $3,000 for PT and SLP services combined and $3,000 for OT services. Under the established targeted review process, some, but not all claims exceeding the MR threshold amount are subject to review. For information on the targeted manual medical review process, go to *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/TherapyCap.html*.

CMS tracks each beneficiary's incurred expenses for therapy services annually and counts them toward the KX modifier and MR thresholds by applying the PFS rate for each service less any applicable multiple procedure payment reduction (MPPR) amount for services of CMS-designated ''always therapy'' services.

As required by section 1833(g)(6)(B) of the Act, added by section 603(b) of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240, January 2, 2013) and extended by subsequent legislation, including section 50202 of the Bipartisan Budget Act of 2018, the PFS-rate accrual process is applied to outpatient therapy services furnished by critical access hospitals (CAHs) even though they may be paid on a cost basis (effective January 1, 2014).

For Maryland hospitals paid under the Maryland All-Payer Model, currently being tested under the authority of section 1115A of the Act (effective January 1, 2016), we use the submitted charge amounts to accrue to the KX modifier and MR thresholds.

After expenses incurred for the beneficiary's outpatient therapy services for the year have exceeded one or both of the KX modifier thresholds, therapy suppliers and providers use the KX modifier on claims for subsequent medically necessary services. By using the KX modifier, the therapist is attesting that the services above the KX modifier thresholds are reasonable and necessary and that there is documentation of medical necessity for the services in the beneficiary's medical record. Claims for outpatient therapy services that exceed the KX modifier thresholds but do not include the KX modifier are denied.

M. Part B Drugs: Application of an Add-On Percentage for Certain Wholesale Acquisition Cost (WAC)-Based Payments

Consistent with statutory provisions in section 1847A of the Act, many current Medicare Fee-For-Service (FFS) payments for separately payable drugs and biologicals furnished by providers and suppliers include an add-on set at 6 percent of the volume-weighted average sales price (ASP) or wholesale acquisition cost (WAC) for the drug or biological (the ''6 percent add-on''). Although section 1847A of the Act does not specifically state what the 6 percent add-on represents, it is widely believed to include services associated with drug acquisition that are not separately paid for, such as handling, storage, other overhead, as well as additional mark-

ups in drug distribution channels. The 6 percent add-on described in section 1847A of the Act has raised concerns because more revenue can be generated from percentage-based add-on payments for expensive drugs, and an opportunity to generate more revenue may create an incentive for the use of more expensive drugs (MedPAC Report to the Congress: Medicare and the Health Care Delivery System June 2015, *http://medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf*, pages 65 through 72). Also, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) March 8, 2016, Issue Briefing pointed out that administrative complexity and overhead costs are not exactly proportional to the price of a drug (*https://aspe.hhs.gov/pdf-report/medicare-part-b-drugs-pricing-and-incentives*). Thus, the suitability of using a percentage of the volume-weighted ASP or WAC of the drug or biological for an add-on payment may vary depending on the price of the drug or how the payment rate has been determined.

Although the add-on percentage for drug payments made under section 1847A of the Act is typically applied to the ASP, a 6 percent add-on is also applied to the WAC to determine the Part B drug payment allowances in the following situations. First, for single source drugs, as authorized in section 1847A(b)(4) of the Act, payment is made using the lesser of ASP or WAC; and section 1847A(b)(1) of the Act requires that a 6 percent add-on be applied regardless of whether WAC or ASP is less. Second, for drugs and biologicals where the ASP during first quarter of sales is unavailable, section 1847A(c)(4) of the Act allows the Secretary to determine the payment amount for the drug or biological based on the WAC or payment methodologies in effect on November 1, 2003. We note that this provision does not specify that an add-on percentage be applied if WAC-based payment is used, nor is an add-on percentage specified in the implementing regulations at § 414.904(e)(4). The application of the add-on percentage to WAC-based payments during a period where partial quarter ASP data was available was discussed in the 2011 PFS final rule with comment (75 FR 73465 through 73466). Third, in situations where Medicare Administrative Contractors (MACs) determine pricing for drugs that do not appear on the ASP pricing files and for new drugs, WAC-based payment amounts may also be used, as discussed in Chapter 17, Section 20.1.3 of the Medicare Claims Processing Manual. This section of the manual describes the use of a 6 percent add-on.

The incorporation of discounts in the determination of payment amounts made for Part B drug varies. Most Part B drug payments are based on the drug's or biological's ASP; as provided in section 1847A(c)(3) of the Act, the ASP is net of many discounts such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase, chargebacks, and rebates (other than rebates under Medicaid drug rebate program). In contrast, the WAC of a drug or biological is defined in section 1847A(c)(6)(B) of the Act as the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data. Because the WAC does not include discounts, it typically exceeds ASP, and the use of a WAC-based payment amount for the same drug results in higher dollar payments than the use of an ASP-based payment amount.

Although discussions about the add-on tend to focus on ASP-based payments (because ASP-based payments are more common than WAC-based payments), the add-on for WAC-based payments has also been raised in the June 2017 MedPAC Report to the Congress (*http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf*, pages 42 through 44). The MedPAC report focused on how the 2 quarter lag in payments determined under section 1847A of the Act led to a situation where undiscounted WAC-based payment amounts determined using information from 2 quarters earlier were used to pay for drugs that providers purchased at a discount. To determine the extent of the discounts, MedPAC sampled new, high-expenditure Part B drugs and found that these drugs' ASPs were generally lower than their WACs. Seven out of the 8 drugs showed pricing declines from initial WAC to ASP one year after being listed in the ASP pricing files with the remaining product showing no change, which suggests purchasers received discounts that WAC did not reflect. MedPAC further cited a 2014 OIG report (OIG, *Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs,* (OEI–12–13–00040), July 2014) to illustrate that there may be differences between WAC and ASP in other instances in which CMS utilizes WAC instead of ASP and noted that OIG found that ''WACs often do not reflect actual market prices for drugs.'' MedPAC also characterized Part B payments based on undiscounted list prices for products that were available at a discount as excessive. The report suggested that greater parity between ASP-based acquisition costs and WAC-based payments for Part B drugs could be achieved and recommended changing the 6 percent add-on for WAC-based payments to 3 percent. A 3 percent change was recommended based on statements made by industry, MedPAC's analysis of new drug pricing, and OIG data. The report also mentioned that discounts on WAC, such as prompt pay discounts, were available soon after the drug went on the market.

In the case of a drug or biological during an initial sales period in which data on the prices for sales for the drug or biological is not sufficiently available from the manufacturer, section 1847A(c)(4) of the Act permits the Secretary to make payments that are based on WAC. In other words, although payments under this section may be based on WAC, unlike section 1847A(b) of the Act (which specifies that certain payments must be made with a 6 percent add-on), section 1847A(c)(4) of the Act does not require that a particular add-on amount or percentage be applied to partial quarter WAC-based pricing. Consistent with section 1847A(c)(4) of the Act, we proposed that effective January 1, 2019, WAC based payments for Part B drugs made under section 1847A(c)(4) of the Act, utilize a 3 percent add-on in place of the 6 percent add-on that is currently being used. We proposed a 3 percent add-on because this percentage is consistent with MedPAC's analysis and recommendations discussed in the paragraph above and cited in its June 2017 Report to the Congress. Although other approaches for modifying the add-on amount, such as a flat fee, or percentages that vary with the cost of a drug, are possible, we proposed a fixed percentage in order to be consistent with other provisions in section 1847A of the Act that specify fixed add-on percentages of 6 percent (section 1847A(b) of the Act) or 3 percent (section 1847A(d)(3)(C) of the Act). A fixed percentage is also administratively simple to implement and administer, predictable, and easy for manufacturers, providers and the public to understand.

We have also reviewed corresponding regulation text at § 414.904(e)(4). To conform the regulation text more closely to the statutory language at section

1847A(c)(4) of the Act, we also proposed to strike the word ''applicable'' from paragraph (e)(4) of § 414.904. Section 1847A(c)(4) of the Act does not use the term ''applicable'' to describe the payment methodologies in effect on November 1, 2003.

We also discussed changing the policy articulated in the Medicare Claims Processing Manual that describes the application of the 6 percent add-on to payment determinations made by MACs for new drugs and biologicals. Chapter 17 section 20.1.3 of the Claims Processing Manual (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf*) states that WAC-based payment limits for drugs and biologicals that are produced or distributed under a new drug application (or other new application) approved by the Food and Drug Administration, and that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, are based on 106 percent of WAC. Invoice-based pricing is used if the WAC is not published. In the Hospital Outpatient Prospective Payment System (OPPS) program, the payment allowance limit is 95 percent of the published Average Wholesale Price (AWP). We discussed permitting MACs to use an add-on percentage of up to 3 percent for WAC-based payments for new drugs. MACs have longstanding authority to make payment determinations when we do not publish a payment limit in our national Part B drug pricing files and when a new drug becomes available. This proposal intended to preserve consistency with our proposed national pricing policy and would apply when MACs perform pricing determinations, for example during the period when ASPs have not been reported. The proposed policy would not alter OPPS payment limits; however, the CY 2019 OPPS proposed rule (83 FR 37046) includes a discussion about proposed changes to certain WAC-based drug payments under the OPPS.

We note that the PFS rule proposals do not include WAC-based payments for single source drugs under section 1847A(b) of the Act, that is, where the statute specifies that the payment limit is 106 percent of the lesser of ASP or WAC.

We have stated in previous rulemaking (80 FR 71101) that it is desirable to have fair reimbursement in a healthy marketplace that encourages product development. We have also stated that we seek to promote innovation to provide more options to patients and physicians, and competition to drive prices down (82 FR 53183). These positions have not changed. However, since 2011, concern about the impact of drug pricing and spending on Part B drugs has continued to grow. From 2011 to 2016, Medicare Part B drug spending increased from $17.6 billion to $28.0 billion, representing a compound annual growth rate of 9.8 percent, with per capita spending increasing 54 percent, from $532 to $818 (Based on Spending and Enrollment Data from the CMS Office of Enterprise Data and Analytics). These increases affect the spending by Medicare and beneficiary out-of-pocket costs. In the context of these concerns, we believe that implementation of these proposals would improve Medicare payment rates by better aligning payments with drug acquisition costs, especially for the growing number of drugs with high annual spending and high launch prices where single doses can cost tens or even hundreds of thousands of dollars. The proposals would also decrease beneficiary cost sharing. A 3 percentage point reduction in the total payment allowance will reduce a patient's 20 percent Medicare Part B copayment—for a drug that costs many thousands of dollars per dose, this can result in significant savings to an individual. The proposed approach would help Medicare beneficiaries afford to pay for new drugs by reducing out of pocket expenses and would help counteract the effects of increasing launch prices for newly approved drugs and biologicals. Finally, the proposals are consistent with recent MedPAC recommendations.

The following is a summary of the comments we received on these proposals.

Comment: Many commenters expressed concerns about the proposed add-on reduction and its effect on providers. Many of these commenters focused on the percentage portion of the add-on, stating that the proposed lower add-on would result in payment at ASP + 1.35 percent because of the sequester reduction.

Response: The Budget Control Act of 2011 (Pub. L. 112–25, enacted August 2, 2011) requires mandatory across-the-board reductions in Federal spending, also known as sequestration. The application of sequestration (after the American Taxpayer Relief Act of 2012 (Pub. L. 112–240, enacted January 2, 2013) postponed sequestration for 2 months) requires the reduction of Medicare payments by 2 percent for many Medicare FFS claims with dates-of-service on or after April 1, 2013. The proposed change to the add-on percentage does not include reductions applied to Medicare payments under sequestration, as sequestration is independent of Medicare payment policy. However, we understand the concerns about the reduction to the add-on and the effects of the sequester resulting in a situation where payment amounts could be potentially insufficient to cover acquisition costs for expensive drugs, such as for specialties like rheumatology, which utilize a narrow range of drugs with similar prices, and for providers who may not be able to acquire drugs below the ASP. The policy we proposed would reduce the add-on for WAC-based payment to 3 percent; it would be limited to new drugs and would not apply to the add-on to ASP-based payment amounts. The 3 percent reduction is discussed in further detail in the comment responses below.

Comment: A number of commenters stated that the 6 percent markup is intended to account for specific costs, such as handling, storage and other administrative expenses.

Response: Section 1847A of the Act does not specifically state what the 6 percent add-on represents, and the accompanying Conference Report to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which added section 1847A to the Act, similarly does not discuss the purpose of the 6 percent add-on (see Conference Report on H.R. 1, November 20, 2003). Although section 1847A of the Act does not specifically state what the add-on represents, it is believed by many that the 6 percent add on includes various activities associated with drug acquisition that are not separately paid for, such as handling, and storage, as well as additional costs, such as overhead and mark-ups in drug distribution channels; however, there is no consensus on the intent of the add-on (MedPAC Report to the Congress: Medicare and the Health Care Delivery System June 2016, *http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0*, page 127).

Comment: Commenters expressed concerns that a payment reduction of 3 percent would affect physicians and limit their utilization of new drugs, particularly in practices where margins are small, such as rural practices and small practices. Commenters were concerned that payments for drugs under the proposed reduction would not cover overhead (such as costs to order and store drugs, and rising costs for compliance with standards for the preparation of sterile drugs for administration to a patient), and other

costs (such as taxes and markups from intermediaries like wholesalers). Commenters stated that such payment reductions would require physicians to take a loss on new drugs or would prevent physicians from providing new drugs in the office. Several commenters disagreed that the markup incentivizes the use of more expensive drugs, while others agreed that financial incentives to use Part B drugs exist, particularly in the case of expensive drugs. One commenter noted that Part B includes some of the most expensive drugs available in the United States. Several commenters also noted that MedPAC data suggested that WAC-based payments with a 3 percent add-on could sometimes be less than ASP based payments with a 6 percent add-on.

Response: The payment methodology in section 1847A of the Act was authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173, enacted on December 8, 2003). Since then, drug prices have increased significantly, sometimes reaching into the tens and even hundreds of thousands of dollars for a single dose of a drug. We agree with commenters that Part B includes payments for very expensive drugs, and at least one GAO study has pointed out that the most new Part B drugs are costly and tend to be biologicals (Medicare Part B: Expenditures for New Drugs Concentrated among a Few Drugs, and Most Were Costly for Beneficiaries. (GAO Publication No. GAO–16–12; *https://www.gao.gov/assets/680/673304.pdf*)). As stated in the previous comment response, the purpose of the 6 percent add-on is not clear, however, we are interested in striking a balance between concerns about providers' overhead costs and concerns about addressing financial incentives that may lead to excessive drug use.

If the add-on is intended to account for administrative complexity, handling, storage and other overhead costs, these factors are not considered to be exactly proportional to current drug prices (*https://aspe.hhs.gov/pdf-report/medicare-part-b-drugs-pricing-and-incentives*). The application of the 6 percent add-on results in large dollar value payments for new drugs that are proportional only to the price of the drug. Further, the application of a 6 percent add-on to an undiscounted price like WAC, rather than a market-based price, can result in additional differences between acquisition cost and payment. This difference can become significant, particularly for higher cost drugs where the 6 percent add-on can be hundreds or even thousands of dollars, and can become even more substantial when WAC exceeds ASP or acquisition cost. We are concerned that as drug prices continue to increase, the add-on is continuing to evolve into a financial incentive that is not consistent with the appropriate use of new Part B drugs.

Many new drugs are expensive; single doses may cost thousands of dollars. Six percent add-ons for expensive drugs may be excessive relative to factors such as the cost to acquire a drug, handling and storage, and other overhead costs. We believe that overhead costs for most new drugs and biologicals are generally comparable to the overhead costs for most other injectable Part B drugs. For example, many heavily utilized injectable Part B drugs and biologicals, including new products, appear to be readily available since they are listed in drug wholesalers' catalogues. With certain exceptions, such as biologicals made from autologous cells, prescribing information indicates that many injectable Part B drugs and biologicals are stable under refrigeration or room temperature and do not require highly specialized storage or shipping conditions. We also note that many newer injectable drugs are also produced in ready to use liquid form, thus additional reconstitution and complicated dose preparation steps are not necessary. For many newer injectable products that were added to the ASP drug files in 2018, prescribing information indicates that dose preparation is comparable to many other sterile injectables and consists of drawing up the drug into a syringe using aseptic technique, and sometimes diluting the dose in a small volume bag of intravenous fluid. Some of the newer products are available in ready to use syringes which are administered directly to the patient with no special preparation steps.

We believe that the 3 percent reduction will help encourage the appropriate utilization of new drugs by lessening the financial incentive to overutilize drugs during their initial period of sales. We will discuss the percentage in more detail in the next comment response, but in general we believe that this reduction will not reduce margins for Part B drugs to an extent that would significantly and negatively affect providers, for several reasons. First, the overhead for many new drugs and biologicals is not likely to be significantly higher than the overhead for existing Part B injectable drugs (as discussed in the paragraph above). Second, the add-on is based on an undiscounted list price that is usually higher than market prices, and many new drugs and biologicals are costly. When the add-on is based on an undiscounted list price, this may contribute to potentially excessive add-on payments, particularly for expensive new drugs. As the WAC of a drug increases, so does the dollar value of the add-on, and this increase is not tied to any other factors, such actual market cost, administrative complexity of ordering the drug, or additional overhead costs, for example. The add-on for a costly drug can add significantly to the payment for a drug; a 6 percent add-on for a $5,000 dose of a drug is $300, while the 6 percent add-on for a $10,000 dose is $600. Third, the duration of the reduction to WAC-based payments for new drugs would be brief, applying only during an initial period as stipulated in section 1847A(c)(4) of the Act, where ASP data for drugs or biologicals (including biosimilars) is not sufficiently available to determine an ASP-based payment. Fourth, based on recent additions to the ASP drug pricing files, the change would affect only a small number of drugs each year. Typically, several drugs are added to the ASP Drug Pricing files each quarter, and not all of those drugs are priced based on WAC; some are added to the pricing files after the initial period of sales and are paid based on ASP. For these reasons, we are not persuaded that the reduction of the add-on for new drugs would have significant impact on margins for most physicians or other providers, including small and rural practices.

While some WAC based payments for new drugs could be less than ASP-based payments, the WAC exceeds the ASP for most new drugs entering the market. Our approach using a percentage of the WAC-based amount provides an administratively simple and straightforward solution for new Part B drugs.

We reiterate that our proposal did not include payments for single source drugs under section 1847A(b)(4) of the Act, where payment is made using the lesser of ASP or WAC. (This methodology applies after CMS receives ASP data for the drug.) Section 1847A(b)(1) of the Act requires that a 6 percent add-on be applied regardless of whether WAC or ASP is less; legislation would be required to change the percentage of the add-on that is specified in this provision.

Comment: Several commenters stated that the MedPAC analysis was too limited and did not support a 3 percent add-on. Some suggested that delaying the add-on reduction and conducting more research was a reasonable alternative. Several commenters noted that manufacturers could increase WAC in response to CMS' change in policy.

Response: The MedPAC analysis encompassed drugs with ASP data after 2005 that were in the top 20 highest expenditures in 2014. The analysis indicated that ASP was lower than WAC soon after a drug is marketed; a range of percentages from 0.0 to −2.7 percent was reported. We believe that the 0.0 to −2.7 percent range may underestimate the average difference between WAC and ASP because the MedPAC's group of 8 drugs did not encompass codes where WAC substantially exceeded ASP, such as certain biosimilars. We also note that this analysis of drugs was not the only factor for MedPAC's recommendation of a 3 percent add-on. The report stated that the recommendation for 3 percent change was also based on industry statements regarding prompt-pay discounts, and previous OIG research (*http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf*, pages 43, 44, 52, and 68). For these reasons, we disagree with commenters that the MedPAC analysis was too limited.

Although the number of new drugs that appear on the ASP Drug Pricing Files with a WAC-based payment amount is limited, we stated in the proposed rule (83 FR 36047) that the average difference between WAC and ASP-based payment limits for a group of 3 recently approved drugs and biologicals that appeared on the ASP Drug Pricing Files (including one biosimilar biological product) was 9.0 percent. Excluding the biosimilar biological product results in a difference of 3.5 percent. These findings agree with the MedPAC's analysis and support the use of a 3 percent reduction to WAC-based payments for new drugs. Given the limited application of this policy change, the sources used by the MedPAC (which include industry statements), and our internal review, we do not believe that additional study or delay is necessary.

We are aware that ASP-based payments may exceed payments based on WAC if the percentage for the WAC add-on is smaller than the ASP add-on. The proposal for this policy change was limited to payments under section 1847A(c)(4) of the Act. We do not have authority to change the add-on for WAC based payments made under section 1847A(b)(4) of the Act or payments based on the ASP, and we have not addressed such payments in this rule. We believe that implementation of this relatively minor change without further delay is a positive step toward addressing high drug prices, including list prices. We acknowledge that manufacturers may increase Part B drug prices and that price increases could apply to both list prices like WAC and market-based prices, such as ASP. Section 1847A of the Act does not provide us with authority to addresses most increases for Part B drug prices (we have limited authority to substitute AMP-based prices for ASP, and authority to use alternative prices in response to certain public health emergencies). Price increases from manufacturers and other sources that add to high drug costs will be considered as we continue our work to address concerns about high drug prices.

Comment: Several commenters pointed out that the proposal does not address prices after the initial period of drug marketing, and that the MedPAC's recommendations about reducing the WAC payment add-on percentage were part of several proposals about Part B drug pricing. Several commenters also stated that the proposal to decrease WAC payments is not consistent with the President's goal to decrease list prices for drugs.

Response: This proposal encompassed a change in policy that could be implemented in a relatively short time period and without additional legislation. The proposal is also consistent with the 2019 President's Budget's proposal. Language in the Major Savings and Reforms document states that if discounts are available for new Part B drugs, the use of WAC-based payments results in Medicare paying more than under ASP-based pricing (*https://www.whitehouse.gov/wp-content/uploads/2018/02/msar-fy2019.pdf*, page 150). The Budget proposal also contained other agenda items that are similar to the MedPAC's 2017 recommendations and would require legislation to implement. Such legislative changes, including authority to limit or to otherwise regulate WAC or other list prices for drugs are outside the scope of this rule; however, other information pertaining to drug pricing will be made public as it is developed. We also note that the use of list prices to determine the payment for Part B drugs is limited and the number of drugs paid using list prices is small. As we continue to work on other approaches to address high drug prices, we plan to monitor Part B drug prices and changes to drug costs that may be related to this policy.

Comment: Many commenters focused on potential negative effects on patients, and expressed concerns that a negative impact on physicians would lead to fewer offices providing new drugs, leading to shifts to higher cost care settings like hospital outpatient departments, and ultimately leading to higher cost sharing payments. A few commenters stated that direct reductions in cost sharing (that is, the amount of money paid by a patient) would be minimal because secondary insurance (like Medigap) or alternative sources of payment are typically available and pay for much of Part B drug cost sharing.

In contrast, several commenters agreed that cost sharing could drop, though the effect would be transient (limited to the early phase of a drug's marketing). However, these commenters generally agree that the CMS proposal was a step in the right direction for addressing the high cost of drugs.

Response: Overall, as discussed in an earlier comment response, we believe that the scope of these changes is modest, will affect few drugs, and will exert a brief effect on Part B drug payment, applying only during the initial quarters when a new drug enters the market. As stated earlier in this section, the overhead for many new drugs and biologicals is not likely to be significantly higher than the overhead for existing Part B injectable drugs, the add-on is based on an undiscounted list price that tends to be higher than market prices, and many new drugs and biologicals are expensive, thus we do not expect a significant effect on providers' margins. Because we do not anticipate a significant or prolonged effect on providers' margins, we also disagree with the position that physicians' offices will be reluctant to administer new drugs and that this reduction to the add-on will negatively affect beneficiaries access to drugs at offices resulting in shifting patients to more expensive settings. As we stated in the proposed rule (83 FR 36047), we believe that the reduction in the WAC-based payment add-on can positively impact individual beneficiaries in situations where they encounter out of pocket cost sharing payments for new and expensive drugs entering the market. We acknowledge that many beneficiaries that receive Part B drugs have supplementary insurance, but for beneficiaries that do not have supplementary insurance, this policy will help reduce out of pocket costs. We would like to reiterate that single doses of new drugs may costs thousands of dollars or more and a 3 percent reduction in the add-on percentage can result in meaningful savings to individual patients. We agree with commenters that a change to the add-on for new drugs is a step in the right direction for addressing the high cost of drugs. Overall, this policy will also provide a modest reduction in spending

for drugs by lowering the total payment for new Part B drugs.

After considering the comments submitted in response to our proposal, consistent with section 1847A(c)(4) of the Act, we are finalizing our proposal to reduce the add-on percentage for WAC based payments for new drugs. Effective January 1, 2019, WAC based payments for new Part B drugs made under section 1847A(c)(4) of the Act, will utilize a 3 percent add-on in place of the 6 percent add-on that is currently being used. Our final policy is consistent with the President's Budget and affects an area where we have flexibility to make a change through regulation. The percentage reduction is also consistent with the MedPAC's analysis and recommendations discussed in this section and cited in its June 2017 Report to the Congress. A fixed percentage is also administratively simple to implement and administer, is predictable, and is easy for manufacturers, providers and the public to understand. We believe that the 3 percent reduction to the add-on for WAC-based payments will create greater parity overall between WAC and ASP for new drugs, biologicals and biosimilars and continue to encourage appropriate utilization of drugs. We are not persuaded that this modest and brief reduction in payments will impair access to new drugs or shift patient care to other settings.

This change does not apply to single source drugs or biologicals paid under section 1847A(b)(4) of the Act where payment is made using the lesser of ASP or WAC; section 1847A(b)(1) of the Act requires that a 6 percent add-on be applied regardless of whether WAC or ASP is less.

Comment: We received no specific comments on the proposal to conform the regulation text more closely to the statutory language at section 1847A(c)(4) of the Act. We proposed striking ''applicable'' from regulation text at § 414.904(e)(4).

Response: We are finalizing this change as proposed and revising regulation text at § 414.904(e)(4) so that the language is more consistent with the statute.

Comment: Several commenters opposed our intent to change the policy articulated in Chapter 17 of the Medicare Claims Processing Manual that describes the application of the 6 percent add-on to payment determinations made by MACs for new drugs and biologicals to reflect our proposal, if finalized. Commenters opposed the Manual changes for the same general reasons that they opposed the proposal to change the WAC-based add-on percentage under section 1847A(c)(4) of the Act. Commenters were also concerned about whether the use of an add-on that could be less than 3 percent would create additional financial stress for providers and whether the manual changes would apply to any WAC-based payment. The commenters also questioned whether CMS has authority to make these changes.

Response: The discussion about changes to Chapter 17 of the Medicare Claims Processing Manual was intended to provide notice of a potential corresponding subregulatory change to align with our regulatory policy if the provision to change the add-on percentage was finalized. Because we finalized the proposal to reduce the WAC-based payment add-on for payments made under the authority in section 1847A(c)(4) of the Act, in the near future we plan to issue Manual instructions that will address contractor pricing for new Part B drugs.

We are clarifying that changes to payments for WAC based drugs discussed in this rule apply only to new drugs and only during the time period while an ASP-based payment limit is not available. This time period begins when a drug is marketed and no ASP data is available for the manufacturer to report to us and ends at the end of the partial quarter pricing period when partial quarter ASP data becomes available to us. We will provide additional guidance or program instructions as appropriate.

The variable percentage that we plan to utilize in the manual, that is, the use of an add-on that is up to 3 percent, addresses the wide range of Part B drug prices. As discussed earlier in this section, the 6 percent add-on payment amount for very expensive drugs can result in very high add-on payments. For example, 6 percent of a $30,000 drug is $1800, while 6 percent of $300,000 is $18,000. We are aware of recently approved Part B drugs that have per dose price points up to several hundred thousand dollars. Our intent is to address the add-on payment that is associated with new drugs before national pricing and potentially other related policies, such as coverage, are developed. Our approach is consistent with provisions in section 1847A(c)(4) of the Act, which does not set a specific percentage for the add-on for drugs where ASP is not available. We also note that section 1847A(c)(5) of the Act provides authority to issue program instructions to implement section 1847A of the Act.

Comment: One commenter expressed concern about the lack of lead time for the changes in drug payment policy.

Response: Notice and comment rulemaking associated with Part B drug payments made under the methodology in section 1847A of the Act typically appears in the annual PFS Rule. Finalized changes to the add-on percentage will not be implemented until January 1, 2019. We believe that using the established process for notice and comment rulemaking is acceptable and provides sufficient notice for the public. As stated earlier in this section, we believe that this change is modest, and its effects on payment for individual drugs will be brief. Further, this change does not require any billing or claims processing changes.

In addition to the comments on the Part B drug add-on percentage for certain drugs discussed previously in this section, we received comments that suggested other alterations to the payment methodology under section 1847A of the Act. These suggestions include replacing a percentage add-on with a flat fee, changes to WAC-based pricing for drugs that are not new, changing payments for drugs that are not paid for under section 1847A of the Act (such as radiopharmaceuticals used in the office), the use of competitive acquisition or value-based payment for Part B drugs, making direct pricing interventions with manufacturers, requiring greater transparency for drug pricing, and educating (or otherwise influencing) providers about Part B drug prescribing. We also received comments pertaining to ASP reporting by manufacturers. Several commenters also questioned the authority for Part B drug payment reductions associated with the sequester. Comments on these issues are also outside the scope of this rule. Therefore, these comments are not addressed in this final rule.

N. Potential Model for Radiation Therapy

Section 3(a) of the Patient Access and Medicare Protection Act (PAMPA) (Pub. L. 114–115, enacted December 28, 2015) revised section 1848 of the Act so that, for the fee schedule established under section 1848(b) of the Act in 2017 and 2018, we must apply the same code definitions and work RVUs under section 1848(c)(2)(C)(ii) of the Act, and the same direct inputs for the PE RVUs for radiation treatment delivery and related imaging services under section 1848(c)(2)(C)(ii) of the Act as those definitions, units, and inputs for such services for the fee schedule established for services furnished in 2016. Section 51009 of the Bipartisan Budget Act of

2018 extended these policies through 2019. Furthermore, section 3(b) of the PAMPA requires the Secretary of Health and Human Services to submit to Congress a report on the development of an episodic APM for payment under the Medicare program under title XVIII of the Act for radiation therapy (RT) services furnished in non-facility settings (''Report to Congress''). In the Report to Congress [7] delivered in November 2017, we discussed the current status of RT services and payment, and reviewed model design considerations for a potential APM for RT services.

For the Report to Congress, the CMS Center for Medicare and Medicaid Innovation (Innovation Center) conducted an environmental scan of current evidence, as well as held a public listening session followed by an opportunity for RT stakeholders to submit written comments about a potential APM. A review of the applicable evidence in the Report to Congress demonstrated that episode payment models can be a tool for improving care and reducing expenditures. We believe that radiation oncology is a promising area of health care for bundled payments, in part, based on the findings in the Report to Congress. The CMS Innovation Center has and will continue to use public information regarding commercial initiatives, as well as stakeholder feedback to help inform the development, implementation, and refinement of design and testing of a potential model that tests payment for RT services under the authority of section 1115A of the Act.

III. Other Provisions of the Proposed Rule

A. Clinical Laboratory Fee Schedule

1. Background

Prior to January 1, 2018, Medicare paid for clinical diagnostic laboratory tests (CDLTs) on the Clinical Laboratory Fee Schedule (CLFS) under sections 1832, 1833(a), (b), and (h), and 1861 of the Social Security Act (the Act). Under the previous methodology, CDLTs were paid based on the lesser of: (1) The amount billed; (2) the local fee schedule amount established by the Medicare Administrative Contractor (MAC); or (3) a national limitation amount (NLA), which is a percentage of the median of all the local fee schedule amounts (or 100 percent of the median for new tests furnished on or after January 1, 2001). In practice, most tests were paid at the NLA. Under the previous system, the CLFS amounts were updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers (CPI–U), and reduced by a multi-factor productivity adjustment and other statutory adjustments, but were not otherwise updated or changed.

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. The CLFS final rule, entitled Medicare Clinical Diagnostic Laboratory Tests Payment System (CLFS final rule), published in the **Federal Register** on June 23, 2016, implemented section 1834A of the Act. Under the CLFS final rule, ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' collected during a ''data collection period'' for their component ''applicable laboratories.'' Applicable information is defined at § 414.502 as, with respect to each CDLT for a data collection period: Each private payor rate for which final payment has been made during the data collection period; the associated volume of tests performed corresponding to each private payor rate; and the specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test. Applicable information does not include information about a test for which payment is made on a capitated basis. An applicable laboratory is defined at § 414.502, in part, as an entity that is a laboratory (as defined under the Clinical Laboratory Improvement Amendments (CLIA) definition at § 493.2) that bills Medicare Part B under its own National Provider Identifier (NPI). In addition, an applicable laboratory is an entity that receives more than 50 percent of its Medicare revenues during a data collection period from the CLFS and/or the Physician Fee Schedule (PFS). We refer to this component of the applicable laboratory definition as the ''majority of Medicare revenues threshold.'' The definition of applicable laboratory also includes a ''low expenditure threshold'' component which requires an entity to receive at least $12,500 of its Medicare revenues from the CLFS for its CDLTs that are not advanced diagnostic laboratory tests (ADLTs).

The first data collection period, for which applicable information was collected, occurred from January 1, 2016 through June 30, 2016. The first data reporting period, during which reporting entities reported applicable information to CMS, occurred January 1, 2017 through March 31, 2017. On March 30, 2017, we announced a 60-day enforcement discretion period of the assessment of civil monetary penalties (CMPs) for reporting entities that failed to report applicable information. Additional information about the 60-day enforcement discretion period is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf*.

In general, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the data collection period and reported to us during the data reporting period, and is equal to the weighted median of the private payor rates for the test. The weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory. The payment amounts established under the CLFS are not subject to any other adjustment, such as geographic, budget neutrality, or annual update, as required by section 1834A(b)(4)(B) of the Act. Additionally, section 1834A(b)(3) of the Act, implemented at § 414.507(d), provides a phase-in of payment reductions, limiting the amounts the CLFS rates for each CDLT (that is not a new ADLT or new CDLT) can be reduced as compared to the payment rates for the preceding year. For the first 3 years after implementation (CY 2018 through CY 2020), the reduction cannot be more than 10 percent per year, and for the next 3 years (CY 2021 through CY 2023), the reduction cannot be more than 15 percent per year. For most CDLTs, the data collection period, data reporting period, and payment rate update occur every 3 years. As such, the next data collection period for most CDLTs will be January 1, 2019 through June 30, 2019, and the next data reporting period will be January 1, 2020 through March 31, 2020, with the next update to CLFS occurring on January 1, 2021. Additional information on the private payor rate-based CLFS is detailed in the CLFS final rule (81 FR 41036 through 41101).

2. Recent Stakeholder Feedback

As we discussed in the CY 2019 PFS proposed rule (83 FR 35856), after the initial data collection and data reporting periods, we received feedback on a range of topics related to the private payor rate-based CLFS. Some commenters expressed concern that the

[7] Report to Congress: Episodic Alternative Payment Model for Radiation Therapy Services. *https://innovation.cms.gov/Files/reports/radiationtherapy-apm-rtc.pdf*.

CY 2018 CLFS payments rates are based on applicable information from only a relatively small number of laboratories. Some commenters stated that, because most hospital-based laboratories were not applicable laboratories, and therefore, did not report applicable information during the initial data reporting period, the CY 2018 CLFS payment rates do not reflect their information and are inaccurate. Other commenters were concerned that the low expenditure threshold excluded most physician office laboratories and many small independent laboratories from reporting applicable information.

We noted in the proposed rule that, in determining payment rates under the private payor rate-based CLFS, one of our objectives is to obtain as much applicable information as possible from the broadest possible representation of the national laboratory market on which to base CLFS payment amounts, for example, from independent laboratories, hospital outreach laboratories, and physician office laboratories, without imposing undue burden on those entities. As we noted throughout the CLFS final rule, we believe it is important to achieve a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a CDLT, and minimizing the reporting burden for entities. In response to this feedback and in the interest of facilitating our goal, we proposed a change to the Medicare CLFS for CY 2019 in section III.A. of the CY 2019 PFS proposed rule. We stated that we believe this proposal may result in more data being used on which to base CLFS payment rates.

In addition to this proposal, we solicited public comments on other approaches that have been requested by some stakeholders who suggested that such approaches would result in CMS receiving even more applicable information to use in establishing CLFS payment rates. The approaches include revising the definition of applicable laboratory and changing the low expenditure threshold. These topics are discussed in this section.

3. Change to the Majority of Medicare Revenues Threshold in Definition of Applicable Laboratory

In order for a laboratory to meet the majority of Medicare revenues threshold, section 1834A(a)(2) of the Act requires that, ''with respect to its revenues under this title, a majority of such revenues are from'' the CLFS and the PFS in a data collection period. In the CLFS final rule, we stated that ''revenues under this title'' are payments received from the Medicare program, which includes fee-for-service payments under Medicare Parts A and B, as well as Medicare Advantage (MA) payments under Medicare Part C, and prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance amounts for Medicare services furnished during the data collection period (81 FR 41043). This total Medicare revenues amount (the denominator in the majority of Medicare revenues threshold calculation) is compared to the total of Medicare revenues received from the CLFS and/or PFS (the numerator in the majority of Medicare revenues threshold calculation). If the numerator is greater than 50 percent of the denominator for a data collection period, the entity has met the majority of Medicare revenues threshold criterion. We reflected that requirement in § 414.502 in the third paragraph of the definition of applicable laboratory.

As we explained in the CY 2019 PFS proposed rule, we have considered that our current interpretation of total Medicare revenues may have the effect of excluding laboratories that furnish Medicare services to a significant number of beneficiaries enrolled in MA plans under Medicare Part C from meeting the majority of Medicare revenues threshold criterion, and therefore, from qualifying as applicable laboratories. For instance, if a laboratory has a significant enough Part C component so that it is receiving greater than 50 percent of its total Medicare revenues from MA payments under Part C, it would not meet the majority of Medicare revenues threshold because its revenues derived from the CLFS and/or PFS would not constitute a majority of its total Medicare revenues. We stated that we believe if we were to exclude MA plan revenues from total Medicare revenues, more laboratories of all types may meet the majority of Medicare revenues threshold, and therefore, the definition of applicable laboratory, because it would have the effect of decreasing the amount of total Medicare revenues and increase the likelihood that a laboratory's CLFS and PFS revenues would constitute a majority of its Medicare revenues.

We stated in the proposed rule that we believe section 1834A of the Act permits an interpretation that MA plan payments to laboratories not be included in the total Medicare revenues component of the majority of Medicare revenues threshold calculation. Rather, MA plan payments to laboratories can be considered to only be private payor payments under the CLFS. We emphasized in the CY 2019 PFS proposed rule that this characterization of MA plan payments is limited to only the CLFS for purposes of defining applicable laboratory. Whether MA plan payments to laboratories or other entities are considered Medicare ''revenues'' or ''private payor payments'' in other contexts in the Medicare program is not relevant to our proposal, and our characterization of MA plan payments as private payor payments for purposes of the CLFS has no bearing on any aspect of the Medicare program other than the CLFS.

As noted above, we defined total Medicare revenues for purposes of the majority of Medicare revenues threshold calculation to include fee-for-service payments under Medicare Parts A and B, as well as MA payments under Medicare Part C, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance amounts for Medicare services furnished during the data collection period. However, section 1834A(a)(8) of the Act, which defines the term ''private payor,'' identifies at section 1834A(a)(8)(B) a ''Medicare Advantage plan under Part C'' as a type of private payor. Under the private payor rate-based CLFS, CLFS payment amounts are based on private payor rates that are reported to CMS. Accordingly, an applicable laboratory that receives MA plan payments is to consider those MA plan payments in identifying its applicable information, which must be reported to CMS. We explained in the proposed rule that we believe it is more logical to not consider MA plan payments under Part C to be both Medicare revenues for determining applicable laboratory status and private payor rates for purposes of reporting applicable information. Congress contemplated that applicable laboratories would furnish MA services, as reflected in the requirement that private payor rates must be reported for MA services. However, under our current definition of applicable laboratory, laboratories that furnish MA services, particularly those that furnish a significant amount, are less likely to meet the majority of Medicare revenues threshold, which means they would be less likely to qualify as applicable laboratories, and as a result, to report private payor rates for MA services.

Therefore, we stated in the proposed rule that after further review and consideration of the new private payor rate-based CLFS, we believe it is appropriate to include MA plan revenues as only private payor payments rather than both Medicare revenues, for the purpose of

determining applicable laboratory status, and private payor payments, for the purpose of specifying what is applicable information. Such a change would have the effect of eliminating the laboratory revenue generated from a laboratory's Part C-enrolled patient population as a factor in determining whether a majority of the laboratory's Medicare revenues are comprised of services paid under the CLFS or PFS. We noted that we believe this change would permit a laboratory with a significant Medicare Part C revenue component to be more likely to meet the majority of Medicare revenues threshold and qualify as an applicable laboratory. In other words, MA payments are currently included as total Medicare revenues (the denominator). In order to meet the majority of Medicare revenues threshold, the statute requires a laboratory to receive the majority of its Medicare revenues from the CLFS and or PFS. If MA plan payments were excluded from the total Medicare revenues calculation, the denominator amount would decrease. If the denominator amount decreases, the likelihood increases that a laboratory would qualify as an applicable laboratory. Therefore, we stated that we believe this proposal responds directly to stakeholders' concerns regarding the number of laboratories for which applicable information must be reported because a broader representation of the laboratory industry may qualify as applicable laboratories, which means we would receive more applicable information to use in setting CLFS payment rates.

For these reasons, we proposed that MA plan payments under Part C would not be considered Medicare revenues for purposes of the applicable laboratory definition. We noted in the CY 2019 PFS proposed rule that if finalized, we would revise paragraph (3) of the definition of applicable laboratory at § 414.502 accordingly. We reiterated that not characterizing MA plan payments under Medicare Part C as Medicare revenues would be limited to the definition of applicable laboratory under the CLFS, and would not affect, reflect on, or otherwise have any bearing on any other aspect of the Medicare program.

In an effort to provide stakeholders a better understanding of the potential reporting burden that may result from this proposal, we provided a summary of the distribution of data reporting that occurred for the first data reporting period. We explained that if we were to finalize the proposed change to the majority of Medicare revenues threshold component of the definition of applicable laboratory, additional laboratories of all types serving a significant population of beneficiaries enrolled in Medicare Part C could potentially qualify as applicable laboratories, in which case their data would be reported to us. As discussed in the proposed rule, we received over 4.9 million records from 1,942 applicable laboratories for the initial data reporting period, which we used to set CY 2018 CLFS rates. Additional analysis shows that the average number of records reported for an applicable laboratory was 2,573. The largest number of records reported for an applicable laboratory was 457,585 while the smallest amount was 1 record. A summary of the distribution of reported records from the first data collection period is illustrated in the Table 25.

TABLE 25—SUMMARY OF RECORDS REPORTED FOR FIRST DATA REPORTING PERIOD

[By applicable laboratory]

Total records	Average records	Min records	Max records	Percentile distribution of records				
				10th	25th	50th	75th	90th
4,995,877	2,573	1	457,585	23	79	294	1,345	4,884

Assuming a similar distribution of data reporting for the next data reporting period, the mid-point of reported records for an applicable laboratory would be approximately 300 (50th percentile for the first data reporting period was 294). However, as illustrated in Table 25, the number of records reported varies greatly, depending on the volume of services performed by a given laboratory. Laboratories with larger test volumes, for instance at the 90th percentile, should expect to report more records as compared to the midpoint used for this analysis. Likewise, laboratories with smaller test volume, for instance at the 10th percentile, should expect to report fewer records as compared to the midpoint.

The following is a summary of the comments we received and our responses to the comments regarding our proposal to modify the definition of applicable laboratory to exclude MA plan payments under Part C as Medicare revenues.

Comment: Many commenters supported CMS' proposal to exclude MA plan payments under Part C from total Medicare revenues and agreed it would help achieve CMS' goal of increasing the number of laboratories reporting applicable information. They stated that by excluding MA plan payments from total Medicare revenues, the denominator of the majority of Medicare revenues threshold, more laboratories of all types with a significant share of revenues from Medicare Part C would be more likely to qualify as an applicable laboratory and report applicable information to CMS. They also agreed that removal of MA plan payments from total Medicare revenues is consistent with the statute, which defines MA plans as a private payor, and therefore will help enable more laboratories to qualify as applicable laboratories. The commenters that supported excluding MA plan payments under Part C from total Medicare revenues urged CMS to finalize the proposal. However, some stakeholders objected to CMS' proposal because it would result in administrative reporting burden for additional laboratories without having a perceptible impact on CLFS rates (because the largest laboratories with the highest test volumes will continue to dominate the weighted median of private payor rates). They stated that increasing the number of laboratories qualifying for applicable laboratory status and imposing additional data reporting burden, with no perceptible impact expected on the CLFS rates, is in direct conflict with the Administration's goal of reducing regulatory burden.

Response: As discussed in the proposed rule, including MA plan payments as total Medicare revenues in the majority of Medicare revenues threshold (as we currently do) dilutes the percentage of total Medicare revenues attributed to CLFS and PFS revenues. As a result, laboratories performing tests for a significant Medicare Part C population are less likely to qualify as an applicable

laboratory and, therefore, to report applicable information to us.

For the additional data reporting burden, as discussed in the Regulatory Impact Analysis in section VII. of the proposed rule (83 FR 36048), we estimated that excluding MA plan payments from total Medicare revenues (the denominator) of the majority of Medicare revenues threshold, and keeping the numerator constant (that is, revenues from only the CLFS and or PFS) yielded an increase of 49 percent in the number of laboratories meeting the majority of Medicare revenues threshold.

We also noted in the proposed rule that there would only be an associated impact to the Medicare rates to the extent the additional applicable laboratories are paid at a higher (or lower) private payor rate, as compared to other laboratories that reported previously *and* to the extent the volume of services performed by these additional applicable laboratories is significant enough to make an impact on the weighted median of private payor rates. Given that the largest laboratories with the highest test volumes dominate the weighted median of private payor rates, and the largest laboratories reported data for the determination of CY 2018 CLFS rates and are expected to report again, we stated that we do not expect the additional reported data resulting from our proposed change to the majority of Medicare revenues threshold to have a predictable, direct impact on CLFS rates. By this we mean that we cannot predict whether the additional applicable laboratories reporting applicable information are paid at a higher (or lower) private payor rate, as compared to other laboratories that reported previously and whether the private payor rate volume of services performed by these additional applicable laboratories is significant enough to make an impact on the weighted median of private payor rates.

However, as we noted in the proposed rule, our proposal to exclude MA plan payments from total Medicare revenues responded directly to stakeholder concerns regarding the number of applicable laboratories reporting applicable information for the initial data reporting period. We believe that enabling more laboratories of all types that furnish testing to a significant Medicare Part C population to qualify as applicable laboratories and report data to CMS directly supports our goal of collecting as much applicable information as possible from the broadest representation of the national laboratory market on which to base CLFS payment amounts. Therefore, we believe receiving additional applicable information from more laboratories of all laboratory types outweighs the additional reporting burden on laboratories.

Comment: One commenter disagreed with CMS' proposal to define MA plan payments as private payor payments and not Medicare revenues for the purpose of determining applicable laboratory status. The commenter stated that MA plans are Medicare plans that rarely negotiate a rate that varies from the Medicare payment rate and that using MA plan payments to develop Medicare rates is simply a circular reference. The commenter also stated that Medicaid managed care plans should not be considered as a private payor because state Medicaid programs may set laboratory test rates at a percentage of the Medicare CLFS, for example, 80 percent of the Medicare CLFS rate. As such, the commenter stated that the use of Medicaid managed care plan data will create a ''downward spiral'' of CLFS rates.

Response: Sections 1834A(a)(8)(B) and (C) of the Act define a private payor to include a Medicare Advantage plan under Part C, and a Medicaid managed care organization (as defined in section 1903(m) of the Act), respectively. Therefore, the statute would not permit us to exclude a Medicare Advantage plan under Part C or a Medicaid managed care organization from the definition of private payor for the purposes of determining the applicable information reported to us from which to set CLFS rates. We understand the commenter's concern regarding the potential circularity of using Medicaid managed care and MA plan data to set Medicare CLFS rates to the extent that Medicaid managed care and MA plan rates are established based on Medicare rates. However, we note that section 1834A(a) of the Act explicitly directs us to use such data in setting the CLFS rates. For the suggestion that including Medicaid managed care plan data will result in a ''downward spiral,'' we note that the statute anticipates that rates will decrease under the new private payor rate-based CLFS and provides a phase-in of payment reductions. Section 1834A(b)(3) of the Act, implemented at § 414.507(d), limits the amounts the CLFS rates for each CDLT (that is not a new ADLT or new CDLT) can be reduced as compared to the payment rates for the preceding year. For the first 3 years after implementation (CY 2018 through CY 2020), the reduction cannot be more than 10 percent per year, and for the next 3 years (CY 2021 through CY 2023), the reduction cannot be more than 15 percent per year. We also note that the Medicaid managed care plans may or may not be obligated to continue to use Medicare rates (or a reduction thereof) as a basis for their rates were such a ''downward spiral'' to occur.

Comment: One commenter urged CMS to conduct a more robust and transparent analysis of this proposal to identify the types of laboratories to which this policy would apply and the relative impact on payment rates. The commenter also requested that CMS release the number of clinical laboratories that previously reported applicable information, based on market segment and geographic locations. The commenter asserted that without such information, it would be premature to implement a proposal that will only increase administrative burden on hospitals and other organizations which will be forced to re-determine their applicable laboratory status.

Response: As discussed previously, our proposal to exclude MA plan payments from the total Medicare revenues for purposes of applying the majority of Medicare revenues threshold would affect laboratories of all types, that is hospital laboratories, large and small independent laboratories, and physician office laboratories that furnish services to a significant Medicare Part C enrollment population. We also explained that since the largest laboratories with the highest test volumes dominate the weighted median of private payor rates, and the largest laboratories reported data for the determination of CY 2018 CLFS rates and are expected to report again, we did not expect the additional reported data resulting from our proposed change to the majority of Medicare revenues threshold to have a predictable, direct impact on CLFS rates. As we noted previously, this means that we cannot predict whether the additional applicable laboratories reporting applicable information are paid at a higher (or lower) private payor rate, as compared to other laboratories that reported previously *and* whether the private payor rate volume of services performed by these ''additional'' applicable laboratories is significant enough to make an impact on the weighted median of private payor rates. However, we noted that we believe this proposal responded directly to stakeholder concerns regarding the number of applicable laboratories reporting applicable information for the initial data reporting period (83 FR 36049). We also noted that in the previous data reporting period we received applicable information from 1,942 applicable laboratories from every state, the District of Columbia, and

Puerto Rico, and that additional summary information regarding data reporting for the Medicare CLFS from the first data reporting period is available on the CLFS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf*.

Given that section 1834A(a)(8)(B) of the Act specifically defines MA plans under Part C as private payors, and an applicable laboratory that receives MA plan payments must consider those MA plan payments in identifying its applicable information for reporting, we believe that it is more logical to consider MA plan payments only as private payor rates for purposes of reporting applicable information, rather than both private payor rates and Medicare revenues. We believe this is consistent with the statute and will help to increase laboratory participation from all types of laboratories. At the same time, we recognize the administrative concerns raised by some commenters regarding the data reporting requirements for laboratories with a significant Medicare Part C revenue component, particularly as some of these laboratories may be small physician offices or independent laboratories, which we have previously discussed as having a significant burden in reporting applicable information. However, as discussed previously in response to comments, we believe that modifying our definition of applicable laboratory so that we may receive applicable information from more laboratories that furnish tests to a significant Medicare Part C population, which are less likely to qualify for applicable laboratory status under the current policy, outweighs the additional reporting burden placed on these laboratories as well as directly supports our goal of collecting as much applicable information as possible from the broadest representation of the national laboratory market on which to base CLFS payment amounts. For these reasons we are finalizing our proposal to modify the definition of applicable laboratory to exclude MA plan revenues from total Medicare revenues (the denominator of the majority of Medicare revenues threshold). We are revising paragraph (3) of the definition of applicable laboratory at § 414.502 accordingly.

Comment: In addition to CMS' proposal to exclude MA plan payments from total Medicare revenues, one commenter recommended that CMS also remove prescription drug payments under Medicare Part D from the description of total Medicare revenues in the applicable laboratory definition. The commenter stated that including Part D payments is illogical because there is no circumstance under which such payments would be related to laboratory testing.

Response: As discussed previously, we are finalizing our proposal to modify the definition of applicable laboratory to exclude MA plan payments from total Medicare revenues, the denominator of the majority of Medicare revenues threshold, so that more types of laboratories may qualify as an applicable laboratory. While the agency did not propose or solicit comments on the possibility of excluding Medicare Part D revenues from total Medicare revenues, we will take the commenter's suggestion into consideration for future refinements to the CLFS. However, we note that if the commenter is correct that there is no circumstance under which such payments would be related to laboratory testing, then whether Part D payments are included or excluded from the denominator would have no effect on the calculation.

4. Solicitation of Public Comments on Other Approaches To Defining Applicable Laboratory

As discussed in the CY 2019 PFS proposed rule (83 FR 35858), and as noted previously, we define applicable laboratory at the NPI level, which means the laboratory's own billing NPI is used to identify a laboratory's revenues for purposes of determining whether it meets the majority of Medicare revenues threshold and the low expenditure threshold components of the applicable laboratory definition. For background purposes, the following summarizes some of the considerations we made in establishing this policy.

In the CLFS proposed rule, entitled Medicare Clinical Diagnostic Laboratory Tests Payment System, published in the October 1, 2015 **Federal Register**, we proposed to define applicable laboratory at the TIN level so that an applicable laboratory would be an entity that reports tax-related information to the IRS under a TIN with which all of the NPIs in the entity are associated, and was itself a laboratory or had at least one component that was a laboratory, as defined in § 493.2. In the CLFS proposed rule, we discussed that we considered proposing to define applicable laboratory at the NPI level. However, we did not propose that approach because we believed private payor rates for CDLTs are negotiated at the TIN level and not by individual laboratory locations at the NPI level. Numerous stakeholders had indicated that the TIN-level entity is the entity negotiating pricing, and therefore, is the entity in the best position to compile and report applicable information across its multiple NPIs when there are multiple NPIs associated with a TIN-level entity. We stated that we believed defining applicable laboratory by TIN rather than NPI would result in the same applicable information being reported, and would require reporting by fewer entities, and therefore, would be less burdensome to applicable laboratories. In addition, we stated that we did not believe reporting at the TIN level would affect or diminish the quality of the applicable information reported. To the extent the information is accurately reported, we expected reporting at a higher organizational level to produce exactly the same applicable information as reporting at a lower level (80 FR 59391 through 59393).

Commenters who objected to our proposal to define applicable laboratory at the TIN level stated that our definition would exclude hospital laboratories because, in calculating the applicable laboratory's majority of Medicare revenues amount, which looks at the percentage of Medicare revenues from the PFS and CLFS across the entire TIN-level entity, virtually all hospital laboratories would not be considered an applicable laboratory. Many commenters expressed particular concern that our proposed definition would exclude hospital outreach laboratories, stating that hospital outreach laboratories, which do not provide laboratory services to hospital patients, are direct competitors of the broader independent laboratory market, and therefore, excluding them from the definition of applicable laboratory would result in incomplete and inappropriate applicable information, which would skew CLFS payment rates. Commenters maintained that CMS needed to ensure reporting by a broad scope of the laboratory market to meet what they viewed as the intent of the statute that all sectors of the laboratory market be included to establish accurate market-based rates (81 FR 41045).

In issuing the CLFS final rule, we found particularly compelling the comments that urged us to adopt a policy that would better enable hospital outreach laboratories to be applicable laboratories because we agreed hospital outreach laboratories should be included in determining the new CLFS payment rates. We believed it was important to facilitate reporting of private payor rates for hospital outreach laboratories to ensure a broader representation of the national laboratory

market to use in setting CLFS payment amounts (81 FR 41045).

We also stated in the CLFS final rule that we believed the intent of the statute was to effectively exclude hospital laboratories as applicable laboratories, based on the statutory language, in particular, regarding the majority of Medicare revenues threshold criterion in section 1834A(a)(2) of the Act. Section 1834A(a)(2) of the Act provides that, to qualify as an applicable laboratory, an entity's revenues from the CLFS and the PFS need to constitute a majority of its total Medicare payments received from the Medicare program for a data collection period. What we found significant was that most hospital laboratories would not meet that majority of Medicare revenues threshold because their revenues under the Inpatient Prospective Payment System (IPPS) and Outpatient Prospective Payment System (OPPS) alone would likely far exceed the revenues they received under the CLFS and PFS. Therefore, we stated that we believe the statute intended to limit reporting primarily to independent laboratories and physician offices (81 FR 41045 through 41047). For a full discussion of the definition of applicable laboratory, see the CLFS final rule (81 FR 41041 through 41051).

a. Stakeholder Continuing Comments and Stakeholder-Suggested Alternative Approaches

As noted above, in response to public comments, we had previously finalized that an applicable laboratory is the NPI-level entity so that a hospital outreach laboratory assigned a unique NPI, separate from the hospital of which it is a part, is able to meet the definition of applicable laboratory and its applicable information can be used for CLFS rate-setting. We stated in the CY 2019 PFS proposed rule that we continue to believe that the NPI is the most effective mechanism for identifying Medicare revenues for purposes of determining applicable laboratory status and identifying private payor rates for purposes of reporting applicable information. Once a hospital outreach laboratory obtains its own unique billing NPI and bills for services using its own unique NPI, Medicare and private payor revenues are directly attributable to the hospital outreach laboratory. By defining applicable laboratory using the NPI, Medicare payments (for purposes of determining applicable laboratory status) and private payor rates and the associated volume of CDLTs can be more easily identified and reported to us. We also noted that we believe that finalizing our proposal to exclude MA plan payments under Medicare Part C from total Medicare revenues in the definition of applicable laboratory may increase the number of entities meeting the majority of Medicare revenues threshold, and therefore, allow them to qualify for applicable laboratory status. We stated that we believe that finalizing the change to the total Medicare revenues component of the applicable laboratory definition and our current policy that requires an entity to bill Medicare Part B under its own NPI, may increase the number of hospital outreach laboratories qualifying as applicable laboratories.

In addition, we noted that we are confident that our current policy supports our collecting sufficient applicable information in the next data reporting period, and that we received sufficient and reliable applicable information with which we set CY 2018 CLFS rates, and that those rates are accurate. We noted that we received applicable information from laboratories in every state, the District of Columbia, and Puerto Rico. This data included private payor rates for almost 248 million laboratory tests conducted by 1,942 applicable laboratories, with over 4 million records of applicable information. As we have noted, the largest laboratories dominate the market, and therefore, most significantly affect the payment weights (81 FR 41049). We stated that given that the largest laboratories reported their applicable information to CMS in the initial data reporting period, along with many smaller laboratories, we believe the data we used to calculate the CY 2018 CLFS rates was sufficient and resulted in accurate weighted medians of private payor rates.

However, we noted that we continue to consider refinements to our policies that could lead to including even more applicable information for the next data reporting period. Therefore, the comments and alternative approaches suggested by commenters, even though some were first raised prior to the CLFS final rule, were presented and offered for comment as part of the proposed rule.

(1) Using Form CMS–1450 UB 04 (and Electronic Equivalent, 837I) 14X Type of Bill (TOB) To Determine Majority of Medicare Revenues and Low Expenditure Thresholds

Although an NPI-based definition of applicable laboratories includes more hospital outreach laboratories than a TIN-based definition, some commenters expressed concern that the NPI-based definition of applicable laboratory may not be sufficient to capture all of the hospital outreach laboratories. These commenters suggested we revise the definition specifically for the purpose of including more hospital outreach laboratories. Under a suggested approach, a laboratory could determine whether it meets the majority of Medicare revenues threshold and low expenditure threshold using only the revenues from services reported on the Form CMS–1450 (approved Office of Management and Budget number 0938–0997) 14x Type of Bill (TOB), which is used only by hospital outreach laboratories. The CMS–1450 14X TOB is the uniform bill (also known as the UB–04) for institutional providers that was approved by the National Uniform Billing Committee (NUBC)[8] at its February 2005 meeting.

The data elements referenced in the UB–04 manual are also used in the electronic claim standard as required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191, enacted August 21, 1996) as per of sections 1171 and 1172 of the Act. Consequently, there was additional emphasis placed on aligning the reporting instructions to closely mirror the HIPAA claim standard for institutional providers for both paper and electronic claims. The TOB is a required element on both the UB 04 and electronic equivalent of the 837I transaction of the HIPAA compliant 005010 standard transaction. The NUBC defines the 14X TOB as an outpatient hospital TOB, and it is used by hospitals to bill a payor for outreach laboratory services for non-patients. As discussed in Transmittal 3425, a non-patient is defined as a beneficiary who is neither an inpatient nor an outpatient of a hospital, but who has a specimen that is submitted for analysis to a hospital and the beneficiary is not physically present at the hospital for purposes of the laboratory service. All hospitals (including Critical Access Hospitals) bill non-patient laboratory tests on a TOB 14X. They are paid under the CLFS, and the Part B deductible and coinsurance do not apply. We believe that laboratory services billed on the CMS 1450 14X encompass all of the laboratory testing services.

To address this stakeholder's concern of including hospital outreach laboratories, we solicited public comments in the CY 2019 PFS on revising the definition of applicable laboratory to permit the revenues identified on the Form CMS–1450 14x

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TOB to be used instead of the revenues associated with the NPI that the laboratory uses in order to determine whether it meets the majority of Medicare revenues threshold (and the low expenditure threshold). Under this approach, the applicable revenues would be based on the bills used for hospital laboratory services provided to non-patients, which are paid under Medicare Part B (that is, the 14x TOB). If we pursued this approach, we explained that we would have to modify the definition of applicable laboratory in § 414.502 by indicating that an applicable laboratory may include an entity that bills Medicare Part B on the Form CMS–1450 14x TOB.

Although using the 14x TOB could alleviate some initial, albeit limited, administrative burden on hospital outreach laboratories to obtain a unique billing NPI, we explained that we would have operational and statutory authority concerns about defining applicable laboratory by the Form CMS–1450 14x TOB, as indicated below.

First, we explained that defining an applicable laboratory using the Form CMS–1450 14x TOB does not identify an entity the same way an NPI does. Whereas an NPI is associated with a provider or supplier to determine specific Medicare revenues, the 14x TOB is merely a billing mechanism that is currently used only for a limited set of services. Under an approach that permits laboratories to meet the majority of Medicare revenues threshold using the 14x TOB, private payor rates (and the volume of tests paid at those rates) would have to be identified that are associated with only the outreach laboratory services of a hospital's laboratory business. However, some private payors, such as MA plans, may not require hospital outreach laboratories to use the 14x TOB for their outreach laboratory services. To the extent a private payor does not require hospital outreach laboratory services to be billed on a 14x TOB (which specifically identifies outreach services), hospitals may need to develop their own mechanism for identifying and reporting only the applicable information associated with its hospital outreach laboratory services. In light of this possible scenario, we requested public comments about the utility of using the 14x TOB in the way we have described and on the level of administrative burden created if we defined applicable laboratory using the Form CMS–1450 14x TOB.

Second, we questioned whether hospitals would have sufficient time after publication of a new final rule that included using the Form CMS–1450 14x TOB, and any related subregulatory guidance, to develop and implement the information systems necessary to collect private payor rate data before the start of the next data collection period, that is, January 1, 2019. Therefore, we solicited public comments as to whether revising the definition of applicable laboratory to use the Form CMS–1450 14x TOB would allow laboratories sufficient time to make the necessary systems changes to identify applicable information before the start of the next data collection period.

Third, we noted that we believe defining applicable laboratory at the NPI level, as we currently do, provides flexibility for hospital outreach laboratories to not obtain a unique billing NPI, which may be burdensome, particularly where a hospital outreach laboratory performs relatively few outreach services under Medicare Part B. For example, under the current definition of applicable laboratory, if a hospital outreach laboratory's CLFS revenues in a data collection period are typically less than the low expenditure threshold, the hospital of which it is a part could choose not to obtain a separate NPI for its outreach laboratory and could thus avoid determining applicable laboratory status for its outreach laboratory component. In contrast, if laboratories were permitted to use the Form CMS–1450 14x TOB, revenues attributed to the hospital outreach laboratory would have to be calculated in every instance where those services exceeded the low expenditure threshold. This would be true even for a hospital outreach laboratory that performs relatively few outreach services under Medicare Part B. Therefore, we also solicited comments concerning this aspect of using the 14x TOB definition.

Fourth, and significantly, we stated that we believe that if we were to utilize such an approach in defining applicable laboratory, all hospital outreach laboratories would meet the majority of Medicare revenues threshold. We noted, at that time, we believed this approach would be inconsistent with the statute. By virtue of the majority of Medicare revenues threshold, the statute defines applicable laboratory in such a way that not all laboratories qualify as applicable laboratories. However, if we were to use the CMS–1450 14x TOB to define an applicable laboratory, all hospital outreach laboratories that use the 14x TOB would meet the majority of Medicare revenues threshold. Accordingly, we requested public comments regarding whether this definition would indeed be inconsistent with the statute, as well as comments that could identify circumstances under this definition whereby a hospital outreach laboratory would not meet the majority of Medicare revenues threshold.

The following is a summary of the comments we received and our responses to the comments regarding the use of the CMS–1450 14x TOB to define an applicable laboratory.

Comment: We received conflicting comments on this potential refinement to the definition of an applicable laboratory. Some commenters supported using the CMS–1450 14x TOB as a mechanism to define an applicable laboratory, and others were opposed to this approach. The commenters who supported this believe that it provides an opportunity for hospital outreach laboratories that have not obtained an NPI separate from the hospital to qualify as an applicable laboratory and report applicable information. These commenters opined that since the 14X TOB is used only to submit claims by hospital outreach laboratories for non-patient claims, this approach would include hospital laboratories without their own NPI who compete in the marketplace with independent clinical laboratories. These commenters also noted that, in their view, this approach would effectuate Congress' intent to determine whether a majority of Medicare revenues attributable to the laboratory part of the hospital—as opposed to the entire hospital—was from the CLFS and/or PFS.

Another commenter stated their view that considerable burden is associated with requiring a hospital outreach laboratory to obtain its own NPI. According to this commenter, a hospital would need to re-credential under a new NPI with each of their payors in order to submit claims and receive payment from each of their payors for their hospital outreach laboratory services. This commenter stated that this process could take more than a year to complete. Accordingly, this commenter concluded that hospital outreach laboratories rarely obtain their own unique NPI (separate from the hospital) and it would not be practical to do so for the single purpose of reporting applicable information to CMS.

Additional commenters in support of refinements to the definition responded to CMS' concern that revenues attributed to the hospital outreach laboratory would have to be calculated in every instance where those services exceeded the low expenditure threshold, even for a hospital outreach laboratory that performs relatively few outreach services under Medicare Part

B. In response to this concern, commenters noted that this refinement to the definition would require hospital outreach laboratories to have the same obligations as other laboratories that exceed the low expenditure threshold and that serve non-hospital patients. Furthermore, commenters suggested that if CMS is concerned that refinements to the definition would result in all hospital outreach laboratories meeting the majority of Medicare revenues threshold, that is the case for almost all independent laboratories, as well, where hospital outreach laboratories compete with independent laboratories in the marketplace. Furthermore, they stated it is reasonable that a laboratory whose revenues are derived primarily from the CLFS and/or PFS and that meets the low expenditure threshold be included in data reporting, regardless if it is a hospital outreach laboratory.

In contrast, several commenters strongly opposed the use of Form CMS–1450 14x TOB to define an applicable laboratory because of their views of the additional administrative burden for hospitals relative to the effect on CLFS rates. These commenters stated that even if every hospital outreach laboratory were to report private payor data, it is unlikely that it would result in a significant change to the weighted median of private payor rates due to the massive amount of data that would be reported by the large independent laboratories. They also agreed with the potential operational feasibility concerns we raised in the proposed rule.

Response: We appreciate the comments raised about the administrative aspects of obtaining an NPI for a hospital outreach laboratory for the sole purpose of reporting data to CMS and the associated administrative burden. We agree that one advantage of using the Form CMS–1450 14x TOB to define an applicable laboratory is that it provides an opportunity for more hospital outreach laboratories to report data for calculating CLFS rates. However, we also recognize that this will result in additional administrative burden on the hospital industry, such as changes to collect and report applicable information. We discuss specific operational concerns in more detail in the sections below. However, we generally believe that this advantage outweighs the potential burden for hospital outreach laboratories, the data collected from hospital outreach laboratories will create a dataset that is a more robust representation of the laboratory testing market, and that this outweighs the potential burden to hospital outreach laboratories. Accordingly, we are finalizing the use of the Form CMS–1450 14x TOB to define applicable laboratories for the next data collection period (January 1, 2019, through June 30, 2019) and the next data reporting period (January 1, 2020, and ends March 31, 2020), subject to other regulatory and subregulatory requirements, such as the regulatory low expenditure threshold.

We also considered the comments regarding the limited impact of this additional data to the weighted median of private payor rates. We believe that we will only know the impact of the data on CLFS rates by collecting data from hospital outreach laboratories. We believe inclusion of this information so that the CLFS rates better reflect the market outweighs the potential added burden on one segment of the market. However, if it becomes apparent that data from hospital outreach laboratories do not result in a significant change in the weighted median of private payor rates, we will revisit the use of the CMS–1450 14x TOB through future rulemaking.

Comment: A few commenters stated that CMS should not be concerned that hospitals will need to develop additional mechanisms to identify applicable information if private payors do not require hospital outreach laboratories to use the CMS–1450 14x TOB. They noted that this point is not relevant to reporting private payor rates because once applicable laboratory status is determined, the hospital outreach laboratory ''can simply report its private payor data for all of its fee for service work that is not part of a capitated plan.'' The commenters stated that the reporting entities for all other laboratory types would have the same burden as hospital outreach laboratories, that is, of identifying and reporting accurate applicable information.

In contrast, several stakeholders raised concerns about the implications this alternative approach would have on identifying applicable information for purposes of reporting that data to us. They stated that the Form CMS–1450 14x TOB will only capture Medicare Part B revenues, while private payor data would not be captured. In other words, the 14x TOB will correctly identify Medicare Part B revenues for purposes of determining applicable laboratory status, but that the hospital would be responsible for correctly identifying and collecting applicable information associated solely with the hospital outreach laboratory. Several commenters stated that billing systems for hospital outreach laboratories are not set up in a manner that allows this type of information to be easily extracted, and therefore, this approach to defining an applicable laboratory would pose a significant operational burden on hospitals.

Response: We note that hospital outreach laboratories who meet the definition of an applicable laboratory would have the same burden of identifying and reporting accurate applicable information as all other laboratory types that meet the definition of an applicable laboratory.

Comment: Some commenters stated that they believe hospitals would have sufficient time to develop and implement the information systems necessary to collect private payor rate data before the start of the next data collection period, and noted that even though the CLFS final rule was published less than 2 weeks prior to the end of the first data collection period, applicable laboratories were able to develop and implement the information systems necessary to collect private payor rate data and report it to CMS. However, several commenters expressed serious concerns about developing the systems to collect applicable information before the next data reporting period. They indicated that finalizing this alternative approach for defining an applicable laboratory would not allow hospital outreach laboratories sufficient time to make the necessary systems changes prior to the start of the next data collection, and as a result, there would be a risk that inaccurate data would be reported.

Response: As discussed previously in this section, the next data collection period is January 1, 2019, through June 30, 2019. A 6-month window follows the data collection period from July 1, 2019, through December 31, 2019 and the next data reporting period begins January 1, 2020, and ends March 31, 2020. While several commenters raised concerns about the operational changes needed for reporting before the next data collection period, we believe that, similar to the retroactive data collection that occurred under the initial private payor rate-based CLFS, hospitals, including the part of the hospital represented by their hospital outreach laboratories, could develop these operational changes in time. For example, hospitals, including the part of the hospital represented by their hospital outreach laboratories, could use the time before and during the next data collection period to develop processes to collect applicable information, the 6-month window between the collection and reporting periods to determine applicable laboratory status and retroactively collect applicable

information to report it before the close of the next data reporting period (March 31, 2020).

Comment: Many commenters noted the concern that hospital outreach laboratories would lose the flexibility to not obtain an NPI for low volume hospital outreach laboratories. For instance, they stated all hospitals would be required to go through the exercise of determining applicable laboratory status for their hospital outreach laboratory components. However, a few commenters indicated that hospital outreach laboratories would have the same obligations as every other laboratory to determine whether it is an applicable laboratory. Therefore, in their view, the loss of flexibility for hospital outreach laboratories to not obtain an NPI should not be a concern.

Response: We agree that the use of Form CMS–1450 14x TOB to define an applicable laboratory will require hospitals to assess applicable laboratory status for all outreach laboratory components, similar to the obligations of other laboratory types. For instance, all independent and physician office laboratories billing Medicare Part B under their own NPI must assess whether they qualify as an applicable laboratory, and if so, report applicable information to us. Consequently, independent and physician office laboratories do not have the flexibility of not reporting private payor data that is currently afforded to hospital outpatient laboratories. Use of the 14x TOB to define an applicable laboratory would equalize the obligations across laboratories, regardless of their affiliation with a hospital, to determine whether they qualify for applicable laboratory status. We note that, insofar as commenters expressed concern about low volume hospital outreach laboratories, our policy regarding laboratories receiving less than a minimum in CLFS revenues remains unchanged. Specifically, hospital outreach laboratories that do not receive at least $12,500 in CLFS revenues on the 14X TOB during a data collection period would be exempt from the reporting requirements.

Comment: Several commenters noted that by using the 14x TOB to define an applicable laboratory, all hospital outreach laboratories would meet the majority of Medicare revenues threshold. They, therefore, raised concerns about the legality of this approach. For instance, some commenters stated their view that Congress did not intend for all hospital outreach laboratories to qualify as applicable laboratories. In contrast, some commenters stated their view that Congress clearly intended for the CLFS to reflect a market-based system that includes hospital outreach laboratories and that it is reasonable for a laboratory with revenues derived primarily from the CLFS and/or PFS that also meets the low expenditure threshold to be an applicable laboratory, regardless of whether it is a hospital outreach laboratory or not.

Response: After further review of this issue, we believe that using Form CMS–1450 14x TOB provides a means of distinguishing services furnished by a hospital outreach laboratory from other services furnished and billed by a hospital using the same NPI. The statute specifically directs us to identify applicable ''laboratories'' and not ''providers'' or ''suppliers.'' We believe that hospital outreach laboratories without unique NPIs furnish clinical laboratory tests paid under the CLFS and PFS, albeit to Medicare beneficiaries who are not hospital patients. Accordingly, we believe such laboratories, should not be exempt from reporting the applicable data merely due to their shared use of a billing entity with a hospital.

Using the laboratory's own billing NPI as the basis for defining applicable laboratory, as we currently do, results in all independent laboratories meeting the statutory ''majority of Medicare revenues'' requirement because most, if not all, of an independent laboratory's Medicare revenues are received from the PFS and or CLFS. Similar to how the use of the NPI results in all independent laboratories meeting the majority of Medicare revenues threshold, using the Form CMS–1450 14x TOB as the basis for defining applicable laboratory would identify all hospital outreach laboratories that meet the statutorily required ''majority of Medicare revenues'' component of applicable laboratory.

We believe that the use of Form CMS–1450 14x TOB as a mechanism for applying the majority of Medicare revenues threshold identifies hospital outreach laboratories that meet this threshold, consistent with the statutory requirement for applicable laboratory status. We further believe that, absent having an NPI separate from the hospital, these hospital outreach laboratories otherwise would be excluded. We do not believe that the statute excludes laboratories that meet the majority of Medicare revenues threshold from potentially qualifying as an applicable laboratory. Therefore, using the 14x TOB to define applicable laboratory is consistent with the statute.

As stated above, accordingly, we are finalizing the use of the Form CMS–1450 14x TOB to define applicable laboratories, subject to other regulatory and subregulatory requirements, such as the regulatory low expenditure threshold.

Comment: Two commenters stated that it is unclear whether the burden associated with considering every hospital outreach laboratory to meet the majority of Medicare revenues threshold and an applicable laboratory (if the low expenditure threshold is also met) would outweigh the additional applicable information that would be reported. Therefore, they requested that we continue evaluating this approach before implementing any changes.

Response: As we stated previously, we generally believe that the advantage of including private payor data from hospital outreach laboratories in setting CLFS rates outweighs the potential burden for hospital outreach laboratories; data collected from hospital outreach laboratories will create a dataset that is a more robust representation of the laboratory testing market. We also note that the timing of the data collection and reporting periods, and the 6 month window in between provide time for laboratories to implement needed operational changes.

Comment: One commenter suggested that an alternative approach to identifying applicable laboratories would be for the hospital to develop an ''adjustment factor'' based on its payment-to-charges ratio to estimate laboratory revenues received from the IPPS and OPPS. The same commenter suggested that we remove the requirement that an applicable laboratory is an entity that bills Medicare Part B under its own NPI and that we amend the majority of Medicare revenues threshold so that ''Medicare revenues'' means payment for claims submitted on a CMS 1500, a CMS 1450 using a 14x TOB, or their electronic equivalents.

Response: We appreciate this suggested approach and we may consider it in future rulemaking.

In conclusion, as stated previously and for the reasons described previously, we are finalizing the use of the Form CMS–1450 14x TOB to define applicable laboratories, subject to other regulatory and subregulatory requirements, such as the regulatory low expenditure threshold.

We note that because of the low expenditure threshold, not all hospital outreach laboratories would meet the definition of an applicable laboratory and therefore not all hospital outreach laboratories would be required to report applicable information to us. In other words, hospital outreach laboratories

that do not receive at least $12,500 in CLFS revenues on the 14X TOB during a data collection period would be exempt from the reporting requirements.

We believe that defining applicable laboratory by the NPI may be preferable to using the CMS–1450 14x TOB for some hospitals and so expect that some hospital outreach laboratories may still want to obtain their own billing NPI separate from the hospital. As such, they may do so and may qualify as an applicable laboratory in this manner. If so, they would report applicable information during the next data reporting period beginning January 1, 2020, through March 31, 2020.

We note that we utilize ongoing subregulatory guidance and provider education materials to provide more details regarding how applicable laboratories, both those identified through NPIs and hospital outreach laboratories identified through the combination of NPI and services reported using the 14x TOBs, are to report the applicable data to CMS. We also note that for hospitals which have an applicable laboratory, whether via its own NPI for its outreach laboratory or by identifying its status with the 14X TOB, the applicable laboratory would be required to report applicable information by March 31, 2020, for services reimbursed for the period between January 1, 2019, and June 30, 2019.

In conclusion, as stated previously, we are finalizing the use of the Form CMS–1450 14x TOB to define applicable laboratories. In other words, we are finalizing modification of the definition of applicable laboratory to also include 14X TOB revenues. We will also revise paragraph (2) of the definition of applicable laboratory at § 414.502 accordingly.

(2) Using CLIA Certificate To Define Applicable Laboratories

Some commenters requested that we use the CLIA certificate rather than the NPI to identify a laboratory that would be considered an applicable laboratory. We discussed in the CLFS proposed rule (80 FR 59392) why not all entities that meet the CLIA regulatory definition at § 493.2 would be applicable laboratories, and therefore, we did not propose to use the CLIA certificate as the mechanism for defining applicable laboratory. However, some commenters to the CLFS proposed rule suggested we use the CLIA certificate to identify the organizational entity that would be considered an applicable laboratory so that each entity that had a CLIA certificate would be an applicable laboratory (81 FR 41045). We considered those comments in the CLFS final rule and discussed why we chose not to adopt that approach.

Among other reasons, we explained in the CLFS final rule that we believed a CLIA certificate-based definition of applicable laboratory would be overly inclusive by including all hospital laboratories, as opposed to just hospital outreach laboratories. In addition, the CLIA certificate is used to certify that a laboratory meets applicable health and safety regulations in order to furnish laboratory services. Unlike, for example, the NPI, with which revenues for specific services can easily be identified, the CLIA certificate is not associated with Medicare billing and cannot be used to identify revenues for specific services. We also indicated that we did not know how a hospital would determine whether its laboratories would meet the majority of Medicare revenues threshold (and the low expenditure threshold) using the CLIA certificate as the basis for defining an applicable laboratory. In addition, we stated that, given the difficulties many hospitals would likely have in determining whether their laboratories are applicable laboratories, we also believed hospitals may object to using the CLIA certificate (81 FR 41045).

However, in light of stakeholders' suggestions to use the CLIA certificate to include hospital outreach laboratories in the definition of applicable laboratories, we solicited public comments on that approach. Under such an approach, the majority of Medicare revenues threshold and low expenditure threshold components of the definition of applicable laboratory would be determined at the CLIA certificate level instead of the NPI level. We explained that if we pursued such an approach, we would have to modify the definition of applicable laboratory in § 414.502 to indicate that an applicable laboratory is one that holds a CLIA certificate under § 493.2 of the chapter. We noted in the CY 2019 PFS proposed rule that we would have concerns, however, about defining applicable laboratory by the CLIA certificate.

First, we explained that as we discussed in the CLFS final rule, given that information regarding the CLIA certificate is not required on the Form CMS–1450 14x TOB, which is the billing form used by hospitals for their laboratory outreach services, it is not clear how a hospital would identify and distinguish revenues generated by its separately CLIA-certified laboratories for their outreach services. Therefore, we solicited public comments regarding the mechanisms a hospital would need to develop to identify revenues if we used the CLIA certificate for purposes of determining applicable laboratory status, as well as comments about the administrative burden associated with developing such mechanisms.

In addition, we understood there could be a scenario where one CLIA certificate is assigned to a hospital's entire laboratory business, which would include laboratory tests performed for hospital patients as well as non-patients (that is, patients who are not admitted inpatients or registered outpatients of the hospital). For example, hospital laboratories with an outreach laboratory component would be assigned a single CLIA certificate if the hospital outreach laboratory has the same mailing address or location as the hospital laboratory. We noted that in this scenario, the majority of Medicare revenues threshold would be applied to the entire hospital laboratory, not just its outreach laboratory component. If a single CLIA certificate is assigned to the hospital's entire laboratory business, the hospital laboratory would be unlikely to meet the majority of Medicare revenues threshold because its laboratory revenues under the IPPS and OPPS alone would likely far exceed the revenues it receives under the CLFS and PFS. As a result, a hospital outreach laboratory that could otherwise meet the definition of applicable laboratory, as currently defined at the NPI level, would not be an applicable laboratory if we were to require the CLIA certificate to define applicable laboratory. Given that this approach could have the effect of decreasing as opposed to increasing the number of applicable laboratories, we requested public comments on this potential drawback of defining applicable laboratory at the CLIA certificate level. We stated in the comment solicitation that feedback on this topic could help inform us regarding potential refinements to the definition of applicable laboratory, and that depending on the comments we receive, it is possible we would consider approaches described in that section. The following is a summary of the comments we received and our responses to the comments regarding the use of the CLIA certificate to define an applicable laboratory.

Comment: Many commenters did not support using the CLIA certificate to define applicable laboratory because of the administrative complexity associated with this approach. Commenters stated that the CLIA certificate has no relationship to actual laboratory revenues, like the NPI does, and therefore, laboratories would need to develop their own mechanisms to attribute Medicare revenues to the CLIA

certificate. Commenters stated that any ''workaround'' to resolve these issues would be extremely burdensome to develop and implement. These same commenters also noted that when one CLIA certificate is assigned to a hospital's entire laboratory business, which would include laboratory tests performed for hospital patients as well as non-patients, the total Medicare revenues component of the majority of Medicare revenues threshold equation would be ''overly inclusive.'' Therefore, they agreed with CMS' concern that hospital outreach laboratories would be unlikely to meet the majority of Medicare revenues threshold under those circumstances because revenues from the IPPS and OPPS alone would likely far exceed the revenues those laboratories receive under the CLFS and PFS. For these reasons, they encouraged CMS to reject the use of the CLIA certificate for defining an applicable laboratory.

Response: We agree that defining applicable laboratory by the CLIA certificate would result in substantial administrative burden for the laboratory industry. From an administrative perspective, we believe the using the CLIA certificate unworkable for the purpose of determining applicable laboratory status because the CLIA certificate is not required on the CMS 1450 14x TOB which is the billing form used by hospital outreach laboratories. Therefore, no revenues can be readily identified by the CLIA certificate. Even if the hospital developed its own mechanism to identify revenues by the CLIA certificate, the CLIA certificate could be assigned to the hospital's entire laboratory business, which includes laboratory tests performed for hospital patients, as well as non-patients. For example, we understand hospital-based laboratories with an outreach component would be assigned a single CLIA certificate if the hospital outreach laboratory has the same mailing address or location as the main laboratory. In this scenario, the applicable laboratory criteria would be applied to the CLIA certificate of the entire hospital laboratory not just its outreach laboratory component. When a single CLIA certificate is assigned to the hospital's entire laboratory business, we believe it would result in the hospital laboratory not meeting the majority of Medicare revenues threshold because its laboratory revenues under the IPPS and OPPS alone will far exceed the revenues it receives under the CLFS and PFS. We also understand that a hospital could have multiple outreach laboratories each with its own CLIA certificate. Therefore, we believe those hospitals would also have difficulties separating Medicare revenues and applicable information among their various CLIA certificates as described below.

Comment: One commenter stated that it is unlikely that a single CLIA certificate would be assigned to both its outreach laboratory (non-patients) and its laboratory that that provides testing for its hospital inpatients and hospital outpatients. The commenter stated that it would be more likely that the outreach laboratory would be at a different location than the hospital and therefore, be assigned its own CLIA certificate even though the outreach laboratory is enrolled in the Medicare program under the hospital's NPI. As such, the commenter stated that an outreach laboratory operates as a distinct laboratory entity by virtue of having its own CLIA certificate and billing on the Form CMS–1450 14x TOB. The commenter suggested that the 14x TOB could be used in combination with each individual CLIA certificate to define applicable laboratory.

Response: We understand that the assignment of CLIA certificates for hospital outreach laboratories could vary depending on the location of the outreach laboratory. As discussed previously, Medicare revenues are not attributed to the CLIA certificate and information regarding the CLIA certificate is not required on the Form CMS–1450 14x TOB. As such, we believe the commenter's suggestion would result in defining applicable laboratory by the Form CMS–1450 14x TOB. We note that in cases in which a hospital owns and operates multiple outreach laboratories at different locations, we believe the administrative burden of attributing Medicare revenues to the CLIA certificate would be even more substantial as there could be several CLIA certificates assigned under the same NPI. In such cases, the hospital would need to attribute laboratory revenues among multiple CLIA certificates under the same billing entity. In other words, if the 14x TOB is used by a hospital to bill for laboratory tests furnished by more than one CLIA certificate under the same NPI, the hospital would need to devise a mechanism to attribute Medicare revenues to each individual CLIA certificate.

5. Solicitation of Public Comments on the Low Expenditure Threshold in the Definition of Applicable Laboratory

a. Decreasing the Low Expenditure Threshold

In the CLFS final rule, we established a low expenditure threshold component in the definition of applicable laboratory at § 414.502, which is reflected in paragraph (4). To be an applicable laboratory, at least $12,500 of an entity's Medicare revenues in a data collection period must be CLFS revenues (with the exception that there is no low expenditure threshold for an entity with respect to the ADLTs it furnishes). We established $12,500 as the low expenditure threshold because we believed it achieved a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a test, and minimizing the reporting burden for laboratories that receive a relatively small amount of revenues under the CLFS. We indicated in the CLFS final rule (81 FR 41049) that once we obtained applicable information under the new payment system, we may decide to reevaluate the low expenditure threshold in future years and propose a different threshold amount through notice and comment rulemaking.

We explained in the CY 2019 PFS proposed rule that we recently heard from some laboratory stakeholders that the low expenditure threshold excludes most physician office laboratories and many small independent laboratories from reporting applicable information, and that by excluding so many laboratories, the payment rates under the new private payor rate-based CLFS reflect incomplete data, and therefore, inaccurate CLFS pricing.

As noted previously, we discussed in the CLFS final rule that we believed a $12,500 low expenditure threshold would reduce the reporting burden on small laboratories. In the CLFS final rule (81 FR 41051), we estimated that 95 percent of physician office laboratories and 55 percent of independent laboratories would not be required to report applicable information under our low expenditure criterion. Although we substantially reduced the number of laboratories qualifying as applicable laboratories (that is, approximately 5 percent of physician office laboratories and approximately 45 percent of independent laboratories), we estimated that the percentage of Medicare utilization would remain high. That is, approximately 5 percent of physician office laboratories would account for approximately 92 percent of CLFS

spending on physician office laboratories and approximately 45 percent of independent laboratories would account for approximately 99 percent of CLFS spending on independent laboratories (81 FR 41051).

We stated that it is our understanding that physician offices are generally not prepared to identify, collect, and report each unique private payor rate from each private payor for each laboratory test code subject to the data collection and reporting requirements, and the volume associated with each unique private payor rate. As such, we explained that we believe revising the low expenditure threshold so that more physician office laboratories are required to report applicable information would likely impose significant administrative burdens on physician offices. We stated that we also believe that increasing participation from physician office laboratories would have minimal overall impact on payment rates given that the weighted median of private payor rates is dominated by the laboratories with the largest test volume. We noted that our participation simulations from the first data reporting period show that increasing the volume of physician office laboratories reporting applicable information has minimal overall impact on the weighted median of private payor rates. For more information on our participation simulations, please visit the CLFS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf*.

We stated in the proposed rule that we continue to believe the current low expenditure threshold strikes an appropriate balance between collecting enough private payor rate data to accurately represent the weighted median of private payor rates while limiting the administrative burden on small laboratories. In addition, as discussed previously in this section, we are finalizing excluding MA plan revenues under Part C from total Medicare revenues in the definition of applicable laboratory, and we noted that we expect more laboratories of all types, including physician office laboratories, may meet the majority of Medicare revenues threshold.

However, we recognized from stakeholders that some physician office laboratories and small independent laboratories that are not applicable laboratories because they do not meet the current low expenditure threshold may still want to report applicable information despite the administrative burden associated with qualifying as an applicable laboratory. Therefore, we sought public comment on revising the low expenditure threshold to increase the level of participation among physician office laboratories and small independent laboratories.

In the proposed rule we explained that one approach could be for us to decrease the low expenditure threshold by 50 percent, from $12,500 to $6,250, in CLFS revenues during a data collection period. Under such an approach, a laboratory would need to receive at least $6,250 in CLFS revenues in a data collection period. We stated that if we were to adopt such an approach, we would need to revise paragraph (4) of the definition of applicable laboratory at § 414.502 to replace $12,500 with $6,250. We solicited public comments on this approach.

We noted that we were particularly interested in comments from the physician community and small independent laboratories as to the administrative burden associated with such a revision to the low expenditure threshold. Specifically, we requested comments on the following issues: (1) Whether physician offices and small independent laboratories currently have adequate staff levels to meet the data collection and data reporting requirements; (2) whether data systems are currently in place to identify, collect, and report each unique private payor rate from each private payor for each CLFS test code and the volume of tests associated with each unique private payor rate; (3) if physician offices and small independent laboratories are generally not prepared to conduct the data collection and data reporting requirements, what is the anticipated timeframe needed for physician office and small independent laboratories to be able to meet the data collection and data reporting requirements; and (4) any other administrative concerns that decreasing the low expenditure threshold may impose on offices and small independent laboratories.

The following is a summary of the comments we received and our responses to the comments regarding the approach of decreasing the low expenditure threshold by 50 percent, from $12,500 to $6,250, in CLFS revenues during a data collection period.

Comment: Many commenters were opposed to reducing the low expenditure threshold because of the administrative burden it would place on physician office laboratories and small independent laboratories. Commenters noted that they experienced difficulties during the initial data collection and data reporting period with determining whether they met the definition of applicable laboratory and therefore if they were required to report applicable information. Some commenters that did report applicable information stated that they experienced significant administrative burden in collecting and compiling information, especially for test codes that involved numerous different sources of payment (such as the beneficiary's primary private payor, the beneficiary's secondary insurance, and coinsurance requirements). Some commenters reported having to remove staff from regular duties to work full time on preparing to report applicable information to CMS. A few commenters noted that physician office laboratories and small independent laboratories do not have the staffing or resources currently available, nor do they anticipate having them available in the future, to identify, collect and report each unique private payor rate for each CLFS test code and the volume of tests associated with each unique private payor rate. As such, commenters encouraged CMS not to decrease the low expenditure threshold component of the definition of applicable laboratory.

Response: We appreciate the comments regarding the administrative burden imposed by the data collection and reporting requirements on physician office laboratories and small independent laboratories and understand that reducing the low expenditure threshold by 50 percent would add more burden on this segment of the laboratory industry. We will consider the commenters' input regarding the low expenditure threshold as we continue to evaluate and refine Medicare CLFS payment policy in the future.

Comment: A few commenters suggested alternative approaches to lowering the low expenditure threshold that involve collecting data for physician office dependent tests and allowing laboratories to voluntarily report applicable information. For example, two commenters suggested that CMS identify laboratory tests predominantly performed by physician office laboratories and collect a statistically representative sample of data from physician office laboratories for the range of tests commonly performed in this setting. Under the commenters' approach, physician office laboratories would be required to report those tests. The commenters stated that this would ensure that the private payor rates for tests mostly performed by physician office laboratories are

represented in the weighted median of private payor rates used to determine CLFS rates. Moreover, a few other commenters suggested that CMS permit voluntary reporting so that laboratories that do not meet the current low expenditure threshold may report applicable information if they choose to.

Response: The suggestions to identify physician office laboratory dependent tests and to permit voluntary reporting have already been addressed in previous rulemaking and we chose not to adopt them (81 FR 41048). We noted that statute is clear about the particular information that is to be reported and on which we must base the new CLFS payment rates. Only applicable information of applicable laboratories is to be reported, and section 1834A(a)(3) of the Act indicates that applicable information is private payor rate information. We also explained that the statute imposes parameters on the collection and reporting of private payor rate information, and section 1834A(b) of the Act specifies that the payment amounts for CDLTs are to be based on the median of the private payor rate information. As such, we stated that we believe the statute supports our policy to prohibit information other than statutorily specified private payor rate information of applicable laboratories from being reported and used to set CLFS payment amounts under the revised CLFS. We also noted that we did not agree with the commenters' recommendation to allow voluntary reporting and at § 414.504(g), we finalized that an entity that does not meet the definition of an applicable laboratory may not report applicable information. We continue to believe that our policy to not allow voluntary reporting is the most appropriate interpretation of the statute, and that applicable information may not be reported for an entity that does not meet the definition of an applicable laboratory.

b. Increasing the Low Expenditure Threshold

We also discussed in the CY 2019 PFS proposed rule that we recognize many small laboratories may not want the additional administrative burden of data collection and reporting and, because their test volume is relatively low, their data is unlikely to have a meaningful impact on the weighted median of private payor rates for CDLTs under the CLFS. In response to comments from smaller laboratories that they prefer to not be applicable laboratories because of the burden of collecting and reporting applicable information, we stated that we could increase the low expenditure threshold in the definition of applicable laboratory by 50 percent, from $12,500 to $18,750, in CLFS revenues during a data collection period. Because physician office laboratories would be less likely to meet a higher threshold, such an approach would decrease the number of physician office laboratories and small independent laboratories required to collect and report applicable information. We noted that we expected decreasing the number of physician office laboratories and small independent laboratories reporting applicable information would have minimal impact on determining CLFS rates because the largest laboratories with the highest test volumes dominate the weighted median of private payor rates.

We stated that if we were to adopt such an approach, we would need to revise paragraph (4) of the definition of applicable laboratory at § 414.502 to replace $12,500 with $18,750. We explained in the proposed rule that we were particularly interested in comments from the physician community and small independent laboratories on the administrative burden and relief of increasing the low expenditure threshold and noted that we believe that feedback on the topics discussed in this section would help inform us regarding potential refinements to the low expenditure threshold. We noted that depending on the comments we received, we would consider approaches described in this section.

The following is a summary of the comments we received and our responses to the comments regarding the approach of increasing the low expenditure threshold by 50 percent, from $12,500 to $18,750, in CLFS revenues during a data collection period.

Comment: Several commenters did not support raising the low expenditure threshold because it would further reduce the amount of applicable information reported from small laboratories. However, one commenter encouraged CMS to increase the low expenditure threshold to exclude even more small laboratories from the administrative burden of collecting and reporting applicable information. A few commenters suggested that CMS not make any changes to the low expenditure threshold at this time and encouraged CMS to allow the program to mature and to only make changes after a careful and transparent review of the data with additional opportunities for public comment.

Response: We appreciate the comments from stakeholders on raising the low expenditure threshold and understand that increasing the low expenditure threshold by 50 percent would lead to fewer physician office laboratories and small independent laboratories from reporting applicable information for purposes of calculating CLFS rates. We will consider the commenters input on increasing the low expenditure threshold as we continue to evaluate and refine Medicare CLFS payment policy in the future, but make no changes to this policy at this time.

c. Additional Comments Received

Comment: Many commenters stated that CMS' implementation of the new private payor rate-based CLFS does not reflect the cost or the value of performing clinical laboratory services and that without meaningful changes to how data is collected from laboratories, Medicare beneficiaries will lose access to the vital laboratory services they rely on to monitor their health and prevent and treat many diseases and conditions. The commenters stated that CMS' regulations, which implemented the private payor rate-based CLFS required under PAMA, prohibit most independent laboratories and physician office laboratories, and virtually all hospital laboratories, from providing data to set Medicare rates, and therefore, results in ''skewed data'' that does not represent true market rates. The commenters stated that Congress directed CMS to implement a market-based payment system in which private market data from all segments of the laboratory industry, including independent laboratories, hospital laboratories, and physician office laboratories, would be collected in order to determine Medicare reimbursement for laboratory tests. To implement a true market based payment system the commenters encouraged CMS to develop payment rates through a statistically valid process to ensure that the private payer data collected accurately represents all sectors of the laboratory market.

Response: In general, section 1834A of the Act requires the payment amount for each CDLT on the CLFS to be based on the applicable information collected from applicable laboratories during a data collection period and reported to CMS during a data reporting period. For most tests on the CLFS, the statute requires the payment amount to be equal to the weighted median of the private payor rates for each test and specifies that the weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory. Given that the largest

laboratories reported their applicable information to CMS in the initial data reporting period, as well as many smaller laboratories, we believe the data we used to calculate the CY 2018 CLFS rates was sufficient and resulted in accurate weighted medians of private payor rates per test as required by the statute. As discussed previously in this section, we are finalizing our proposal to exclude MA plan payments under Part C from total Medicare revenues for purposes of the applicable laboratory definition. We believe this change will permit laboratories of all types with a significant Medicare Part C revenue component to be more likely to meet the majority of Medicare revenues threshold and qualify as an applicable laboratory. As a result of this change, we believe that applicable information from a broader segment of the laboratory industry will be reported for purposes of calculating the CLFS rates. As stated previously, we are finalizing the use of the Form CMS–1450 14x TOB to define applicable laboratories, subject to other regulatory and subregulatory requirements, such as the regulatory low expenditure threshold.

Comment: One commenter stated that the reductions in Medicare payment rates for laboratory tests result directly from CMS' regulatory decisions to relieve most laboratories of reporting burdens. According to the commenter, excluding so many laboratories from the data reporting requirements results in median prices that are not representative across the clinical laboratory industry. As such, the commenter noted that the market data upon which Medicare reimbursement is based does not reflect the market composition of the clinical laboratory industry. In other words, exempting low-volume and many hospital laboratories from reporting does not allow for Medicare prices to reflect the full range of payment amounts paid to varying entities. The commenter encouraged CMS to collect data from a broader segment of the laboratory industry and suggested that we weight private payor rates by market share (that is, prices typically paid per reporting entity), instead of based on overall volume per test.

Response: As discussed in response to the previous comment, section 1834A of the Act generally requires the payment amount for each CDLT on the CLFS to be based on the applicable information collected from applicable laboratories during a data collection period and reported to CMS during a data reporting period. Because for most tests, the payment amount is equal to the median of the private payor rates weighted by volume, the largest laboratories with the highest test volumes will most significantly affect the payment rates. Because of this, we established and implemented a low expenditure threshold to alleviate administrative burden on small laboratories. We believe that our current method of calculating the weighted median of private payor rates is appropriate and consistent with the statute. Given that the largest laboratories reported their applicable information to us in the initial data reporting period, along with many smaller laboratories, we believe the data we used to calculate the CY 2018 CLFS rates was sufficient and resulted in accurate weighted medians of private payor rates as required by statute. As noted above, we are finalizing changes to the definition of an applicable laboratory, which we believe will lead to an even more robust data collection from which to calculate payment rates for the next CLFS update.

Comment: Many commenters stated that the administrative burden for the first data reporting period was overwhelming and they offered suggestions on how to reduce the reporting burden on applicable laboratories. Many commenters suggested that CMS implement a ''data aggregation system'' consistent with statutory authority. In addition, a few commenters requested that CMS allow flexibility to exclude manual remittances from the definition of applicable information and therefore from data reporting. One commenter requested an ''across the board waiver'' from the reporting requirement for all small medical practices.

Response: We addressed the comment requesting exclusion of manual remittances from the definition of applicable information in the CLFS final rule (81 FR 41053 through 41054). We explained that the statute is clear that applicable information, which is used to set CLFS payment amounts, must be reported for applicable laboratories for a data collection period, and it defines applicable information, in part, as the payment rate that was paid by each private payor for the test during a data collection period and the volume of such tests for each such payor for the data collection period. As such, we stated that we believe the statute does not support selective reporting of applicable information for applicable laboratories. If the laboratory meets the definition of applicable laboratory, the applicable information for that laboratory must be reported. In addition, given that the statute requires applicable information to be reported for applicable laboratories, we do not believe granting an ''across the board waiver'' from the reporting requirements for all small laboratories would be consistent with statute. We believe that the low expenditure threshold would continue to exclude the majority of small laboratories from the applicable laboratory definition and, therefore, from data reporting.

With regard to the commenters suggesting that we implement aggregate reporting, we note that section 1834A(a)(6) of the Act permits the Secretary, beginning with January 1, 2019, to establish rules to aggregate reporting in situations where an applicable laboratory has more than one payment rate for the same payor for the same test or more than one payment rate for different payors for the same test. While the agency did not propose or solicit comments on implementing aggregate data reporting, we will take the commenters' suggestion into consideration for future refinements to the CLFS. However, to help reduce administrative burden for the next data reporting period, we will allow reporting entities the option to condense certain applicable information at the TIN-level, instead of reporting for each applicable laboratory individually at the NPI level. We will provide more information regarding the condensed reporting option through subregulatory guidance during the next data collection period.

Comment: One commenter suggested that CMS adopt a 90-day data collection period instead of the current 6-month data collection period to alleviate some of the burden associated with collecting applicable information.

Response: While we did not propose or solicit comments on changing the data collection period, we will take the commenter's suggestion into consideration for future refinements to the CLFS.

Comment: One commenter raised concerns about the integrity of the data reported during the first data reporting period. The commenter mentioned that the CLFS final rule was released just prior to the end of the first data collection period and as a result, laboratories struggled to collect information and submit the required data accurately. The commenter noted that many laboratories still do not have the systems in place to determine the private payor payment rates for each test and the associated volume paid at each rate, therefore exacerbating the potential for inaccurate reporting in the next data reporting period. The commenter was particularly concerned about how inaccurate data affects newer tests in which the volume of services has

remained relatively low as compared to well established laboratory procedures. For instance, because of the low volume of applicable information being reported for Tier 1 and Tier 2 molecular pathology procedures, the commenter stated that any inaccurate data reported has a greater impact on these test codes. The commenter noted that expanding the definition of an applicable laboratory would likely result in additional reporting errors and therefore, did not support any revisions to the definition of an applicable laboratory. Instead, the commenter urged CMS to refine the reporting process and implement measures to safeguard data integrity in future reporting periods. Specifically, the commenter requested that CMS consider implementing a data aggregation system for future data reporting periods, consistent with statutory authority. The commenter noted that a data aggregation system may guarantee more complete reporting and expand the ability of laboratories to report accurate data.

Response: We share the commenter's interest in collecting accurate data. As discussed previously, we are finalizing changes to the definition of applicable laboratory in § 414.502. We did not propose changes to the CLFS data reporting requirements or solicit comments on how to safeguard against inaccurate data. We will consider the issues raised by the commenter for future rulemaking. As noted in response to another comment, for the next data reporting period we will permit the reporting entity to condense applicable information for its applicable laboratories at the TIN level, instead of reporting for each of its applicable laboratories individually, and will issue subregulatory guidance on this topic.

Comment: One commenter stated that in general ''our market based system is flawed'' because it allows companies to profit on people's health. The commenter stated that the CLFS should be based on recovering costs only and not profit. The commenter noted that such approach will lead to a decrease in cost for laboratory testing and a standardization of fees across the industry.

Response: As previously noted, section 1834A of the Act generally requires the payment amount for each CDLT on the CLFS to be based on the applicable information collected from applicable laboratories during a data collection period and reported to us during a data reporting period. Basing CLFS rates on laboratory costs would not be permissible under the statute.

Comment: One commenter stated that uncertainty regarding the definition of an ADLT has discouraged some laboratories from applying for ADLT status, and suggested that we should implement the regulatory requirements in a manner that ''recognizes the uniqueness of the results generated by each precision diagnostic test due to its use of a proprietary algorithm validated in a unique patient cohort.''

Response: We did not propose or solicit any comments regarding changes to the definition of an ADLT, therefore, this comment is not within the scope of this rulemaking.

B. Changes to the Regulations Associated With the Ambulance Fee Schedule

1. Overview of Ambulance Services

a. Ambulance Services

Under the ambulance fee schedule, the Medicare program pays for ambulance transportation services for Medicare beneficiaries under Medicare Part B when other means of transportation are contraindicated by the beneficiary's medical condition and all other coverage requirements are met. Ambulance services are classified into different levels of ground (including water) and air ambulance services based on the medically necessary treatment provided during transport.

These services include the following levels of service:

- For Ground—

++ Basic Life Support (BLS) (emergency and non-emergency).

++ Advanced Life Support, Level 1 (ALS1) (emergency and non-emergency).

++ Advanced Life Support, Level 2 (ALS2).

++ Paramedic ALS Intercept (PI).

++ Specialty Care Transport (SCT).

- For Air—

++ Fixed Wing Air Ambulance (FW).

++ Rotary Wing Air Ambulance (RW).

b. Statutory Coverage of Ambulance Services

Under sections 1834(l) and 1861(s)(7) of the Act, Medicare Part B (Supplemental Medical Insurance) covers and pays for ambulance services, to the extent prescribed in regulations, when the use of other methods of transportation would be contraindicated by the beneficiary's medical condition.

The House Ways and Means Committee and Senate Finance Committee Reports that accompanied the 1965 Social Security Amendments suggest that the Congress intended that—

- The ambulance benefit cover transportation services only if other means of transportation are contraindicated by the beneficiary's medical condition; and

- Only ambulance service to local facilities be covered unless necessary services are not available locally, in which case, transportation to the nearest facility furnishing those services is covered (H.R. Rep. No. 213, 89th Cong., 1st Sess. 37 and Rep. No. 404, 89th Cong., 1st Sess. Pt 1, 43 (1965)).

The reports indicate that transportation may also be provided from one hospital to another, to the beneficiary's home, or to an extended care facility.

c. Medicare Regulations for Ambulance Services

The regulations relating to ambulance services are set forth at 42 CFR part 410, subpart B, and 42 CFR part 414, subpart H. Section 410.10(i) lists ambulance services as one of the covered medical and other health services under Medicare Part B. Therefore, ambulance services are subject to basic conditions and limitations set forth at § 410.12 and to specific conditions and limitations included at §§ 410.40 and 410.41. Subpart H of part 414 describes how payment is made for ambulance services covered by Medicare Part B.

2. Ambulance Extender Provisions

a. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), (Pub. L. 110–275, enacted July 15, 2008) amended section 1834(l)(13)(A) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008, and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

- For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.

- For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

The payment add-ons under section 1834(l)(13)(A) of the Act have been extended several times. Most recently, section 50203(a)(1) of the Bipartisan Budget Act of 2018 (BBA) (Pub. L. 115–123, enacted February 9, 2018) amended section 1834(l)(13)(A) of the Act to extend the payment add-ons through

December 31, 2022. Thus, these payment add-ons apply to covered ground ambulance transports furnished before January 1, 2023. We proposed to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement. (For further information regarding the implementation of this provision for claims processing, please see CR 10531. For a discussion of past legislation extending section 1834(l)(13) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74438 through 74439), the CY 2015 PFS final rule with comment period (79 FR 67743) and the CY 2016 PFS final rule with comment period (80 FR 71071 through 71072)).

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase, and does not require any substantive exercise of discretion on the part of the Secretary.

We received two comments on this proposal. The following is a summary of those comments along with our response.

Comment: One commenter supported the 5-year extension of the add-on payments and appreciates CMS' implementation of the statutory requirement, and stated these provisions are critical to ensuring the delivery of ambulance services. Another commenter stated that due to the staffing and distances that might be involved in the use of ambulance services in varying areas (for example, urban, rural and super rural), these add-ons payments will assist in appropriate reimbursements for these services.

Response: We appreciate the commenters' support.

After consideration of the comments received, we are finalizing our proposal, without modification, to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

b. Amendment to Section 1834(l)(12) of the Act

Section 414(c) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173, enacted December 8, 2003) (MMA) added section 1834(l)(12) to the Act, which specified that, in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations. Using the methodology specified in the July 1, 2004 interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment increase was applied to ground ambulance transports that originated in a ''qualified rural area,'' that is, to transports that originated in a rural area included in those areas comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of rural census tract). This rural bonus is sometimes referred to as the ''Super Rural Bonus'' and the qualified rural areas (also known as ''super rural'' areas) are identified during the claims adjudicative process via the use of a data field included in the CMS-supplied ZIP code file.

The Super Rural Bonus under section 1834(l)(12) of the Act has been extended several times. Most recently, section 50203(a)(2) of the BBA amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2022. Therefore, we are continuing to apply the 22.6 percent rural bonus described in this section (in the same manner as in previous years) to ground ambulance services with dates of service before January 1, 2023 where transportation originates in a qualified rural area. Accordingly, we proposed to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement. (For further information regarding the implementation of this provision for claims processing, please see CR 10531. For a discussion of past legislation extending section 1834(l)(12) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74439 through 74440), CY 2015 PFS final rule with comment period (79 FR 67743 through 67744) and the CY 2016 PFS final rule with comment period (80 FR 71072)).

This statutory provision is self-implementing. It requires an extension of this rural bonus (which was previously established by the Secretary) through December 31, 2022, and does not require any substantive exercise of discretion on the part of the Secretary.

We received two comments on this proposal. The following is a summary of those comments along with our response.

Comment: One commenter supported the 5-year extension of this provision and appreciates CMS' implementation of the statutory requirement and noted this provision is critical to ensuring the delivery of ambulance services. Another commenter stated that due to the staffing and distances that might be involved in the use of ambulance services in varying areas (for example, urban, rural and super rural), these add-ons payments will assist in appropriate reimbursements for these services.

Response: We appreciate the commenters' support.

After consideration of the comments received, we are finalizing our proposal, without modification, to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

3. Amendment to Section 1834(l)(15) of the Act

Section 637 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240, enacted January 2, 2013) added section 1834(l)(15) of the Act to specify that the fee schedule amount otherwise applicable under the preceding provisions of section 1834(l) of the Act shall be reduced by 10 percent for ambulance services furnished on or after October 1, 2013, consisting of non-emergency BLS services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B) of the Act) furnished other than on an emergency basis by a provider of services or a renal dialysis facility. In the CY 2014 PFS final rule with comment period (78 FR 74440), we revised § 414.610 by adding paragraph (c)(8) to conform the regulations to this statutory requirement.

Section 53108 of the BBA amended section 1834(l)(15) of the Act to increase the reduction from 10 percent to 23 percent effective for ambulance services (as described in section 1834(l)(15) of the Act) furnished on or after October 1, 2018. The 10 percent reduction applies for ambulance services (as described in section 1834(l)(15) of the Act) furnished during the period beginning on October 1, 2013 and ending on September 30, 2018. Accordingly, we proposed to revise § 414.610(c)(8) to conform the regulations to this statutory requirement.

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate decrease, and does not require any substantive exercise of discretion on the part of the Secretary. Accordingly, for ambulance services described in section

1834(l)(15) of the Act furnished during the period beginning on October 1, 2013 and ending on September 30, 2018, the fee schedule amount otherwise applicable (both base rate and mileage) is reduced by 10 percent, and for ambulance services described in section 1834(l)(15) of the Act furnished on or after October 1, 2018, the fee schedule amount otherwise applicable (both base rate and mileage) is reduced by 23 percent. (For further information regarding application of this mandated rate decrease, please see CR 10549.)

We received two comments on this proposal. The following is a summary of those comments along with our response.

Comment: One commenter supported the reduction of payment for these ambulance services and stated that the payment adjustment for non-emergency, BLS transports for ESRD beneficiaries is at an appropriate level. Another commenter stated that for accountable care organizations, transportation for dialysis services constitutes the largest portion of ambulance spending. According to the commenter, because patients often do not receive medical care during the transportation, they supported the reduction to the ambulance fee schedule for the transportation of patients with ESRD for renal dialysis services.

Response: We appreciate the commenters' support.

After consideration of the comments received, we are finalizing our proposal, without modification, to revise § 414.610(c)(8) to conform the regulations to the statutory requirement described above.

C. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Payment for Care Management Services

In the CY 2018 PFS final rule, we revised the payment methodology for Chronic Care Management (CCM) services furnished by RHCs and FQHCs, and established requirements and payment for general Behavioral Health Integration (BHI) and psychiatric Collaborative Care Management (CoCM) services furnished in RHCs and FQHCs, beginning on January 1, 2018.

For CCM services furnished by RHCs or FQHCs between January 1, 2016, and December 31, 2017, payment is at the PFS national average payment rate for CPT 99490. For CCM, general BHI, and psychiatric CoCM services furnished by RHCs or FQHCs on or after January 1, 2018, we established 2 new HCPCS codes. The first HCPCS code, G0511, is a General Care Management code for use by RHCs or FQHCs when at least 20 minutes of qualified CCM or general BHI services are furnished to a patient in a calendar month. The second HCPCS code, G0512, is a psychiatric CoCM code for use by RHCs or FQHCs when at least 70 minutes of initial psychiatric CoCM services or 60 minutes of subsequent psychiatric CoCM services are furnished to a patient in a calendar month.

The payment amount for HCPCS code G0511 is set at the average of the 3 national non-facility PFS payment rates for the CCM and general BHI codes and updated annually based on the PFS amounts. The 3 codes are CPT 99490 (20 minutes or more of CCM services), CPT 99487 (60 minutes or more of complex CCM services), and CPT 99484 (20 minutes or more of BHI services).

The payment amount for HCPCS code G0512 is set at the average of the 2 national non-facility PFS payment rates for CoCM codes and updated annually based on the PFS amounts. The 2 codes are CPT 99492 (70 minutes or more of initial psychiatric CoCM services) and CPT 99493 (60 minutes or more of subsequent psychiatric CoCM services).

For practitioners billing under the PFS, we proposed for CY 2019 a new CPT code, 994X7, which would correspond to 30 minutes or more of CCM furnished by a physician or other qualified health care professional and is similar to CPT codes 99490 and 99487. For RHCs and FQHCs, we proposed to add CPT code 994X7 as a general care management service and to include it in the calculation of HCPCS code G0511. That is, we proposed that starting on January 1, 2019, RHCs and FQHCs would be paid for HCPCS code G0511 based on the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 994X7. We note that CPT code 994X7 was a placeholder code, and the final code is CPT code 99491.

We proposed to revise § 405.2464 to reflect the current payment methodology that was finalized in the CY 2018 PFS and incorporate the addition of the new CPT code to HCPCS code G0511.

2. Communication Technology-Based and Remote Evaluation Services

RHC and FQHC visits are face-to-face (in-person) encounters between a patient and an RHC or FQHC practitioner during which time one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, nurse practitioners, physician assistants, certified nurse midwives, clinical psychologists, and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse furnishing care to a homebound RHC or FQHC patient. A Transitional Care Management service can also be an RHC or FQHC visit. A Diabetes Self-Management Training (DSMT) service or a Medical Nutrition Therapy (MNT) service furnished by a certified DSMT or MNT provider may also be an FQHC visit.

RHCs are paid an all-inclusive rate (AIR) for medically-necessary, face-to-face visits with an RHC practitioner. The rate is subject to a payment limit, except for those RHCs that have an exception to the payment limit for being ''provider-based'' (see § 413.65). FQHCs are paid the lesser of their charges or the FQHC Prospective Payment System (PPS) rate for medically-necessary, face-to-face visits with an FQHC practitioner. Only medically-necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner can be RHC or FQHC billable visits.

The RHC and FQHC payment rates reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day, and are not adjusted for the complexity of the patient health care needs, the length of the visit, or the number or type of practitioners involved in the patient's care.

Services furnished by auxiliary personnel (such as nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment. This may include services furnished prior to or after the billable visit that occur within a medically appropriate time period, which is usually 30 days or less.

RHCS and FQHCs are also paid for care management services, including chronic care management services, general behavioral health integration services, and psychiatric Collaborative Care Model services. These are typically non-face-to-face services that do not require the skill level of an RHC or FQHC practitioner and are not included in the RHC or FQHC payment methodologies.

For practitioners billing under the PFS, we proposed for CY 2019 separate payment for certain communication technology-based services. This includes what is referred to as ''Brief Communication Technology-Based Services'' for a ''virtual check-in'' and separate payment for remote evaluation of recorded video and/or images. The ''virtual check-in'' visit would be

billable when a physician or non-physician practitioner has a brief (5 to 10 minutes), non-face-to-face check in with a patient via communication technology to assess whether the patient's condition necessitates an office visit. This service could be billed only in situations where the medical discussion was for a condition not related to an E/M service provided within the previous 7 days, and does not lead to an E/M service or procedure within the next 24 hours or at the soonest available appointment. We also proposed payment for practitioners billing under the PFS for remote evaluation services. This payment would be for the remote evaluation of patient-transmitted information conducted via pre-recorded ''store and forward'' video or image technology, including interpretation with verbal follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment. We stated that both of these services would be priced under the PFS at a rate that reflects the resource costs of these non-face-to-face services relative to other PFS services, including face-to-face and in-person visits.

The RHC and FQHC payment models are distinct from the PFS model in that the payment is for a comprehensive set of services and supplies associated with an RHC or FQHC visit. A direct comparison between the payment for a specific service furnished in an RHC or FQHC and the same service furnished in a physician's office is not possible, because the payment for RHCs and FQHCs is a per diem payment that includes the cost for all services and supplies rendered during an encounter, and payment for a service furnished in a physician's office and billed under the PFS is only for that service.

We recognize that there are occasions when it may be beneficial to both the patient and the RHC or FQHC to utilize communication technology-based services to determine the course of action for a health issue. Currently under the RHC and FQHC payment systems, if the communication results in a face-to-face billable visit with an RHC or FQHC practitioner, the cost of the prior communication would be included in the RHC AIR or the FQHC PPS. However, if as a result of the communication it is determined that a visit is not necessary, there would not be a billable visit and there would be no payment.

RHCs and FQHCs furnish services in rural and urban areas that have been determined to be medically underserved areas or health professional shortage areas. They are an integral component of the Nation's health care safety net, and we want to ensure that Medicare patients who are served by RHCs and FQHCs are able to communicate with their RHC or FQHC practitioner in a manner that enhances access to care, consistent with evolving medical care. Particularly in rural areas where transportation is limited and distances may be far, we believe the use of communication technology-based services may help some patients to determine if they need to schedule a visit at the RHC or FQHC. If it is determined that a visit is not necessary, the RHC or FQHC practitioner would be available for other patients who need their care.

When communication technology-based services are furnished in association with an RHC or FQHC billable visit, the costs of these services are included in the RHC AIR or the FQHC PPS and are not separately billable. However, if there is no RHC or FQHC billable visit, these costs are not paid as part of an RHC AIR or FQHC PPS payment. We therefore proposed that, effective January 1, 2019, RHCs and FQHCs receive an additional payment for the costs of communication technology-based services or remote evaluation services that are not already captured in the RHC AIR or the FQHC PPS payment when the requirements for these services are met.

We proposed that RHCs and FQHCs receive payment for communication technology-based or remote evaluation services when at least 5 minutes of communication technology-based or remote evaluation services are furnished by an RHC or FQHC practitioner to a patient who has been seen in the RHC or FQHC within the previous year. These services may only be billed when the medical discussion or remote evaluation is for a condition not related to an RHC or FQHC service provided within the previous 7 days, and does not lead to an RHC or FQHC service within the next 24 hours or at the soonest available appointment, since in those situations the services are already paid as part of the RHC or FQHC per-visit payment.

We proposed to create a new virtual communication G-code for use by RHCs and FQHCs only, with a payment rate set at the average of the PFS national non-facility payment rates for HCPCS code GVCI1 for communication technology-based services, and HCPCS code GRAS1 for remote evaluation services. RHCs and FQHCs would be able to bill the virtual communication G-code either alone or with other payable services. The payment rate for the virtual communication G-code would be updated annually based on the PFS amounts. We note that HCPCS codes GCVI1 and GRAS1 were placeholder codes, and the final HCPCS codes are G2012 and G2010, respectively.

We also proposed to waive the RHC and FQHC face-to-face requirements when these services are furnished to an RHC or FQHC patient. Coinsurance would be applied to FQHC claims, and coinsurance and deductibles would apply to RHC claims for these services. Services that are currently being furnished and paid under the RHC AIR or FQHC PPS payment methodology will not be affected by the ability of the RHC or FQHC to receive payment for additional services that are not included in the RHC AIR or FQHC PPS.

3. Other Options Considered

We considered other options for payment for these services. First, we considered adding communication technology-based and remote evaluation services as an RHC or FQHC stand-alone service. Under this option, payment for RHCs would be at the AIR, and payment for FQHCs would be the lesser of total charges or the PPS rate. We did not propose this payment option because these services do not meet the requirements for an RHC or FQHC billable visit and payment at the RHC AIR or FQHC PPS would result in a payment rate incongruent with efficiencies inherent in the provision of the technology-based services.

The second option we considered was to allow RHCs and FQHCs to bill HCPCS codes G2012 or G2010 separately on an RHC or FQHC claim. We did not propose this payment option because we believe that a combined G-code is less burdensome and will allow expansion of these services without adding additional codes on an RHC or FQHC claim.

4. Comments and Responses

We invited comments on this proposal. In particular, we were interested in comments regarding the appropriateness of payment for communication technology-based and remote evaluation services in the absence of an RHC or FQHC visit, the burden associated with documentation for billing these codes (RHC or FQHC practitioner's time, medical records, etc.), and any potential impact on the per diem nature of RHC and FQHC billing and payment structure as a result of payment for these services.

The following is a summary of the comments we received regarding the addition of CPT code 99491 to the codes used to determine the payment for HCPCS code G0511 in RHCs and FQHCs, and the proposed requirements and payment for a new G-code for virtual communication for payment for communication technology-based and remote evaluation services. The majority of the commenters were very supportive of both proposals, and some requested clarification on issues related to billing, cost reporting, and payment for care management and virtual communication services in RHCs and FQHCs.

Comment: Several commenters requested clarification of how the inclusion of the new chronic care management code, CPT code 99491 (previously referred to as CPT code 994X7), would impact the payment of HCPCS code G0511 (the RHC and FQHC General Care Management code), and requested assurance that adding this code to the codes used to determine the payment for HCPCS code G0511 would not result in a lower payment rate.

Response: In the CY 2018 PFS final rule, we stated that if a new care management code is proposed and subsequently finalized for practitioners billing under the PFS, we would review the new code to determine if it should be included in the calculation of the RHC and FQHC General Care Management Code. The determination of whether a new care management code should be added to the codes used to determine the payment rate is based on the applicability of the service in RHCs and FQHCs, and may result in either an increase or decrease in the payment amount for HCPCS code G0511.

CPT code 99491 is for 30 minutes or more of CCM furnished by a physician or other qualified health care professional. Since this is similar to CPT codes 99490 and 99487, we determined that it should be included in the RHC and FQHC General Care Management code, which is paid using HCPCS code G0511. The CY 2019 payment rate for this code is expected to be $74.26, and the payment rate for CY 2019 payment rate for HCPCS code G0511 is expected to be approximately $67, which will result in a higher payment for HCPCS code G0511 than it would have been if CPT code 99491 was not added to the codes used to determine the rate. The rate is adjusted annually based on the PFS payment rates for these codes.

Comment: A commenter stated that the care management services included in the PFS are already contemplated and included in the RHC AIR and the FQHC PPS payments, which are designed to cover all activities related to a comprehensive primary care visit, even if they do not occur on the same day. The commenter did not support separate payment to RHCs and FQHCs for care management services, and stated that paying separately for these services results in duplicative payment. The commenter also noted that because the care management payment is made through the RHC and FQHC payment systems, it does not trigger a budget-neutrality adjustment and therefore represents additional spending for the Medicare program and its beneficiaries.

Response: Comprehensive, high quality, and coordinated primary care has always been an integral part of RHC and FQHC services in their communities, We respectfully disagree with the suggestion that the type of structured chronic care management and behavioral health integration services that are now separately paid as care management are already included in the RHC AIR or the FQHC PPS payment methodologies. These services have specific requirements which have not typically or routinely been provided by RHCs or FQHCs, and therefore have not been factored into either the RHC AIR or the FQHC PPS rate. RHC and FQHC payments are not subject to the budget neutrality provisions of the PFS, and we believe that the cost-saving potential of these services is likely to offset any additional Medicare spending.

Comment: A commenter encouraged CMS to evaluate the additional costs of providing CCM services for people with limited English proficiency and to adjust payment accordingly in future rulemaking.

Response: We are aware that some RHCs and FQHCs have a higher than average rate of patients with limited English proficiency, which may sometimes require additional time or resources. However, once the minimum requirements for care management are met, the RHC or FQHC can bill for the service, and the rate is based on the average cost of furnishing the services.

Comment: Several commenters noted their support for a new G-code for payment for communication technology-based and remote evaluation services and requested that CMS investigate its authority to allow FQHCs to serve as distant site providers for telehealth services to Medicare beneficiaries.

Response: Although both telehealth and virtual communication services use technology to communicate, these are separate and distinct services. Telehealth services are considered a substitute for an in-person visit, and are therefore paid at the same rate as it would have been had it been furnished in person. With some exceptions, telehealth services require the use of interactive audio and digital telecommunication systems that permit real-time communication between the practitioner at the distant site and the beneficiary at the originating site. The communication technology-based and remote evaluation services that we proposed are not a substitute for a visit, but are instead brief discussions with the RHC or FQHC practitioner to determine if a visit is necessary. If the discussion between the RHC or FQHC practitioner and the Medicare beneficiary results in a billable visit, then the usual RHC or FQHC billing would occur. The virtual communication G-code would only be separately payable if the discussion between the RHC or FQHC practitioner does not result from or lead to an RHC or FQHC billable visit. The payment rate for communication technology-based services are valued based on the shorter duration of time and the efficiencies associated with the use of communication technology.

Section 1834(m)(4)(C)(ii) of the Act authorizes RHCs and FQHCs to serve as telehealth ''originating sites'' (that is, where the patient is located) for qualified telehealth services. Section 1834(m)(1) of the Act, which describes distant site telehealth services (where the practitioner is located), does not include RHCs and FQHCs. We do not have the authority to allow RHCs and FQHCs to furnish distant site telehealth services, and RHCs and FQHCs may not bill for distant site telehealth services under the PFS.

Comment: Some commenters supported a separate payment for communication technology-based and remote evaluation services using a virtual communication G-code because these new services were not included in the calculation of the Medicare FQHC PPS rate, but requested that CMS reconsider the payment amount for these services. The commenters suggested that because an FQHC practitioner is required and the face-to-face requirements for these services are waived, the payment should be on par with a traditional FQHC visit.

Response: We disagree with the suggestion that the payment be on par with a regular FQHC visit. If the communication technology-based or remote evaluation service results in a face-to-face visit with an RHC or FQHC practitioner, the cost of the brief communication with the RHC or FQHC practitioner would already be included in the RHC AIR or the FQHC PPS payment. If the communication

technology-based or remote evaluation service does not originate from or result in a face-to-face visit with an RHC or FQHC practitioner, the RHC or FQHC may bill using the new virtual communication G-code. The payment rate for these services under the PFS reflects the resource costs of these non-face-to-face services relative to other PFS services, including face-to-face and in-person visits. We did not propose payment for these services as an RHC or FQHC visit or at the same payment rate as an RHC or FQHC visit because these services do not meet the requirements for an RHC or FQHC billable visit, and payment at the RHC AIR or FQHC PPS would result in a payment rate incongruent with efficiencies inherent in the provision of these communication services.

Comment: Commenters recommended not implementing any type of frequency limitation, especially as RHCs and FQHCs learn to utilize these services for their patients. Commenters stated that any frequency limitation would be arbitrary, may have the opposite effect of the provision's intended purpose to encourage innovative ways to provide comprehensive care to Medicare beneficiaries, that the reimbursement rate does not provide a financial incentive for overuse of this service, and that the cost of virtual visits, even if unlimited, would more than offset the cost of even one emergency room visit.

Response: We agree that frequency limitations should not be implemented at this time.

Comment: Some commenters questioned the feasibility of billing for virtual communication services because they noted that the coinsurance requirement will discourage individuals from utilizing virtual communication services to assess whether or not they need to come in for an E/M visit, and will create patient confusion and dissatisfaction if they receive a bill for these services.

Response: We are aware that coinsurance can be a barrier for some beneficiaries, but we do not have the statutory authority to waive the coinsurance requirement. RHCs and FQHCs should inform their patients that coinsurance applies, and provide information on the availability of assistance to qualified patients in meeting their cost sharing obligations, or any other programs to provide financial assistance, if applicable.

Comment: A few commenters expressed concern about how care management is currently reported and how virtual communication services will be reported on the RHC cost report. The commenters stated that although care management services are considered RHC services, they are reported separately on line 80 in the non-reimbursable section of the cost report, and as a result, they are not considered allowable costs on the RHC cost report. The commenters stated that this process is administratively cumbersome, exposes the RHC to an audit risk, and represents a significant barrier for RHCs in offering care management services. The commenters suggested that the costs included on line 80 should only be the direct costs associated with care management services, which would allow RHCs to more easily identify those costs and assure them that they are completing this form correctly. The commenters noted similar concerns for the reporting of virtual communication services, and recommended that CMS allow the costs associated with virtual communication to be reported in the reimbursable section of the RHC cost report.

Response: Reducing administrative burden and encouraging the appropriate use of services is a high priority for CMS, and we appreciate the detailed comments and suggested changes regarding the reporting of care management and virtual communication services on the RHC cost report. Cost reporting information in typically provided in subregulatory guidance, and we will carefully consider these comments.

Comment: A commenter questioned how virtual communication that occurs during non-RHC hours would be billed and calculated on the cost report.

Response: Services such as care management and virtual communication services are not billable visits in RHCs and FQHCs and may occur outside of the RHC's or FQHC's posted hours. As stated previously, information on cost reporting will be provided in subregulatory guidance.

Comment: Some commenters recommended removing the timeframe restrictions for billing virtual communication services, stating that they are vague, arbitrary, administratively burdensome, or that allowing daily check in would improve health and reduce costs. Other commenters suggested modifying the timeframe limitations with a clear cut-off that RHCs and FQHCs can track and calculate, such as within the previous 3 days or subsequent 24 hours, or the previous and subsequent 24 hours. One commenter stated that the timeframe restrictions would require RHCs and FQHCs to review prior patient clinical activity, assess the diagnostic category of any recent activity, and then delay for 24 hours to ascertain whether the service is followed by a clinical visit, rather than billing immediately for the services. This commenter also stated that most computer billing systems are not set up for this type of review, and a supplemental billing process would be costly, and noted that there are no restrictions on face-to-face visits in RHCs or FQHCs.

Response: PFS payments for HCPCS code G2012 (communication technology-based services), and HCPCS code G2010 (remote evaluation services) are based on the descriptor for CPT code 99441 (Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion). HCPCS code G0071, the new virtual communication G-code for RHCs and FQHCs, is set at the average of the PFS national non-facility payment rates for HCPCS codes G2012 and G2010, and would be billed by the RHC or FQHC when the minimum requirements for either of these codes are met.

Except for the Initial Preventive Physical Exam and the Annual Wellness Visit, RHC and FQHC visits do not have frequency limitations, and a patient could have more than one RHC or FQHC billable visit in the same week if it is a medically-necessary, face-to-face visit with an RHC or FQHC practitioner. If a service is not medically-necessary, or is not furnished by an RHC or FQHC practitioner, or does not require the skill level of an RHC or FQHC practitioner, it would not be a billable visit. Since the RHC AIR and FQHC PPS payment methodologies are designed to include all services and supplies incident to a visit, the absence of time restrictions could result in duplicate payment to the RHC or FQHC. Since the virtual communication payment is designed to provide payment to the RHC or FQHC when there is no billable visit, the time restrictions are necessary to avoid any duplicate payment.

Communication technology-based and remote evaluation services are initiated by a patient who has been seen in the past year by the RHC or FQHC practitioner, and in many cases, a review of prior patient clinical activity and diagnoses would be necessary as part of the virtual communication with the patient. Since most RHCs and FQHCs are utilizing electronic health records, we expect that RHCs and

FQHCs will be able to comply with the time restrictions without any additional burden. It is also our understanding that most RHCs and FQHCs (like other providers and supplies) may not always submit a claim immediately upon furnishing a service. As with any new service, we expect that there would be a period of adjustment, and we will monitor implementation to determine if changes are necessary.

Comment: Commenters questioned if an RHC could bill for virtual communication services if the discussion results in the patient going to an emergency room, an urgent care center, or a specialist not affiliated with the RHC or FQHC, or if it leads to an ''incident-to'' service at the RHC (such as an injection) that is not a billable visit.

Response: If the discussion with the RHC or FQHC practitioner does not occur within 7 days of an RHC or FQHC visit, and does not result in an RHC or FQHC visit with 24 hours or the soonest available appointment with an RHC or FQHC practitioner, and all other requirements are met, the RHC or FQHC could bill for virtual communication services. This would apply even if the patient is subsequently seen in an emergency room, urgent care center, or by a non-RHC or FQHC practitioner, or has a subsequent non-billable service in the RHC or FQHC such as an injection.

Comment: A commenter questioned if communication technology-based and remote evaluation services could be used by RHC and FQHC practitioners to help beneficiaries determine whether they should visit an RHC or FQHC for DSMT services, and states that this would allow RHC and FQHC practitioners to reach beneficiaries in both rural and urban underserved area and improve the lives of beneficiaries with diabetes. Another commenter questioned if the new virtual communication codes for RHCs and FQHCs would impact payment for DSMT in FQHCs.

Response: We agree that outreach and education to communities on diabetes prevention services are important, especially in rural and urban underserved areas. However, communication technology-based and remote evaluation services would be billable by RHCs and FQHCs only when the discussion requires the skill level of the RHC or FQHC practitioner. If the discussion could be conducted by a nurse, health educator, or other clinical personnel, it would not be billable as a virtual communication service. Payment for DSMT in FQHCs would not be impacted by the new virtual communication codes.

Comment: A commenter agreed that virtual communication services should be limited to established patients (seen by an RHC or FQHC practitioner within the previous year), and recommends that audio-only technology (that is, telephone) should be allowed for virtual check-ins because many RHC or FQHC patients may not have access to technology capabilities beyond audio-only communication.

Response: We note that while other technology can be used, telephone discussions are acceptable for billing the virtual communication G-code.

Comment: A commenter suggested that CMS should consider redefining what constitutes a billable RHC visit and develop a new and expansive definition so that new healthcare services such as care management and virtual communication services can be incorporated in the RHC cost-based model in the same manner as face-to-face billable visits.

Response: We welcome suggestions on modifying program requirements, but redefining RHC and FQHC billable visits is outside the scope of this regulation.

Comment: A commenter stated that the proposed PFS change for CPT code 99213 will result in independent RHCs and provider-based RHCs with more than 50 beds being paid $10 less per visit than practitioners billing under the PFS. The commenter stated that this will cause some RHCs to leave the RHC program, resulting in higher costs to Medicare, and questioned what can be done to raise the RHC capped encounter payment.

Response: RHCs are paid based on their costs, subject to a payment limit set out at section 1833(f) of the Act, except for those RHCs that have an exception to the payment limit, and is adjusted annually based on the Medicare Economic Index. We do not have the authority to make changes in the RHC payment rate.

Comment: A commenter questioned if this proposed change will impact the FQHC payment rate.

Response: The RHC AIR and the FQHC PPS would not be impacted by these changes.

Comment: A commenter questioned if the new virtual communication G-code would be accepted by Medicare Advantage Plans.

Response: HCPCS code G0071 is part of the HCPCS code set and must be accepted by all payers as a HIPAA standard (45 CFR 162.1002). RHCs and FQHCs should consult their associated MA plans for billing information.

Comment: A commenter questioned whether the two new add-on codes proposed for inherent visit complexity would apply to RHCs and FQHCs and be eligible for separate payment in addition to their standard all inclusive rate, and several commenters requested that RHCs and FQHCs be allowed to bill separately for interprofessional internet consultations.

Response: The two new add-on codes proposed for inherent visit complexity are for practitioners billing under the PFS, and do not apply to RHCs and FQHCs. The RHC AIR and the FQHC PPS includes all costs associated with a billable visit, and therefore consultations with other practitioners are not separately billable.

Comment: We received comments on allowing RNs to provide billable visits in RHCs, allowing FQHCs to bill for assessment and care planning for patients with cognitive impairment, reducing the requirements for psychiatric collaborative care management services in RHCs and FQHCs, providing separate payment to RHCs and FQHCs for medications to treat alcohol and substance use disorders, revising payment for pneumococcal vaccines, and reducing the requirements for patient consent for care management services.

Response: These comments are beyond the scope of this rule.

5. Finalized Provisions

As a result of the comments, we are finalizing the following provisions:

- Effective January 1, 2019, the payment rate for HCPCS code G0511 (General Care Management Services) is set at the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 99491.
- Effective January 1, 2019, RHCs and FQHCs are paid for HCPCS code G0071 (Virtual Communication Services), when HCPCS code G0071 is on an RHC or FQHC claim, either alone or with other payable services, and at least 5 minutes of communication technology-based or remote evaluation services are furnished by an RHC or FQHC practitioner to a patient who has had an RHC or FQHC billable visit within the previous year, and the medical discussion or remote evaluation is for a condition not related to an RHC or FQHC service provided within the previous 7 days, and does not lead to an RHC or FQHC visit within the next 24 hours or at the soonest available appointment. We are adding a new paragraph (e) to § 405.2464 to reflect this payment and making additional minor conforming changes to this section.
- HCPCS code G0071 is set at the average of the national non-facility PFS payment rates for HCPCS code G2012

(communication technology-based services) and HCPCS code G2010 (remote evaluation services) and is updated annually based on the PFS national non-facility payment rate for these codes.

- RHC and FQHC face-to-face requirements are waived when these services are furnished to an RHC or FQHC patient. Coinsurance and deductibles apply to RHC claims for G0071 and coinsurance applies to FQHC claims for G0071.

6. Other Regulatory Updates

In addition to the regulatory change described in this section of the rule, we are finalizing the following technical corrections for accuracy:

- Removal of the extra section mark in the definition of ''Federally qualified health center (FQHC)'' in § 405.2401.
- Replacing the word ''his'' with ''his or her'' in the definition of ''Secretary'' in § 405.2401.
- Reordering the occurrence of RHC and FQHC in § 405.2462(g).

7. Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

Section 6083 of the SUPPORT for Patients and Communities Act (Pub. L. 115–271, enacted on October 24, 2018) provides additional payments to RHCs and FQHCs for services furnished for the treatment of opioid use disorders by practitioners meeting certain requirements. We anticipate guidance from the Department of Health and Human Services on the implementation of this provision will be forthcoming.

D. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of the Protecting Access to Medicare Act (PAMA) (Pub. L. 113–93, enacted April 1, 2014) amended Title XVIII of the Act to add section 1834(q) of the Act directing us to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. The CY 2016 PFS final rule with comment period addressed the initial component of the new Medicare AUC program, specifying applicable AUC. In that rule (80 FR 70886), we established an evidence-based process and transparency requirements for the development of AUC, defined provider-led entities (PLEs) and established the process by which PLEs may become qualified to develop, modify or endorse AUC. The first list of qualified PLEs was posted on the CMS website at the end of June 2016 at which time their AUC libraries became specified applicable AUC for purposes of section 1834(q)(2)(A) of the Act. The CY 2017 PFS final rule addressed the second component of this program, specification of qualified clinical decision support mechanisms (CDSMs). In the CY 2017 PFS final rule (81 FR 80170), we defined CDSM, identified the requirements CDSMs must meet for qualification, including preliminary qualification for mechanisms documenting how and when each requirement is reasonably expected to be met, and established a process by which CDSMs may become qualified. We also defined applicable payment systems under this program, specified the first list of priority clinical areas, and identified exceptions to the requirement that ordering professionals consult specified applicable AUC when ordering applicable imaging services. The first list of qualified CDSMs was posted on the CMS website in July 2017.

The CY 2018 PFS final rule addressed the third component of this program, the consultation and reporting requirements. In the CY 2018 PFS final rule (82 FR 53190), we established the start date of January 1, 2020 for the Medicare AUC program for advanced diagnostic imaging services. It is for services ordered on and after this date that ordering professionals must consult specified applicable AUC using a qualified CDSM when ordering applicable imaging services, and furnishing professionals must report AUC consultation information on the Medicare claim. We further specified that the AUC program will begin on January 1, 2020 with a year-long educational and operations testing period during which time AUC consultation information is expected to be reported on claims, but claims will not be denied for failure to include proper AUC consultation information. We also established a voluntary period from July 2018 through the end of 2019 during which ordering professionals who are ready to participate in the AUC program may consult specified applicable AUC through qualified CDSMs and communicate the results to furnishing professionals, and furnishing professionals who are ready to do so may report AUC consultation information on the claim (*https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10481.pdf*). Additionally, to incentivize early use of qualified CDSMs to consult AUC, we established in the CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstances Policy for the Transition Year final rule with comment period and interim final rule (hereinafter ''CY 2018 Quality Payment Program final rule'') a high-weight improvement activity for ordering professionals who consult specified AUC using a qualified CDSM for the Merit-based Incentive Payment System (MIPS) performance period that began January 1, 2018 (82 FR 54193).

In the CY 2019 PFS proposed rule, we proposed additions to the definition of applicable setting, clarification around who may perform the required AUC consultation using a qualified CDSM under this program, clarification that reporting is required across claim types and by both the furnishing professional and furnishing facility, changes to the policy for significant hardship exceptions for ordering professionals under this program, mechanisms for claims-based reporting, and a solicitation of feedback regarding the methodology to identify outlier ordering professionals.

1. Background

AUC present information in a manner that links: A specific clinical condition or presentation; one or more services; and an assessment of the appropriateness of the service(s). Evidence-based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients based on their individual clinical presentation. For purposes of this program, AUC is a set or library of individual appropriate use criteria. Each individual criterion is an evidence-based guideline for a particular clinical scenario based on a patient's presenting symptoms or condition.

AUC need to be integrated as seamlessly as possible into the clinical workflow. CDSMs are the electronic portals through which clinicians access the AUC during the patient workup. They can be standalone applications that require direct entry of patient information, but may be more effective when they are integrated into electronic health records (EHRs). Ideally, practitioners would interact directly with the CDSM through their primary user interface, thus minimizing interruption to the clinical workflow.

2. Statutory Authority

Section 218(b) of the PAMA added a new section 1834(q) of the Act entitled, ''Recognizing Appropriate Use Criteria for Certain Imaging Services,'' which directs the Secretary to establish a new program to promote the use of AUC. Section 1834(q)(4) of the Act requires

ordering professionals to consult with specified applicable AUC through a qualified CDSM for applicable imaging services furnished in an applicable setting and paid for under an applicable payment system; and payment for such service may only be made if the claim for the service includes information about the ordering professional's consultation of specified applicable AUC through a qualified CDSM.

3. Discussion of Statutory Requirements

There are four major components of the AUC program under section 1834(q) of the Act, and each component has its own implementation date: (1) Establishment of AUC by November 15, 2015 (section 1834(q)(2) of the Act); (2) identification of mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3) of the Act); (3) AUC consultation by ordering professionals, and reporting on AUC consultation by January 1, 2017 (section 1834(q)(4) of the Act); and (4) annual identification of outlier ordering professionals for services furnished after January 1, 2017 (section 1834(q)(5) of the Act). We did not identify mechanisms for consultation by April 1, 2016. Therefore, we did not require ordering professionals to consult CDSMs or furnishing professionals to report information on the consultation by the January 1, 2017 date.

a. Establishment of AUC

In the CY 2016 PFS final rule with comment period, we addressed the first component of the Medicare AUC program under section 1834(q)(2) of the Act—the requirements and process for establishment and specification of applicable AUC, along with relevant aspects of the definitions under section 1834(q)(1) of the Act. This included defining the term ''provider-led entity'' and finalizing requirements for the rigorous, evidence-based process by which a PLE would develop AUC, upon which qualification is based, as provided in section 1834(q)(2)(B) of the Act and in the CY 2016 PFS final rule with comment period. Using this process, once a PLE is qualified by us, the AUC that are developed, modified or endorsed by the qualified PLE are considered to be specified applicable AUC under section 1834(q)(2)(A) of the Act. We defined PLE to include national professional medical societies, health systems, hospitals, clinical practices and collaborations of such entities such as the High Value Healthcare Collaborative or the National Comprehensive Cancer Network. Qualified PLEs may collaborate with third parties that they believe add value to their development of AUC, provided such collaboration is transparent. We expect qualified PLEs to have sufficient infrastructure, resources, and the relevant experience to develop and maintain AUC according to the rigorous, transparent, and evidence-based processes detailed in the CY 2016 PFS final rule with comment period.

In the same rule we established a timeline and process under § 414.94(c)(2) for PLEs to apply to become qualified. Consistent with this timeline the first list of qualified PLEs was published at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/PLE.html* in June 2016 (OMB Control Number 0938–1288).

b. Mechanism for AUC Consultation

In the CY 2017 PFS final rule, we addressed the second major component of the Medicare AUC program—the specification of qualified CDSMs for use by ordering professionals for consultation with specified applicable AUC under section 1834(q)(3) of the Act, along with relevant aspects of the definitions under section 1834(q)(1) of the Act. This included defining the term CDSM and finalizing functionality requirements of mechanisms, upon which qualification is based, as provided in section 1834(q)(3)(B) of the Act and in the CY 2017 PFS final rule. CDSMs may receive full qualification or preliminary qualification if most, but not all, of the requirements are met at the time of application. The preliminary qualification period began June 30, 2017 and ends when the AUC consulting and reporting requirements become effective on January 1, 2020. The preliminarily qualified CDSMs must meet all requirements by that date. We defined CDSM as an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient's specific clinical condition. Tools may be modules within or available through certified EHR technology (as defined in section 1848(o)(4) of the Act) or private sector mechanisms independent from certified EHR technology or a mechanism established by the Secretary.

In the CY 2017 PFS final rule, we established a timeline and process in § 414.94(g)(2) for CDSM developers to apply to have their CDSMs qualified. Consistent with this timeline, the first list of qualified CDSMs was published at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html* in July 2017 (OMB Control Number 0938–1315).

c. AUC Consultation and Reporting

In the CY 2018 PFS final rule, we addressed the third major component of the Medicare AUC program—consultation with applicable AUC by the ordering professional and reporting of such consultations under section 1834(q)(4) of the Act. We established a January 1, 2020 effective date for the AUC consultation and reporting requirements for this program. We also established a voluntary period during which early adopters can begin reporting limited consultation information on Medicare claims from July 2018 through December 2019. During the voluntary period there is no requirement for ordering professionals to consult AUC or furnishing professionals to report information related to the consultation. On January 1, 2020, the program will begin with an educational and operations testing period and during this time we will continue to pay claims whether or not they correctly include AUC consultation information. Ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on or after January 1, 2020; and furnishing professionals must report the AUC consultation information on the Medicare claim for these services ordered on or after January 1, 2020.

Consistent with section 1834(q)(4)(B) of the Act, we also established that furnishing professionals must report the following information on Medicare claims for advanced diagnostic imaging services as specified in section 1834(q)(1)(C) of the Act and defined in § 414.94(b), furnished in an applicable setting as defined in section 1834(q)(1)(D) of the Act, paid for under an applicable payment system as defined in section 1834(q)(4)(D) of the Act, and ordered on or after January 1, 2020: (1) The qualified CDSM consulted by the ordering professional; (2) whether the service ordered would or would not adhere to specified applicable AUC, or whether the specified applicable AUC consulted was not applicable to the service ordered; and (3) the NPI of the ordering professional (if different from the furnishing professional). Clarifying revisions to the reporting requirement are discussed later in this preamble.

Section 1834(q)(4)(C) of the Act provides for exceptions to the AUC consultation and reporting requirements in the case of: A service ordered for an

individual with an emergency medical condition, a service ordered for an inpatient and for which payment is made under Medicare Part A, and a service ordered by an ordering professional for whom the Secretary determines that consultation with applicable AUC would result in a significant hardship. In the CY 2017 PFS final rule, we adopted a regulation at § 414.94(h)(1)(i) to specify the circumstances under which AUC consultation and reporting requirements are not applicable. These include applicable imaging services ordered: (1) For an individual with an emergency medical condition (as defined in section 1867(e)(1) of the Act); (2) for an inpatient and for which payment is made under Medicare Part A; and (3) by an ordering professional who is granted a significant hardship exception to the Medicare EHR Incentive Program payment adjustment for that year under § 495.102(d)(4), except for those granted under § 495.102(d)(4)(iv)(C). In the CY 2019 PFS proposed rule, we proposed changes to the conditions for significant hardship exceptions, and we summarize and respond to public comments on our proposals later in this preamble. We remind readers that, consistent with section 1834(q)(4)(A) of the Act, ordering professionals must consult AUC for every applicable imaging service furnished in an applicable setting and paid under an applicable payment system unless a statutory exception applies.

Section 1834(q)(4)(D) of the Act specifies the applicable payment systems for which AUC consultation and reporting requirements apply and, in the CY 2017 PFS final rule, consistent with the statute, we defined applicable payment system in our regulation at § 414.94(b) as: (1) The PFS established under section 1848(b) of the Act; (2) the prospective payment system for hospital outpatient department services under section 1833(t) of the Act; and (3) the ambulatory surgical center payment system under section 1833(i) of the Act.

Section 1834(q)(1)(D) of the Act specifies the applicable settings in which AUC consultation and reporting requirements apply: A physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other ''provider-led outpatient setting determined appropriate by the Secretary.'' In the CY 2017 PFS final rule, we added this definition to our regulation at § 414.94(b). Proposed additional applicable settings are discussed later in this preamble.

d. Identification of Outliers

The fourth component of the Medicare AUC program is specified in section 1834(q)(5) of the Act, Identification of Outlier Ordering Professionals. The identification of outlier ordering professionals under this paragraph facilitates a prior authorization requirement that applies for outlier professionals beginning January 1, 2020, as specified under section 1834(q)(6) of the Act. Because we established a start date of January 1, 2020 for AUC consultation and reporting requirements, we will not have identified any outlier ordering professionals by that date. As such, implementation of the prior authorization component is delayed. However, we did finalize in the CY 2017 PFS final rule the first list of priority clinical areas to guide identification of outlier ordering professionals as follows:

- Coronary artery disease (suspected or diagnosed).
- Suspected pulmonary embolism.
- Headache (traumatic and non-traumatic).
- Hip pain.
- Low back pain.
- Shoulder pain (to include suspected rotator cuff injury).
- Cancer of the lung (primary or metastatic, suspected or diagnosed).
- Cervical or neck pain.

We did not include proposals to expand or modify the list of priority clinical areas in this final rule.

4. Proposals for Continuing Implementation

In the CY 2019 PFS proposed rule, we proposed to amend § 414.94 of our regulations, ''Appropriate Use Criteria for Certain Imaging Services,'' to reflect the following policies.

a. Expanding Applicable Settings

Section 1834(q)(1)(D) of the Act specifies that the AUC consultation and reporting requirements apply only in an applicable setting, which means a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary. In the CY 2017 PFS final rule, we codified this definition in § 414.94(b). We proposed to revise the definition of applicable setting to add an independent diagnostic testing facility (IDTF).

We believe the addition of IDTFs to the definition of applicable setting will ensure that the AUC program is in place across outpatient settings in which outpatient advanced diagnostic imaging services are furnished. IDTFs furnish services for a large number of Medicare beneficiaries; nearly $1 billion in claims for 2.4 million beneficiaries in 2010 (OEI–05–09–00560). An IDTF is independent of a hospital or physician's office and diagnostic tests furnished by an IDTF are performed by licensed, certified non-physician personnel under appropriate physician supervision (§ 410.33). Like other applicable settings, IDTFs must meet the requirements specified in § 410.33 of our regulations to be enrolled to furnish and bill for advanced diagnostic imaging and other IDTF services. Services that may be provided by an IDTF include, but are not limited to, magnetic resonance imaging (MRI), ultrasound, x-rays, and sleep studies. An IDTF may be a fixed location, a mobile entity, or an individual non-physician practitioner, and diagnostic procedures performed by an IDTF are paid under the PFS. IDTF services must be furnished under the appropriate level of physician supervision as specified in § 410.33(b); and all procedures furnished by the IDTF must be ordered in writing by the patient's treating physician or non-physician practitioner. As such, we believe the IDTF setting is a provider-led outpatient setting appropriate for addition to the list of applicable settings under section 1834(q)(1)(D), and we proposed to add IDTF to our definition of applicable setting under § 414.94(b) of the regulations.

We note that under the PFS, payment for many diagnostic tests including the advanced diagnostic imaging services to which the AUC program applies can be made either ''globally'' when the entire service is furnished and billed by the same entity; or payment can be made separately for the technical component (TC) of the service and the professional component (PC) when those portions of the service are furnished and billed by different entities. In general, the TC for an advanced diagnostic imaging service is the portion of the test during which the patient is present and the image is captured. The PC is the portion of the test that involves a physician's interpretation and report on the captured image. For example, when a CT scan is ordered by a patient's treating physician, the entire test (TC and PC) could be furnished by a radiologist in their office and billed as a ''global'' service. Alternatively, the TC could be furnished and billed by an IDTF, and the PC could be furnished and billed by a radiologist in private practice. By adding IDTFs as an

applicable setting, we believe we would appropriately and consistently apply the AUC program across the range of outpatient settings where applicable imaging services are furnished.

We proposed to revise the definition of applicable setting under § 414.94(b) to include an IDTF. We invited comments on this proposal and on the possible inclusion of any other applicable setting. We reminded commenters that application of the AUC program is not only limited to applicable settings, but also to services for which payment is made under applicable payment systems (the PFS, the OPPS, and the ASC payment system).

The following is a summary of the comments we received on revising the definition of applicable setting under § 414.94(b) to include an IDTF and on the possible inclusion of any other applicable setting.

Comment: The majority of commenters supported adding IDTF to the definition of applicable setting. These commenters agreed that this addition would apply the AUC program appropriately and consistently across outpatient settings where applicable advanced diagnostic imaging services are furnished and reported. In contrast, a few commenters were concerned with expanding the definition of applicable setting until CMS and other impacted stakeholders have a better understanding of the program and 3 to 5 years of experience with it. These commenters suggested that any expanded definition will add complexity and make implementation even more difficult by the 2020 required start date as the addition of another applicable setting would require broader reporting of AUC consultation information. To this end, these commenters requested modification to the proposal to allow some flexibility on the timeline to add IDTFs as an applicable setting. Finally, a few commenters requested that the definition of applicable setting be further expanded to include any office-based service, including for example, situations in which physicians have an MRI in their own office.

Response: We appreciate these perspectives by the commenters. We continue to believe that the IDTF setting is a provider-led outpatient setting appropriate for addition to the list of applicable settings under section 1834(q)(1)(D) of the Act, and are finalizing this definition as proposed. We disagree that the definition will add complexity as we seek consistency in applying our regulations across outpatient settings in which outpatient advanced diagnostic imaging services are furnished, and would be concerned with applying these requirements in different settings along different timelines. Because we did not propose adding other settings to this definition we will not expand it further in this final rule, but will continue to monitor claims for advanced diagnostic imaging services across the Medicare program. We remind readers that the physician's office (including one where advanced imaging equipment is located), hospital outpatient department (including an emergency department), and an ambulatory surgical center are already included in the definition of applicable setting.

After considering the comments, we are finalizing the proposal revising the definition of applicable setting under § 414.94(b) to include an IDTF.

b. Consultations by Ordering Professionals

Section 1834(q)(1)(E) of the Act defines the term ''ordering professional'' as a physician (as defined in section 1861(r)) or a practitioner described in section 1842(b)(18)(C) who orders an applicable imaging service. The AUC consultation requirement applies to these ordering professionals. We proposed that the consultation with AUC through a qualified CDSM may be performed by auxiliary personnel under the direction of the ordering professional and incident to the ordering professional's services, when the consultation is not performed personally by the ordering professional whose NPI will be listed on the order for an advanced imaging service.

In response to the CY 2018 PFS proposed rule, we received several public comments requesting clarification regarding who is required to perform the consultation of AUC through a qualified CDSM. Commenters not only sought clarification, but also provided recommendations for requirements around this topic. Some commenters recommended that CMS strictly interpret the statutory language and only allow the clinician placing the order to perform the consultation and others recommended that CMS allow others to perform the AUC consultation on behalf of the clinician.

Section 1834(q)(4)(A)(i) of the Act requires an ordering professional to consult with a qualified CDSM, and this was codified in our regulations at § 414.94(j). The statute does not explicitly provide for consultations under the AUC program to be fulfilled by other professionals, individuals or organizations on behalf of the ordering professional; however, we continue to seek ways to minimize the burden of this new Medicare program and understand that many practices currently use clinical staff, working under the direction of the ordering professional, to interact with the CDSM for AUC consultation and subsequent ordering of advanced diagnostic imaging. Therefore, we proposed to modify paragraph § 414.94(j) to specify that additional individuals may perform the required AUC consultation.

When the AUC consultation is not performed personally by the ordering professional, we proposed the consultation may be performed by auxiliary personnel incident to the ordering physician or non-physician practitioner's professional service. We believed this approach was appropriate under this program and still accomplishes the goal of promoting the use of AUC. This proposed policy would allow the ordering professional to exercise their discretion to delegate the performance of this consultation. It is important to note that the ordering professional is ultimately responsible for the consultation as their NPI is reported by the furnishing professional on the claim for the applicable imaging service; and that it is the ordering professional who could be identified as an outlier ordering professional and become subject to prior authorization based on their ordering pattern.

We proposed to revise the AUC consultation requirement specified at § 414.94(j) to specify that the AUC consultation may be performed by auxiliary personnel under the direction of the ordering professional and incident to the ordering professional's services.

The following is a summary of the comments we received on this proposal. Overall commenters either agreed or disagreed with the proposal to expand who can perform the consultation with a qualified CDSM, and the commenters that agreed with the concept of the proposal either requested clarification around the term auxiliary personnel or recommended that we use more specific language to describe eligible personnel.

Comment: Some commenters were completely against the concept of this proposal and did not support allowing anyone beyond the ordering professional to perform the AUC consultation stating that allowing anyone other than the ordering professional to perform the consultation would undermine the intent of the AUC program and increase administrative burden. A few of those commenters suggested that expanding the scope of individuals who can perform the consultation would actually increase

burden and confusion for ordering professionals. Others opposed the proposal on the basis that the educational goals of the program would be undermined or auxiliary personnel would manipulate the information to achieve adherent responses. These commenters wanted ordering professionals to be directly exposed to AUC. Some of the commenters that agreed with the proposal specifically stated that the intent of the AUC program would not be diminished by expanding AUC consultation beyond the ordering professional. However, the vast majority of commenters agreed that expanding beyond the ordering professional allows flexibility and the opportunity for the AUC consultation requirement to be less burdensome on the ordering professional.

Response: We agree that the AUC program should be a learning program for ordering professionals. However, to balance the burden put upon ordering professionals and their offices to comply with this program as well as focus on the educational component of this program, we maintain that expanding AUC consultations to individuals beyond the ordering professional is an important step. We envision that the ordering professionals will, even when they do not personally perform the AUC consultation, remain closely involved and will engage with the individual to whom they delegate the task of performing the consultation. For many ordering professionals, this delegation may save time when they routinely order tests that are consistently considered to adhere to AUC. In those cases, the back-and-forth between the ordering professional and the individual who conducts the consultation may be minimal. We anticipate that, when an AUC consultation is performed by someone other than the ordering professional and the result is that the imaging service does not adhere to the consulted AUC, that information will be provided back to the ordering professional to allow them to consider whether a different test (or no test) should be ordered, or if the original order is still appropriate for the patient. Additionally, ordering professionals may still choose to personally perform the consultation. This may be ideal for ordering professionals with CDSMs that allow for seamless interaction, such as the case of a CDSM integrated within an EHR.

Regardless of who performs the AUC consultation, the ordering professional is ultimately responsible for the order and may become subject to prior authorization if they demonstrate a pattern of non-adherent orders. Therefore, the ordering professional not only has a vested interest in terms of providing the right test for their patient, but also to monitor the frequency with which they order tests that do not adhere to AUC.

Comment: While the majority of commenters agreed with expanding who, beyond the ordering professional, can personally perform the consultation with a qualified CDSM, they expressed either confusion with the term ''auxiliary personnel'' or recommended additional regulatory language to more specifically identify the scope of individuals who could perform the AUC consultation. Other commenters questioned the applicability of ''incident to'' provisions since consulting AUC through a CDSM is not a billable service.

Some commenters suggested additional language that would identify specific licensed professionals, lay out training requirements, allow for medical assistants or credentialed clinical staff, cite state scope of practice laws, or require that the individual be present in the office of the ordering professional. These commenters stated that the AUC consultation should not be an administrative task that can be performed by any staff member, such as a receptionist or data entry clerk. The underlying concern of commenters that wanted to explicitly allow only clinical personnel to consult AUC was that the individual performing an AUC consultation would need to understand the patient's medical information, the advanced imaging service being recommended and the clinical information that is returned by the CDSM. Commenters stated that this understanding on the part of the individual who performs the AUC consultation was particularly important when a CDSM indicates that the order is not adherent to AUC.

Some commenters specifically addressed our proposal that the individual who consults AUC must be under the direction of the ordering professional. At least one commenter noted the need for direct supervision while another said the individual should be physically located in the office of the ordering professional as opposed to off-site. Other commenters suggested that we use language that allows for maximum flexibility.

One commenter gave an example that drew parallels between CDSMs and Computerized Provider Order Entry (CPOE) systems, and suggested the same requirements should apply to individuals consulting CDSMs. The commenter stated that for CPOE entries to count toward meeting Medicaid Meaningful Use thresholds, the entry must be made by a licensed healthcare professional or credentialed medical assistant. Similarly, the commenter suggested the consultation should be performed consistent with state scope of practice laws since the use of CPOE is limited to those individuals referenced above, as it is within their state scope of practice to enter orders into medical records.

Response: We agree with comments suggesting that the language we proposed could potentially cause confusion, and we understand the disagreement among commenters regarding precisely who, beyond the ordering professional, should be eligible to perform the AUC consultation. We further agree that the concept of services incident to a physician's professional services may not be directly relevant to the action of consulting AUC using a CDSM. We proposed using ''incident to'' as a description of the relationship between the ordering professional and the auxiliary personnel consulting the AUC.

We also agree that there are similarities between CPOE systems and CDSMs, and that individuals using these systems should have some level of knowledge of the clinical information they are inputting and, importantly, the information they receive back from the system. However, we also agree with the view of most commenters that ordering professionals should have flexibility to delegate the AUC consultation task. We also agree that the learning and educational aspects of AUC are more likely to be realized when there is real communication between the ordering professional and the person performing the consultation. While we proposed the consultation could be performed incident to the ordering professional's service, we agree with commenters that the ''incident to'' concept is difficult to apply to a service that is not billable and does not require the patient to be present. We further agree with comments recommending that there be good communication and a close relationship between the ordering professional and individual consulting the AUC. In the case of consulting AUC, we believe it is important that the individual who uses the CDSM is working under the ordering professional, and that the individual is available to the ordering professional to discuss the results of the consultation and any responsive adjustments to planned orders.

Comment: A few commenters suggested allowing the furnishing professional to occasionally consult AUC using a CDSM. Another

commenter questioned whether auxiliary personnel would be permitted to change the order based on the AUC consultation and an additional commenter questioned whether physical therapists could write orders.

Response: While a furnishing professional may consult AUC as they wish for other purposes, such a consultation would not suffice for purposes of the AUC consultation required under this program. The AUC consultation must be performed by the ordering professional or an individual to whom the ordering professional has delegated it; and the ordering professional may only delegate the required AUC consultation to an individual as specified in our final policy. The furnishing professional may perform their own AUC consultation to verify information; however, that would not replace the consultation that is required to be performed by the ordering professional or their appropriately designated surrogate. The AUC program does not change the scope of professionals permitted under law to write or change orders for advanced diagnostic imaging services.

Comment: Some commenters questioned whether there was statutory authority to allow anyone other than the ordering professional to personally perform the AUC consultation with a CDSM.

Response: We do not believe it is inconsistent with the statute to allow an individual other than the ordering professional to perform the AUC consultation with a qualified CDSM. Moreover, regardless of who performs the act of consulting with a qualified CDSM, it is important to understand that the ordering professional remains ultimately responsible for the AUC consultation and communication of the consultation information to the furnishing professional.

Comment: A commenter who disagreed with our proposal to permit certain individuals other than the ordering professional to perform the AUC consultation suggested that the proposal is counter to the intent of the existing regulation at § 414.94(k) finalized in the CY 2018 PFS final rule. The commenter suggested that educating ordering professionals regarding the optimal use of advanced imaging services can only be accomplished when ordering professionals are directly exposed to AUC.

Response: We believe the intent of the statutory provisions requiring the AUC program is to increase appropriate ordering of advanced imaging services through a learning system, and that can still be achieved even if we allow delegation of the consultation when the individual performing it has the proper training and is working under the appropriate direction of the ordering professional.

Comment: One commenter requested a specific set of standards or training requirements for such auxiliary personnel to ensure that diagnostic imaging services comply with AUC requirements.

Response: At this time, we are not in a position to establish training requirements or standards tailored to the AUC program for individuals that may be delegated the AUC consultation.

Based on the public comments received, we do not believe it would be appropriate to move forward with the proposal to specify the scope of individuals who can perform the AUC consultation as auxiliary personnel. We are modifying our proposal in response to comments, and conforming the regulation at § 414.94(j)(2), to clarify that, in the event of a significant hardship, the requirement to consult AUC does not apply and specify that, when not personally performed by the ordering professional, the consultation with a qualified CDSM may be performed by clinical staff under the direction of the ordering professional. We have used the term clinical staff elsewhere in the Medicare program to identify the individuals that may perform care management services including chronic care management (CCM), behavioral health integration (BHI) and transitional care management (TCM) services. These services involve some non-face-to-face services along with clinical activities around the care plan and communication and coordination with the patient's other healthcare professionals. For care management, the clinical staff requirement ensures that the individual performing the service must have the level of clinical knowledge necessary to effectively coordinate and communicate with the treating clinician. Similarly, in the case of the AUC program, the individual performing the AUC consultation must have sufficient clinical knowledge to interact with the CDSM and communicate with the ordering professional. After considering public comments on our proposal, we have concluded that allowing clinical staff to perform the AUC consultation under the direction of the ordering professional is a better fit with the AUC program than our proposal, and is responsive to public comments asserting that the concept of ''incident to'' is not relevant in the context of the AUC program. We believe the policy we are finalizing, to allow the AUC consultation to be performed by clinical staff under the direction of the ordering professional, further reflects a balance between those commenters who wanted only the ordering professional to perform the consultation and those who suggested we should allow the consultation to be delegated. Clinical staff will have a level of knowledge that allows for effective communication of advanced diagnostic imaging orders, interaction with AUC, and engagement with the ordering professional, while they remain under the direction of the ordering professional.

c. Reporting AUC Consultation Information

Section 1834(q)(4)(B) of the Act requires that payment for an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system may only be made if the claim for the service includes certain information about the AUC consultation. As such, the statute requires that AUC consultation information be included on any claim for an outpatient advanced diagnostic imaging service, including those billed and paid under any applicable payment system (the PFS, OPPS or ASC payment system). When we initially codified the AUC consultation reporting requirement in § 414.94(k) through rulemaking in the CY 2018 PFS final rule, we specified only that ''furnishing professionals'' must report AUC consultation information on claims for applicable imaging services. This led some stakeholders to believe that AUC consultation information would be required only on practitioner claims. To better reflect the statutory requirements of section 1834(q)(4)(B) of the Act, we proposed to revise our regulations to clarify that AUC consultation information must be reported on all claims for an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system. The revised regulation would more clearly express the scope of advanced diagnostic imaging services that are subject to the AUC program, that is, those furnished in an applicable setting and paid under an applicable payment system.

The language codified in § 414.94(k) uses the term furnishing professional to describe who must report the information on the Medicare claims. We recognize that section 1834(q)(1)(F) of the Act specifies that a ''furnishing professional'' is a physician (as defined in section 1861(r)) or a practitioner described in section 1842(b)(18)(C) who furnishes an applicable imaging service.

However, because section 1834(q)(4)(B) of the Act, as described above, clearly includes all claims paid under applicable payment systems without exclusion, we believe that the claims from both furnishing professionals and facilities must include AUC consultation information. In other words, we would expect this information to be included on the practitioner's claim for the PC of the applicable advanced diagnostic imaging service and on the provider's or supplier's claim for the facility portion or TC of the imaging service.

As such, we proposed to revise § 414.94(k) to clearly reflect the scope of claims for which AUC consultation information must be reported, and to clarify that the requirement to report AUC consultation information is not limited to the furnishing professional. The following is a summary of the comments we received.

Comment: Some commenters stated that they appreciate the clarification that the requirement to report AUC consultation information is not limited to the furnishing professional. These commenters thanked CMS for addressing the increasingly common instances in which the TC and PC of an advanced diagnostic imaging service are performed at separate locations. Additionally, these commenters acknowledged that the clarification recognizes situations when payment can be made globally, to include both the TC and PC furnished and billed by the same entity, and situations of Method II billing by critical access hospitals. In contrast, other commenters opposed the reporting of AUC consultation information on all claims, specifically the facility claims, for an applicable imaging service furnished in an applicable setting and paid under an applicable payment system. These commenters noted that requiring the reporting of AUC consultation information does not appropriately target the ordering professionals for whom the AUC program is intended, and creates a duplicative effort when CMS receives AUC consultation information from both facilities and furnishing professionals for different parts of the same exam. A few other commenters expressed concern that requiring two sources of AUC consultation information that relates to the same test for the same patient could result in situations where one source was inaccurate or provides conflicting information.

Response: The statutory requirement under section 1834(q)(4)(B) of the Act specifies that payment for an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system may only be made if the claim for the service includes certain information about the AUC consultation. We recognize that this requirement to report AUC consultation information is not placed on the ordering professional, but rather on those submitting claims for the advanced diagnostic imaging service that the ordering professional orders. We also recognize that the TC or facility portion of an applicable imaging service is frequently furnished and billed by a different entity than the PC portion of the service. We do not currently do any matching or comparison of separate claims for the PC and TC or facility portion of an advanced diagnostic imaging service. Rather, we process these separate claims individually, and have no immediate plans to begin doing otherwise for purposes of the AUC program. We hope to learn more about the implementation of this program, including issues such as these commenters have raised, during the educational and operations testing period.

After considering the comments, we are finalizing without modification the proposal to revise § 414.94(k) to clearly reflect the scope of claims for which AUC consultation information must be reported, and to make this requirement consistent with section 1834(q)(4)(B) of the Act.

d. Claims-Based Reporting

In the CY 2018 PFS proposed rule (82 FR 34094) we discussed using a combination of G-codes and modifiers to report the AUC consultation information on the Medicare claim. We received numerous public comments objecting to this potential solution. In the 2018 PFS final rule, we agreed with many of the commenters that additional approaches to reporting AUC consultation information on Medicare claims should be considered, and we learned from many commenters that reporting a unique consultation identifier (UCI) would be a less burdensome and preferred approach. The UCI would include all the information required under section 1834(q)(4)(B) of the Act including an indication of AUC adherence, non-adherence and not applicable responses. Commenters noted that capturing a truly distinguishing UCI on the claim will allow for direct mapping from a single AUC consultation to embedded information within a CDSM. We indicated that we would work with stakeholders to further explore the concept of using a UCI to satisfy the requirements of section 1834(q)(4)(B) of the Act, which will be used for Medicare claims processing and, ultimately, for the identification of outlier ordering professionals, and consider developing a taxonomy for a UCI.

We had the opportunity to engage with some stakeholders over the last 6 months and we understand that some commenters from the previous rule continue to be in favor of a UCI, while some may have changed their position upon further consideration.

We provide the following information to summarize alternatives we considered. We had originally considered assigning a G-code for every qualified CDSM with a code descriptor containing the name of the qualified CDSM. The challenge to this approach arises when there is more than one advanced imaging service on a single claim. We could attribute a single G-code to all of the applicable imaging services for the patient's clinical condition on the claim, which might be appropriate if each AUC consultation for each service was through the same CDSM. If a different CDSM was used for each service (for example, when services on a single claim were ordered by more than one ordering professional and each ordering professional used a different CDSM) then multiple G-codes could be needed on the claim. Each G-code would appear on the claim individually as its own line item. As a potential solution, we considered the use of modifiers, which are appealing because they would appear on the same line as the CPT code that identifies the specific billed service. Therefore, information entered onto a claim would arrive into the claims processing system paired with the relevant AUC consultation information.

When reporting the required AUC consultation information based on the response from a CDSM: (1) The imaging service would adhere to the applicable AUC; (2) the imaging service would not adhere to such criteria; or (3) such criteria were not applicable to the imaging service ordered, three modifiers could be developed. These modifiers, when placed on the same line with the CPT code for the advanced imaging service would allow this information to be easily accessed in the Medicare claims data and matched with the imaging service.

Stakeholders have made various suggestions for a taxonomy that could be used to develop a UCI to report the required information. Stakeholders have also considered where to place the UCI on the claim. We understand the majority of solutions suggested by stakeholders involving a UCI are claim-

level solutions and would not allow us to attribute the CDSM used or the AUC adherence status (adherent or not adherent, or not applicable) to a specific imaging service. As such, the approach of using a UCI would not identify whether an AUC consultation was performed for each applicable imaging service reported on a claim form, or be useful for purposes of identifying outlier ordering professionals in accordance with section 1834(q)(5) of the Act.

We have received ideas from stakeholders that are both for and against the two approaches we have identified; and we appreciate the stakeholders that have provided additional information or engaged us in this discussion. Internally, we have explored the possibility of using, and feasibility of developing, a UCI; and concluded that, although we initiated this approach during the CY 2018 PFS final rule, it is not feasible to create a uniform UCI taxonomy, determine a location of the UCI on the claims forms, obtain the support and permission by national bodies to use claim fields for this purpose, and solve the underlying issue that the UCI seems limited to claim-level reporting. Using coding structures that are already in place (such as G-codes and modifiers) would allow us to establish reporting requirements prior to the start of the program (January 1, 2020).

Since we did not finalize a proposal in the CY 2018 PFS final rule, we proposed in this rule to use established coding methods, to include G-codes and modifiers, to report the required AUC information on Medicare claims. This would allow the program to be implemented by January 1, 2020. We will consider future opportunities to use a UCI and look forward to continued engagement with and feedback from stakeholders.

The following is a summary of comments we received on this proposal.

Comment: The majority of commenters agreed with our proposed approach of using G-codes and modifiers to append AUC information on claims. Of those commenters, most stated that the approach is not without flaws, including increased workflow challenges and complexity, time needed for staff to learn and incorporate these changes into billing practices, and the limited information modifiers may convey for outlier identification purposes. We summarize and respond to comments on these issues below. However, they acknowledged that there is a lack of better alternatives. Other commenters disagreed with the proposal, and recommended CMS not require claims-based reporting until a UCI can be reported on claims. In addition to those recommending a delay in reporting, others suggested that CMS not require claims-based reporting at all and instead allow information to be transmitted directly from qualified CDSMs to CMS.

Response: We agree with commenters that G-codes and modifiers may not be the ideal solution. However, it is important that we make strides to implement this program and prepare stakeholders for the method of reporting in the immediate years of the program. We will continue to discuss with stakeholders the potential of using a UCI in the future. There are hurdles to overcome with respect to the use of a UCI that are discussed in the comment summaries and responses below. Some of these include understanding how UCI information would be used in the development of the eventual outlier ordering professional methodology, and where it would be appended to the claim. In addition, there is disagreement among stakeholders regarding whether the UCI would contain a taxonomy and embed meaningful information. Additionally, as we have consulted with stakeholders responsible for updating the claims forms, which would be necessary to establish a field to report a UCI on claims, we understand that it would be a matter of years before the forms could be updated. As such, the prospect of developing and using a UCI is not a realistic immediate solution.

Comment: There were disagreements and concerns among commenters that support the use of G-codes to identify which qualified CDSM was consulted. Some were concerned that CMS could not develop G-codes quickly enough to keep pace with newly qualified CDSMs and that the total number of G-codes would be unwieldy. Others supported the use of a single generic G-code to describe that a qualified CDSM was consulted but would not identify a particular CDSM. Another commenter pointed out that a G-code would not be necessary on claims when a CDSM was not consulted, rather, only a modifier (placed on the same line as the CPT code for the imaging service) would be used in these circumstances.

Commenters pointed out that claims for both the furnishing facility and furnishing professional are capable of reporting G-codes and modifiers, but identified an issue related to resorting of information on claims as they are processed through the system. In other words, the codes billed on separate claim lines can come through the system and end up in a different order than how they originally appeared when the claim was submitted. This means CMS cannot presume to pair an imaging service reported on a specific claim line with a specific G-code when more than one imaging service appears on the claim. A commenter suggested that furnishing professionals could split their claims so only one imaging service and one G-code would appear on each claim. Commenters pointed out that while this is possible on the furnishing professional claim, it is not possible on the furnishing facility claim due to other rules involving facility billing and same-day procedures.

Response: We are optimistic that we can issue G-codes in a timely manner upon qualifying new CDSMs. There are a number of CDSMs already qualified and G-codes could be issued for those prior to the start of the educational and operations testing period set to begin in 2020. We could secure additional G-codes with general descriptors to describe ''newly qualified CDSM A,'' ''newly qualified CDSM B,'' etc. to be ready for assignment to a specific CDSM upon qualification. That would allow some time for the descriptor to be changed to reflect the name of the CDSM, but also enable immediate use of the appropriate G-code for reporting purposes. This information will be contained in standard coding information issued by the agency as well as on the AUC website that lists all qualified CDSMs.

Regarding the use of one generic G-code to describe that a qualified CDSM was consulted, we are not confident that this would satisfy the statutory requirement under section 1834(q)(4)(B) of the Act to report which qualified CDSM was consulted. However, we may find that generic codes are needed as a temporary measure as we move forward with implementation.

If a CDSM is not consulted, for example due to the ordering professional attesting to a significant hardship, then we agree that a distinct G-code for that purpose is not necessary. Rather the modifier describing that hardship could be placed on the same claim line as the CPT code for the imaging service.

We agree with commenters that the issue of claims processing system resorting of claims information is problematic. When multiple imaging services are reported on a single claim, it will not be possible to pair the G-code describing which CDSM was consulted with the imaging service for which it was consulted. While we could require the furnishing professional to split the claim, we are not committing to that solution at this point but will explore that option as we move forward with implementation. Another possible

solution, though still imperfect, could be to list the G-code on a line and place the modifiers describing AUC adherence on the line with the CPT code describing the imaging service. This model could work when the same ordering professional has ordered all of the furnished imaging services on the claim, and if we presume that an ordering professional will consistently use only one qualified CDSM. We appreciate commenters raising these issues and we will continue to explore options to address them.

Comment: One commenter suggested that, instead of G-codes, CPT codes should be developed to identify the qualified CDSM consulted.

Response: Initially we do not believe it will be possible for AMA–CPT to issue CPT codes identifying qualified CDSMs in time for the program to begin. We do, however, understand that there may be benefits to making these codes Level 1 HCPCS codes that are issued by AMA–CPT as opposed to HCPCS Level 3 codes (G-codes). We will look into the benefits and potential problems of using CPT codes to describe which qualified CDSM was consulted. An initial concern we have, in addition to timing to accommodate the start of the AUC program, is whether CPT code descriptors could be changed quickly enough to accommodate newly qualified CDSMs and whether CPT codes would be set aside for future use.

Comment: Many commenters observed that, under this AUC program, qualified CDSMs must generate and provide a certification or documentation at the time of order that documents which qualified CDSM was consulted, the name and NPI of the ordering professional that consulted the CDSM, and whether the service ordered would or would not adhere to specified applicable AUC or whether the specified applicable AUC consulted was not applicable to the service ordered. As a result, these commenters assumed that the CDSM would also communicate the relevant G-codes and modifiers, and requested that CMS clarify that qualified CDSMs are required to explicitly communicate their assigned G-code and the adherence modifier to the ordering professional. The commenters stated that absent this clarification, some CDSMs may simply convey their name and an indication (other than the relevant modifier) as to whether the ordered service ''adhered,'' or ''didn't adhere,'' or the AUC ''didn't apply'' to the imaging test. The commenters were concerned that if CDSMs provide AUC consultation results in this way, it would create additional burden for ordering professionals to manually assign coding information to be transmitted for billing purposes.

A few of these commenters stated that they requested this clarification because they noted: (1) Each qualified CDSM will know its G-code and can readily convert their adherence rating system into modifiers, (2) the required data could be transmitted between EHR and CDSM vendors and communicated between professionals in a standardized manner, and (3) accuracy of consultation reporting would improve.

Response: Commenters accurately described what information must be included in the certification or documentation generated by a qualified CDSM at the time of order, and this is specified in our regulation at § 414.94(g)(1)(vi). As we move forward in finalizing our approach for claims-based reporting where CDSMs will be represented through G-codes, and AUC adherence represented through modifiers, we agree with commenters that CDSMs should include the G-codes and modifiers in their certification or documentation. We would like to see CDSMs begin to do this as the specific G-codes and modifiers become available. And as the commenters noted, this would seem to be a simple thing for CDSMs to do. If we do not see CDSMs making such adjustments to their certification or documentation, we will consider imposing a requirement in regulation.

Comment: Commenters had varying views of using a UCI to report consultation information on claims. Some commenters were interested in moving forward with the UCI requirement when the claims forms are adjusted to accommodate this new information. Others disagreed on whether or not a taxonomy with embedded meaning was necessary. Some of these commenters supported a UCI issued by the qualified CDSM that was unique to that CDSM. A G-code would also appear on the claim that would identify which qualified CDSM was consulted and then the UCI would be used to pair the information with the data in the CDSM specific to that consultation. Others supported a UCI with a taxonomy with embedded meaning so one could look at the UCI and know, without accessing additional information, which CDSM was consulted and the outcome of that consultation. We also heard from commenters that the UCI could be lengthy and therefore prone to transcription errors when entering information on the order or the claim form.

Response: We will continue to consult with stakeholders about the future possibility of using the UCI.

Comment: Numerous commenters were concerned about the requirements for claims-based reporting of AUC consultation information when the claims are not yet able to accommodate new types of information. Most of these commenters expressed concern about the placement of the UCI and other commenters pointed out that the furnishing facility claim does not contain a designated location for the ordering professional's NPI.

Response: We agree with these concerns and will work with the appropriate stakeholders to identify a possible future location for a UCI to be appended to claims. We are not committing to using the UCI at this time but will be open to exploring the possibility of developing a UCI that could be appended to claims in the future. We will also work to better understand and identify a potentially appropriate place on the furnishing facility claim to include the ordering professional's NPI, and to understand whether changes to that claim form may be needed. In the short term we will consider other implementation options so that fields on the claims are not used improperly.

Comment: Several commenters sought clarification on how, absent a UCI, AUC claims-based information as reported by the furnishing professional and facility would be reconciled with the AUC consultation performed by the ordering professional as there is interest in establishing best practices for retaining this information. These commenters requested clarification on who bears responsibility if such data are not available during an audit, considering that the ordering professional interacts with the CDSM and provides the information that the furnishing provider submits on the claim.

Response: It is the responsibility of the ordering professional to consult AUC and to provide that consultation information to the furnishing professional; and it is the responsibility of the furnishing professional and facility to accurately report that information on claims for applicable imaging services. We will take into account the specific roles of ordering and furnishing professionals and facilities as the program develops and we begin to engage in program monitoring activities.

Comment: Many commenters noted the practice of ''exam substitution'' permitted by Sections 80.6.2–80.6.4 of Chapter 15 of the Medicare Benefit Policy Manual when the furnishing

professional determines a different diagnostic imaging service should be ordered in certain circumstances and the ordering practitioner is not available to provide a new order. To this end, commenters recommended additional proposals to modify the reporting method using G-codes and modifiers by creating additional modifiers for those orders that (1) are initiated in one location and furnished at a different point of service, (2) furnished after a second consultation has occurred, or (3) are the result of interpretation-only services.

Response: We thank these commenters for their suggestions on additional modifiers and will consider these recommendations during implementation.

Based on the public comments we are finalizing the proposal to use G-codes and modifiers to report consultation information on claims. We appreciate that commenters pointed out concerns and technical issues regarding this approach and we will work to address them during implementation.

e. Significant Hardship Exception

We proposed to revise § 414.94(i)(3) of our regulations to adjust the significant hardship exception requirements under the AUC program. We proposed criteria specific to the AUC program and independent of other programs. An ordering professional experiencing any of the following when ordering an advanced diagnostic imaging service would not be required to consult AUC using a qualified CDSM, and the claim for the applicable imaging service would not be required to include AUC consultation information. The proposed criteria include:

- Insufficient internet access;
- EHR or CDSM vendor issues; or
- Extreme and uncontrollable circumstances.

Insufficient internet access is specific to the location where an advanced diagnostic imaging service is ordered by the ordering professional. EHR or CDSM vendor issues may include situations where ordering professionals experience temporary technical problems, installation or upgrades that temporarily impede access to the CDSM, vendors cease operations, or we de-qualify a CDSM. We expect these situations to generally be irregular and unusual. Extreme and uncontrollable circumstances include disasters, natural or man-made, that have a significant negative impact on healthcare operations, area infrastructure or communication systems. These could include areas where events occur that have been designated a federal Emergency Management Agency (FEMA) major disaster or a public health emergency declared by the Secretary. Based on 2016 data from the Medicare EHR Incentive Program and the 2019 payment year MIPS eligibility and special status file, we estimate that 6,699 eligible clinicians could submit such a request due to extreme and uncontrollable circumstances or as a result of a decertification of an EHR, which represents less than 1 percent of available ordering professionals.

In the CY 2017 PFS final rule, for purposes of the AUC program significant hardship exceptions, we provided that those who received significant hardship exceptions in the following categories from § 495.102(d)(4) would also qualify for significant hardship exceptions for the AUC program:

- Insufficient internet Connectivity (as specified in § 495.102(d)(4)(i)).
- Practicing for less than 2 years (as specified in § 495.102(d)(4)(ii)).
- Extreme and Uncontrollable Circumstances (as specified in § 495.102(d)(4)(iii)).
- Lack of Control over the Availability of CEHRT (as specified in § 495.102(d)(4)(iv)(A)).
- Lack of Face-to-Face Patient Interaction (as specified in § 495.102(d)(4)(iv)(B)).

In the CY 2018 PFS proposed rule, we proposed to amend the AUC significant hardship exception regulation to specify that ordering professionals who are granted reweighting of the Advancing Care Information (ACI) performance category to zero percent of the final score for the year under MIPS per § 414.1380(c)(2) due to circumstances that include the criteria listed in § 495.102(d)(4)(i), (d)(4)(iii), and (d)(4)(iv)(A) and (B) (as outlined in the bulleted list above) would be excepted from the AUC consultation requirement during the same year that the re-weighting applies for purposes of the MIPS payment adjustment. This proposal removed § 495.102(d)(4)(ii), practicing for less than 2 years, as a criterion since these clinicians are not MIPS eligible clinicians and thus would never meet the criteria for reweighting of their MIPS ACI performance category for the year.

In response to public comments, we did not finalize the proposed changes to the significant hardship exceptions in the CY 2018 PFS final rule and instead decided further evaluation was needed before moving forward with any modifications. Our original intention was to design the AUC significant hardship exception process in alignment with the process for the Medicare EHR Incentive Program for eligible professionals, and then for the MIPS ACI (now Promoting Interoperability) performance category. Under section 1848(a)(7)(A) of the Act, the downward payment adjustment for eligible professionals under the Medicare EHR Incentive Program will end in 2018, and we are unable to continue making reference to a regulation relating to a program that is no longer in effect. As we have continued to evaluate both policy options and operational considerations for the AUC significant hardship exception, we have concluded that the most appropriate approach, which we consider to be more straightforward and less burdensome than the current approach, involves establishing significant hardship criteria and a process that is independent from other Medicare programs. We also note as we have in the past that the AUC program is a real-time program with a need for real-time significant hardship exceptions. This is in contrast to the way significant hardship exceptions are handled under MIPS where the hardship might impact some or all of a performance period, or might impact reporting, both of which occur well before the MIPS payment adjustment is applied in a subsequent year. We recognize that when a significant hardship arises, an application process to qualify for an exception becomes a time consuming hurdle for health care providers to navigate, and we believe that it is important to minimize the burden involved in seeking significant hardship exceptions. As such, we proposed that ordering professionals would self-attest if they are experiencing a significant hardship at the time of placing an advanced diagnostic imaging order and such attestation would be supported with documentation of significant hardship. Ordering professionals attesting to a significant hardship would communicate that information to the furnishing professional with the order and it would be reflected on the furnishing professional's and furnishing facility's claim by appending a HCPCS modifier. The modifier would indicate that the ordering professional has self-attested to experiencing a significant hardship and communicated this to the furnishing professional with the order. Claims for advanced diagnostic imaging services that include a significant hardship exception modifier would not be required to include AUC consultation information.

In addition to the proposals above, we invited the public to comment on any

additional circumstances that would cause the act of consulting AUC to be particularly difficult or challenging for the ordering professional, and for which it may be appropriate for an ordering professional to be granted a significant hardship exception under the AUC program. Although we understand the desire by some for significant hardship categories unrelated to difficulty in consulting AUC through a CDSM, we remind readers that circumstances that are not specific to AUC consultation, such as the ordering professional being in clinical practice for a short period of time or having limited numbers of Medicare patients, would not impede clinicians from consulting AUC through a CDSM as required to meet the requirements of this program.

The following is a summary of the comments we received on the modifications to the significant hardship exceptions and additional circumstances for consideration as needing significant hardship exceptions.

Comment: Some commenters requested that clinicians in the Quality Payment Program be excepted from or considered automatically in compliance with the AUC program requirements. Some of these commenters specified that an exception should apply to all primary care practitioners, others suggested an exception should apply to all clinicians in the Quality Payment Program, and several commenters requested that hospitals and health systems be exempt from reporting AUC consultation information. One commenter requested that facility and institutional providers be exempt. Acknowledging that the statutory language in section 218(b) of the PAMA does not include such an exception, some of these commenters clarified that CMS should seek legislative authority to add such an exception.

Response: As added by section 218(b) of the PAMA, section 1834(q)(4)(B) of the Act specifies that AUC consultation information must be included on all claims for applicable imaging services when furnished in an applicable setting and paid under an applicable payment system, which includes the physician fee schedule, prospective payment system for hospital outpatient department services and the ambulatory surgical center payment system. Section 1834(q)(4)(C) of the Act also set forth specific exceptions, including for a service ordered for an individual with an emergency medical condition, a service ordered for an inpatient for which payment is made under Medicare Part A, or for a service ordered by an ordering professional for whom AUC consultation would result in a significant hardship. In the case of significant hardship, section 1834(q)(4)(C)(iii) of the Act provides for such exceptions in situations when the Secretary determines, on a case-by-case basis, that an ordering professional is exempt because ''consultation with applicable appropriate use criteria would result in a significant hardship, such as in the case of a professional who practices in a rural area without sufficient internet access.'' Given these statutory provisions, blanket exceptions, considered significant hardships or otherwise, for clinicians in the Quality Payment Program, for facility or institutional providers, or for hospitals and health systems, would not be consistent with the statutory requirements. While we understand that stakeholders may view the AUC program as duplicative of the Quality Payment Program, we also note that there are specific and distinct differences between the programs. The AUC program was established to promote appropriate use of advanced diagnostic imaging and improve ordering patterns for these services through the consultation of AUC with real time reporting requirements and payment implications. While some components of the Quality Payment Program can involve using AUC and clinical decision support, their use is not mandatory, and the Quality Payment Program provides numerous options for participation across all MIPS performance categories. In contrast, consultation with AUC using a CDSM is required for each order for an applicable imaging service furnished in an applicable setting and paid under an applicable payment system under the AUC program. If amendments are made to the AUC statutory provisions, we will adjust our regulations throughout § 414.94 accordingly. However, at this time, we do not have the authority to include exceptions to the AUC program beyond the scope of those specified in section 1834(q)(4)(C) of the Act.

Comment: Some commenters requested an additional significant hardship category based on a low-volume threshold for practices with low patient volumes, low number of covered services or a low number of Medicare charges. Some commenters supported this request by noting the increased cost and burden a small practice would be required to undertake to meet the requirements of the AUC program.

Response: As noted above, we believe that significant hardships are reflective of situations that would impede clinicians from consulting AUC through a CDSM. As the program is structured and given the availability of qualified CDSMs that are free of charge, we do not agree that ordering professionals in practices with low patient volumes, low number of covered services or a low number of Medicare charges would be impeded from consulting AUC. While we do understand that participation in the AUC program may result in increased cost and burden, which could arguably be disproportionate for these types of low volume practices, we do not have the authority to include exceptions to the AUC program beyond the scope of those specified in section 1834(q)(4)(C) of the Act.

Comment: Several commenters provided recommendations for other categories of significant hardship exceptions. One commenter requested an exception for professionals when the PLE they rely upon becomes unavailable, and another commenter requested a significant hardship exception when there is a lack of AUC for the service(s) requiring consultation or AUC are outdated. Another commenter suggested that new physicians be excepted from the AUC program and another identified imaging services ordered as the result of a clinical research protocol as a potential significant hardship.

Response: We disagree with adding these scenarios to the significant hardship exceptions under this program. For unavailable PLEs and AUC, we established specific requirements for both qualified PLEs and CDSMs that address the two situations included above. First, qualified CDSMs are required to make available, at a minimum, specified applicable AUC that reasonably address common and important clinical scenarios within all priority clinical areas and be able to incorporate specified applicable AUC from more than one qualified PLE. Should a qualified PLE cease to exist or otherwise become unavailable, then the qualified CDSM through which the AUC for that qualified PLE is consulted would no longer meet the requirements to be a qualified CDSM (assuming it does not incorporate AUC from another qualified PLE), and as such, would be de-qualified as a CDSM under this program. As noted above, de-qualification of a CDSM would be an allowable circumstance for an ordering professional to attest to a significant hardship due to EHR or CDSM vendor issues. Second, when an ordering professional consults a qualified CDSM and there are no AUC applicable to the service ordered, that information would be reported on the claim as such. In these situations, the qualified CDSM is required under § 414.94(g)(1)(vi) to

generate and provide a certification or documentation at the time of order that documents whether the specified applicable AUC consulted was not applicable to the service ordered. The ordering professional is then required to provide that information to the furnishing professional and facility so that it can be reported as specified under § 414.94(k). The absence of applicable AUC does not constitute an exception from the requirement to consult AUC using the qualified CDSM in an effort to find specified applicable AUC for the order. Third, qualified PLEs are required to review their AUC regularly and update them at least annually when appropriate; and qualified CDSMs are required to make any updated AUC content available within 12 months of the qualified PLE's update(s). Finally, we do not believe that being a new physician or conducting clinical research would cause the act of consulting AUC to be particularly difficult or challenging for the ordering professional.

Comment: Several commenters revisited previously expressed concerns about the emergency services exception. The commenters requested clarification around what constitutes an emergency medical condition. One commenter suggested that CMS revise the regulatory language to allow exceptions when an emergency medical condition is suspected for cases in which clinicians, in their best judgment, believe a patient may be experiencing a medical emergency at the time of order. This commenter noted that this approach was the intent of section 218(b) of the PAMA as explained by a member of Congress who was involved in drafting the statutory language, and that the reference to section 1867(e) of the Act instead of section 1867(a) of the Act was an inadvertent drafting error. One commenter requested that CMS delay requiring AUC consultations in the emergency department until the ambiguity over what services are considered emergency services is resolved.

Response: Section 1834(q)(4)(C)(i) of the Act provides for an exception to the AUC consultation and reporting requirements in the case of a service ordered for an individual with an emergency medical condition as defined in section 1867(e)(1) of the Act, not section 1867(a) of the Act as the commenter suggests. The regulation reflects the current statutory language and we will not amend our regulation in response to these comments. As stated in our response to comments in the CY 2017 PFS final rule with comment, we agree that exceptions granted for an individual with an emergency medical condition include instances where an emergency medical condition is suspected, but not yet confirmed. This may include, for example, instances of severe pain or severe allergic reactions. In these instances, the exception is applicable even if it is determined later that the patient did not in fact have an emergency medical condition.

Comment: Many commenters generally supported the proposed significant hardship categories and self-attestation approach, with one commenter specifically encouraging oversight of AUC and the use of significant hardship exceptions. However, many other commenters challenged the proposed approach to annotating the significant hardship self-attestation on every Medicare claim. Specifically, they requested that a blanket exception or single attestation be applied over a period of time to avoid increased burden of communicating and reporting a significant hardship attestation on every advanced diagnostic imaging order, and suggested using a significant hardship exception modifier on the subsequent claim(s) after the single attestation. One commenter noted that the approach as proposed by CMS is more burdensome than requiring the use of an applications process.

Response: Because the AUC program requires real time reporting on Medicare claims, we believe the best way to ensure clinicians have the ability and flexibility to use the significant hardships allowable under this program is to establish a mechanism for real time application of significant hardship attestations. To accomplish this, inclusion of the relevant significant hardship modifier on each Medicare claim offers the most straightforward approach, enabling ordering professionals to use a significant hardship exception as needed and without more complicated, time consuming steps that could result in a delay in the transmission, acceptance and processing of the imaging order for the ordering and furnishing professionals, as well as a delay in care for the patient. We note that applying a blanket exception for a specific period of time for ordering professionals based on a single significant hardship attestation would introduce a level of complexity and burden to the process that was not identified by requestors. Following such a single attestation, furnishing professionals (as well as CMS) would need to keep track of which ordering professionals had attested to a significant hardship as well as the period of time applicable to each attestation every time an order is received and a claim is prepared, submitted and processed. We disagree with commenters that inclusion of significant hardship information on each imaging order and subsequent claim imposes extensive burden, or that other approaches would be less burdensome and achieve the same goal of allowing for a real time significant hardship exception process under the real time AUC program.

Comment: Many commenters posed specific requests for clarification around the proposed significant hardship exception categories. One commenter requested further clarity and a broader application of insufficient internet access and extreme and uncontrollable circumstances to include, respectively, situations out of the control of the ordering professional like slow internet and no physical access to the CDSM, lost CDSM usernames and passwords and other situations preventing an ordering professional from consulting at the time of the patient encounter. Other commenters requested clarification around how orders would be made during downtime and how and when to document the significant hardship and by whom. A few commenters did not understand how de-certification of an EHR would qualify as a significant hardship since there are no certification requirements related to the AUC program. Others requested further information on how hardship information must be reported on the claim, specific information on coding a significant hardship, how to handle emergency situations and what to report when orders are changed.

Response: We appreciate the comments submitted requesting further clarification around exactly how significant hardship exceptions will be operationalized. We note that many of the questions posed are specific to claims reporting details. We expect to provide further details and clarification in the claims processing instructions that we expect to release following the final rule.

We describe insufficient internet access as specific to the location where an advanced diagnostic imaging service is ordered by the ordering professional. To further clarify, we note that in addition to ordering imaging services in an area without sufficient internet access, a significant hardship may apply when ordering professionals would face insurmountable barriers to obtaining infrastructure to have internet access (that is, lack of broadband). We do not believe that occasions of slow internet constitute a significant hardship.

We describe EHR or CDSM vendor issues as situations where ordering professionals experience temporary technical problems, installation or upgrades that temporarily impede access to the CDSM, vendors cease operations, or we de-qualify a CDSM and note that we expect these situations to be irregular and unusual. De-certification of an EHR would qualify as a significant hardship when the ordering professionals' qualified CDSM is integrated into their EHR, and the ordering professional's access to the CDSM is temporarily impeded due to installation issues associated with switching to a new vendor. We do not agree that losing CDSM usernames and passwords constitutes a significant hardship under the AUC program. Self-attestation for this significant hardship should be used as needed when the situations described above occur. We have not established limitations around using the EHR or CDSM vendor issues or the other significant hardship exceptions, but may monitor the use of these exceptions to ensure misuse or overuse does not become a problem.

We describe extreme and uncontrollable circumstances to include disasters, natural or man-made, that have a significant negative impact on healthcare operations, area infrastructure or communication systems. We also explain these may include areas where events occur that have been designated by FEMA as a major disaster or a public health emergency declared by the Secretary. To further clarify, these circumstances are events that are entirely outside the control of the ordering professional that prevent the ordering professional from consulting AUC through a qualified CDSM. We believe the hardship criteria under this program are similar to other programs such as MIPS and Promoting Interoperability, particularly the flexibility that is given to clinicians to identify extreme and uncontrollable circumstances.

Comment: Several commenters submitted a variety of additional comments and questions about the proposed significant hardship exceptions. One commenter questioned why the AUC hardships are not completely aligned with Quality Payment Program hardships. One stated that interpretation-only services do not need to include documentation of AUC consultation because professionals with no face-to-face encounters are excepted. One commenter questioned why an ordering professional with a significant hardship exception would need to communicate AUC consultation information, and suggested that they should only need to communicate the exception information to the furnishing professional and facility. A few commenters recommended that furnishing professionals should be held harmless when ordering professionals self-attest to experiencing a significant hardship.

Response: As explained above, the AUC program requires real time reporting of information on the Medicare claims for payment purposes. The Quality Payment Program is not a real time program but instead uses data from prior performance years to determine status and potential payment adjustments in future years. This distinct and significant difference, along with statutory differences between the programs, necessitates a separate significant hardship exception approach and process for the AUC program. As discussed throughout this section, we have made efforts to align significant hardship exception concepts with the Quality Payment Program as closely as possible; however, we are unable to achieve full alignment due to the innate programmatic differences. For ordering professionals without face-to-face patient interactions, we did not include this circumstance in our proposals and do not provide for such an exception in this final rule. The degree of patient interaction does not create in itself a significant hardship to consultation with applicable AUC. For communicating consultation information on the imaging order when a significant hardship is experienced, the commenter is correct. No AUC consultation information is to be communicated when an ordering professional self-attests to experiencing a significant hardship and communicates that on the order. This confusion likely arose from language that we inadvertently included in the preamble and have corrected for the final rule. Section 1834(q)(4)(B) of the Act requires certain information to be included on the claim for applicable imaging services under this program. As long as the furnishing professional and facilities correctly include the required information or append the appropriate hardship modifier, the claims will not be denied for failing to include AUC consultation information, and the furnishing professionals and facilities are not held responsible for the self-attestation made by the ordering professional. As noted above, we may monitor the use of these exceptions to ensure misuse or overuse does not become a problem, with the understanding that they reflect the ordering professional's self-attestation, not a representation made by the furnishing professional or facility. It is not appropriate for furnishing professionals or facilities to append significant hardship modifiers at their discretion; and we note that support for the use of such a modifier should be included by the ordering professional in the patient's medical record.

After considering the public comments, we are finalizing the significant hardship categories of insufficient internet access, EHR or CDSM vendor issues, and extreme and uncontrollable circumstances and updating this language in § 414.94(i)(3) of our regulations. We are also finalizing our proposal to allow ordering professionals experiencing a significant hardship to self-attest and include that information on the order for the advanced diagnostic imaging service, which the furnishing professional or facility would then communicate on the Medicare claim for the service by appending a HCPCS modifier identifying the ordering professional's self-attested significant hardship category.

f. Identification of Outliers

As previously mentioned, the fourth component of the AUC program specified in section 1834(q)(5) of the Act, is the identification of outlier ordering professionals. In our efforts to start a dialogue with stakeholders, we invited the public to submit their ideas on a possible methodology for the identification of outlier ordering professionals who would eventually be subject to a prior authorization process when ordering advanced diagnostic imaging services. Specifically, we solicited comments on the data elements and thresholds that we should consider when identifying outliers. We also intend to perform and use analysis to assist us in developing the outlier methodology for the AUC program. Our existing prior authorization programs generally do not specifically focus on outliers. We are interested in hearing ideas from the public on how outliers could be determined for the AUC program. Because we would be concerned about data integrity and reliability, we do not intend to include data from the educational and operations testing period in CY 2020 in the analysis used to develop our outlier methodology. Since we intend to evaluate claims data to inform our methodology we expect to address outlier identification and prior authorization more fully in CY 2022 or 2023 rulemaking. We appreciate the feedback received from public commenters and as noted above, we

expect to solicit additional public comment to inform our methodology through rulemaking before finalizing our approach.

5. Summary

We appreciate the commenters that continue to provide their perspective and feedback on this program. Based on those comments we will finalize the following:

We will finalize as proposed to add IDTFs to the definition of applicable settings under § 414.94(b) of this program. We will also finalize as proposed that furnishing professionals and all furnishing entities are required to report AUC consultation information on the claim as specified under § 414.94(k). In addition we will finalize as proposed the significant hardship exception criteria and process under § 414.94(i)(3) to be specific to the AUC program and independent of other Medicare programs.

We will not finalize as proposed the proposal to allow the AUC consultation, when not personally performed by the ordering professional, to be performed by auxiliary personnel incident to the ordering professional's services. Rather we are finalizing under § 414.94(j)(2) that when delegated by the ordering professional, clinical staff under the direction of the ordering professional may perform the AUC consultation with a qualified CDSM.

Additionally, we will move forward with plans to use G-codes and modifiers to report AUC consultation information on the Medicare claims.

We will continue to post information on our website for this program, accessible at *www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html*.

E. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

1. Background

Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for the incentive payments made to Medicaid EPs and eligible hospitals for the adoption, implementation, upgrade, and meaningful use of CEHRT. We have implemented these statutory provisions in prior rulemakings to establish the Medicaid Promoting Interoperability Program.

Under sections 1848(o)(2)(A)(iii) and 1903(t)(6)(C)(i)(II) of the Act, and the definition of ''meaningful EHR user'' in regulations at § 495.4, one of the requirements of being a meaningful EHR user is to successfully report the clinical quality measures selected by CMS to CMS or a state, as applicable, in the form and manner specified by CMS or the state, as applicable. Section 1848(o)(2)(B)(iii) of the Act requires that in selecting electronic clinical quality measures (eCQMs) for EPs to report under the Promoting Interoperability Program, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required. We have taken steps to align various quality reporting and payment programs that include the submission of eCQMs.

In the ''Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices'' final rule (82 FR 37990, 38487) (hereafter referred to as the ''FY 2018 IPPS/LTCH PPS final rule''), we established that, for 2017, Medicaid EPs would be required to report on any six eCQMs that are relevant to the EP's scope of practice. In proposing and finalizing that change, we indicated that it is our intention to align eCQM requirements for Medicaid EPs with the requirements of Medicare quality improvement programs, to the extent practicable.

2. eCQM Reporting Requirements for EPs Under the Medicaid Promoting Interoperability Program for 2019

CMS annually reviews and revises the list of eCQMs for each MIPS performance year to reflect updated clinical standards and guidelines. In section III.I.3.h.(2)(b)(i) of this final rule, we amend the list of available eCQMs for the CY 2019 performance period. To keep eCQM specifications current and minimize complexity, we proposed to align the eCQMs available for Medicaid EPs in 2019 with those available for MIPS eligible clinicians for the CY 2019 performance period (83 FR 35871). Specifically, we proposed that the eCQMs available for Medicaid EPs in 2019 would consist of the list of quality measures available under the eCQM collection type on the final list of quality measures established under MIPS for the CY 2019 performance period.

We explained that we believed that this proposal would be responsive to stakeholder feedback supporting quality measure alignment between MIPS and the Medicaid Promoting Interoperability Program for EPs, and that it would encourage EP participation in the Medicaid Promoting Interoperability Program by allowing those that are also MIPS eligible clinicians the ability to report the same eCQMs as they report for MIPS in 2019. In addition, we explained that we believed that aligning the eCQMs available in each program would ensure the most uniform application of up-to-date clinical standards and guidelines possible.

We explained that we anticipated that this proposal would reduce burden for Medicaid EPs by aligning the requirements for multiple reporting programs, and that the system changes required for EPs to implement this change would not be significant, particularly in light of our belief that many EPs will report eCQMs to meet the quality performance category of MIPS and therefore should be prepared to report on the available eCQMs for 2019. We explained that we expected that this proposal would have only a minimal impact on states, by requiring minor adjustments to state systems for 2019 to maintain current eCQM lists and specifications.

We also requested comments on whether in future years of the Medicaid Promoting Interoperability Program beyond 2019, we should include all e-specified measures from the core set of quality measures for Medicaid and the Children's Health Insurance Program (CHIP) (the Child Core Set) and the core set of health care quality measures for adults enrolled in Medicaid (Adult Core Set) (hereinafter together referred to as ''Core Sets'') as additional options for Medicaid EPs.

Sections 1139A and 1139B of the Act require the Secretary to identify and publish core sets of health care quality measures for child Medicaid and CHIP beneficiaries and adult Medicaid beneficiaries. These measure sets are required by statute to be updated annually and are voluntarily reported by states to CMS. These core sets comprise measures that specifically focus on populations served by the Medicaid and CHIP programs and are of particular importance to their care. Several of these Core Set measures are included in the MIPS eCQM list, but some are not. We explained that we believe that including, as eCQM reporting options for Medicaid EPs, the e-specified measures from the Core Sets that are not

also on the MIPS eCQM list would increase EP utilization of these measures and provide states with better data to report. At this time, the only measure within the Core Sets that would not be available as an option for Medicaid EPs in 2019 (because it is not on the MIPS eCQM list for Performance Year 2019) is NQF–1360, ''Audiological Diagnosis No Later Than 3 Months of Age.'' However, as these Core Sets are updated annually, in future years there may be other eCQMs that would not be on the MIPS eCQM list, and that could be included.

For 2019, we proposed that Medicaid EPs would report on any six eCQMs that are relevant to their scope of practice, regardless of whether they report via attestation or electronically. After we removed the NQS domain requirements for Medicaid EPs' 2017 eCQM submissions in the FY 2018 IPPS/LTCH PPS final rule, we have found that allowing EPs to report on any six quality measures that are relevant to their practice has increased EPs' flexibility to report pertinent data. In addition, this policy of allowing Medicaid EPs to report on any six measures relevant to their scope of practice would generally align with the MIPS data submission requirement for eligible clinicians using the eCQM collection type for the quality performance category, which is established at § 414.1335(a)(1). MIPS eligible clinicians who elect to submit eCQMs must generally submit data on at least six quality measures, including at least one outcome measure (or, if an applicable outcome measure is not available, one other high priority measure). We refer readers to § 414.1335(a) for the data submission criteria that apply to individual MIPS eligible clinicians and groups that elect to submit data with other collection types.

We proposed that for 2019 the Medicaid Promoting Interoperability Program would adopt the MIPS requirement that EPs report on at least one outcome measure (or, if an outcome measure is not available or relevant, one other high priority measure).

We also requested comments on how high priority measures should be identified for Medicaid EPs. We proposed (83 FR 35872) to use all three of the following methods to identify which of the available measures are high priority measures, but invited comments on other possibilities.

1. We proposed to use the same set of high priority measures for EPs participating in the Medicaid Promoting Interoperability Program that the MIPS program has identified for eligible clinicians. As discussed in section III.I.3.h.(2)(b)(i) of this final rule, we proposed to amend § 414.1305 to revise the definition of high priority measure for purposes of MIPS to mean an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure, beginning with the 2021 MIPS payment year.

2. For 2019, we also proposed to identify as high priority measures the available eCQMs that are included in the previous year's Core Sets and that are also included on the MIPS list of eCQMs. We explained that because the Core Sets are released at the beginning of each year, it would not be possible to update the list of high-priority eCQMs with those added to the current year's Core Sets. We also explained that CMS has already identified the measures included in the Core Sets as ones that specifically focus on populations served by the Medicaid and CHIP programs and are particularly important to their care. The eCQMs that would be available for Medicaid EPs to report in 2019, that are both part of the Core Sets and on the MIPS list of eCQMs, and that would be considered high priority measures under our proposal are: CMS2, ''Preventive Care and Screening: Screening for Depression and Follow-Up Plan''; CMS4, ''Initiation and Engagement of Alcohol and Other Drug Dependence Treatment''; CMS122, ''Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)''; CMS125, ''Breast Cancer Screening''; CMS128, ''Anti-depressant Medication Management''; CMS136, ''Follow-Up Care for Children Prescribed ADHD Medication (ADD)''; CMS153, ''Chlamydia Screening for Women''; CMS155, ''Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents''; and CMS165, ''Controlling High Blood Pressure.''

3. We also proposed to give each state the flexibility to identify which of the available eCQMs selected by CMS are high priority measures for Medicaid EPs in that state, with review and approval from CMS, through their State Medicaid HIT Plans (SMHP), similar to the flexibility granted states to modify the definition of Meaningful Use at § 495.332(f). We explained that we believe this proposal would give states the ability to identify as high priority those measures that align with their state health goals or other programs within the state. We proposed to amend § 495.332(f) to provide for this state flexibility to identify high priority measures.

We proposed that any eCQMs identified via any of these mechanisms be considered to be high priority measures for EPs participating in the Medicaid Promoting Interoperability Program for 2019.

We also proposed that the eCQM reporting period for EPs in the Medicaid Promoting Interoperability Program would be a full CY in 2019 for EPs who have demonstrated meaningful use in a prior year, in order to align with the corresponding performance period in MIPS for the quality performance category. We explained that we continue to align Medicaid Promoting Interoperability Program requirements with requirements for other CMS quality programs, such as MIPS, to the extent practicable, to reduce the burden of reporting different data for separate programs. In addition, we explained that we have found that clinical quality data from an entire year reporting period is significantly more useful than partial year data for quality measurement and improvement because it gives states a fuller picture of a health care provider's care and patient outcomes. We proposed that the eCQM reporting period for Medicaid EPs demonstrating meaningful use for the first time, which was established in the final rule entitled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017'' (80 FR 62762) (hereafter referred to as ''Stage 3 final rule''), would remain any continuous 90-day period (80 FR 62892).

We explained that we will adjust future years' requirements for reporting eCQMs in the Medicaid Promoting Interoperability Program through rulemaking, and will continue to align the quality reporting requirements, as logical and feasible, to minimize EP burden.

Comment: Many commenters stated that they support the alignment of the eCQMs available for Medicaid EPs in 2019 with those available for MIPS eligible clinicians for the CY 2019 performance period. These commenters stated that alignment between the two programs helps reduce health care provider reporting burden. In addition, several commenters noted that the MIPS eCQM list is geared toward adults and that including measures from the Child Core Set in future years, after 2019, would add measures that are more applicable to certain specialties that serve Medicaid and CHIP beneficiaries, such as pediatricians and pediatric dentists.

Response: We appreciate these comments, and we continue to look for

opportunities to align programs, make measures more relevant to Medicaid EPs, and reduce reporting burden when possible.

Comment: Several commenters supported the proposal to include any e-specified measures from the Adult Core Set and Child Core Set that are not also on the MIPS eCQM list, in order to align with other CMS programs, as well as to provide a wider variety of measures that are specifically applicable to Medicaid EPs.

Response: We agree that the measures included in the Adult Core Set and the Child Core Set are targeted toward Medicaid patients and Medicaid health care providers. These Core Sets are tools states can use to monitor and improve the quality of health care provided to Medicaid and CHIP enrollees. Although under statute, state reporting on these measure sets is voluntary, we aim to increase the number of states reporting on a uniform set of measures and to support states in using these measures to drive quality improvement for the beneficiaries they serve.

Comment: One commenter stated that the e-specified Adult Core Set and Child Core Set measures that are not also on the MIPS eCQM list should not be included in future years of the Medicaid Promoting Interoperability Program beyond 2019 because the Medicaid Promoting Interoperability Program is approaching the final years of participation and Medicaid EPs are already aware of the requirements they need to meet to be a meaningful EHR user. In addition, the same commenter stated that adding additional measures from the Core Sets would create a large burden on all states to update their attestation systems for the one or two remaining participation years.

Response: We appreciate this comment, but point out that the burden to states would be no greater than including any additional measures that may be added to the MIPS eCQM set in future years, if CMS continues to align the MIPS and Medicaid Promoting Interoperability Program eCQM requirements. We also point out that many of the positive comments regarding this proposal came from states that appreciated the proposal to align with other CMS reporting requirements. Those commenters did not indicate that such a requirement would impose a significant burden on states.

After careful consideration of the comments, we are finalizing without change our proposal to amend the list of available eCQMs for the CY 2019 performance period. To keep eCQM specifications current and minimize complexity, we are aligning the eCQMs available for Medicaid EPs in 2019 with those available for MIPS eligible clinicians for the CY 2019 performance period. Specifically, the eCQMs available for Medicaid EPs in 2019 will consist of the list of quality measures available under the eCQM collection type on the final list of quality measures established under MIPS for the CY 2019 performance period.

We did not propose to include the e-specified measures within the Adult Core Set and Child Core Set that are not also on the MIPS eCQM list for eCQM reporting in the Medicaid Promoting Interoperability Program in 2019, due to timing and logistical feasibility. However, we intend to reevaluate whether to add these measures when proposing eCQM reporting requirements for the Medicaid Promoting Interoperability Program for 2020 and beyond.

Comment: Many commenters stated their support for aligning the Medicaid Promoting Interoperability Program with the MIPS requirement that eligible clinicians who elect to submit eCQMs must generally submit data on at least six quality measures, including at least one outcome measure (or, if an applicable outcome measure is not available, one other high priority measure).

Response: We thank these commenters and we will continue to look for opportunities to align the programs and reduce reporting burden when possible.

Comment: One commenter stated that there are relatively few pediatric-appropriate measures in the Medicaid Promoting Interoperability Program and MIPS, and therefore recommended that CMS provide specific clarification that pediatric providers would not be held responsible for adult measures that are not necessarily applicable to pediatrics.

Response: We acknowledge that not all Medicaid EPs may find six measures applicable to their scope of practice. Therefore, we note that our policy continues to allow Medicaid EPs to report eCQMs with zero in the denominator, which indicates that they have no data on that eCQM in their EHR from the reporting period. If fewer than six measures are relevant to a Medicaid EP's scope of practice, he or she may submit ''zero denominator'' eCQMs that his or her CEHRT is able to calculate to meet the requirement to report six measures. If an EP's CEHRT contains no data on a specific eCQM, when states are auditing EP's submissions, it may create a rebuttable presumption that that measure falls outside of the EP's scope of practice. However, unless they cannot otherwise report on six measures, we encourage EPs to report on eCQMs that contain data, which are more likely to be within their scope of practice, instead of reporting eCQMs with a zero denominator.

Comment: One commenter stated that some specialists may have difficulty finding an outcome or high priority measure applicable to their scope of practice. The commenter also noted that this difficulty is alleviated under MIPS with the group reporting option, which is not available under the Medicaid Promoting Interoperability Program.

Response: In light of this concern, we now explain that if no outcome or high priority measures apply to a Medicaid EP's scope of practice and there is no data for any of the outcome or high priority measures reportable by his or her CEHRT, he or she may report on six non-outcome and non-high priority measures that are applicable to his or her scope of practice.

Comment: One commenter inquired as to a state's responsibility for auditing the eCQMs a Medicaid EP submits, how a state would ensure that the reported eCQMs are within the EP's scope of practice, and how a state would know whether there was an unselected relevant outcome or high priority measure.

Response: Under § 495.368, states are required to combat fraud and abuse and ensure that incentive payments are made properly per the requirements of the program, including the eCQM reporting requirements. In regard to this particular requirement, we believe that Medicaid EPs are in the best position to determine which measures are applicable to their scope of practice, not the state. Therefore, when verifying EPs' submissions, either at prepayment or during a post-payment audit, states should give Medicaid EPs the widest reasonable latitude to determine which eCQMs are relevant to their scope of practice. For instance, an EP should be able to meet the eCQM reporting requirements by submitting non-zero data for six relevant eCQMs, including one outcome or high-priority measure, regardless of whether there may be an unselected eCQM *more* relevant to his or her practice. That is, as we noted above, we do not think EPs should be reporting on eCQMs with a zero denominator unless that is the only way the EP can report on six measures. We encourage states to provide technical assistance to Medicaid EPs and to design their attestation systems in such a way that will assist EPs to meet this program requirement, and that will help avoid recouping incentive payments.

After careful consideration of the comments, we are finalizing our

proposal that for 2019, Medicaid EPs will report on any six eCQMs that are relevant to the EP's scope of practice, regardless of whether they report via attestation or electronically. We are also finalizing the proposal that for 2019 the Medicaid Promoting Interoperability Program will adopt the MIPS requirement that EPs report on at least one outcome measure (or, if an applicable outcome measure is not available or relevant, one other high priority measure). Additionally, in response to comments summarized above, we now explain that if no outcome or high priority measure is relevant to a Medicaid EP's scope of practice, he or she may report on any six eCQMs that are relevant.

Comment: Some commenters approved of our proposal to allow states to indicate which eCQMs are high priority measures for that state's Medicaid agency.

Response: We thank these commenters for their comments.

Comment: A few commenters opposed offering states the flexibility to identify high priority eCQMs because it can cause additional cost to states for technology updates, and additional burden for vendors to customize and make software updates in a short timeframe. They also commented that having differences among states can cause burden on Medicaid EPs.

Response: We do not believe that this flexibility and variation between states will cause any additional burden for states, vendors or Medicaid EPs. Allowing states to identify their own high priority measures is entirely optional. If a state chooses not to identify additional high priority measures, the state would need to take no additional action. Furthermore, we expect that providing this option for states will reduce Medicaid EP burden, as it will give EPs a wider range of options to meet the requirement that they report on at least one outcome measure, or on at least one high priority measure if an outcome measure is not available or relevant. Additionally, as we explain above, if no outcome or priority measure is relevant to a Medicaid EP's scope of practice, he or she may instead report on any six measures that are relevant.

Finally, this proposal should not increase burden on CEHRT vendors. States may select high priority measures only from the list of eCQMs that are already available for Medicaid EPs to meet the requirements of the program. Medicaid EPs are not required to select any of their state-specific high priority measures. Therefore, the CEHRT need not vary between states, but must be able to calculate and report on at least one outcome measure (or, if an applicable outcome measure is not available or relevant, one other high priority measure) relevant to the provider's scope of practice, whether or not that is a state-specific high priority measure.

We received no comments on the first and second methods of identifying high priority measures for the Medicaid Promoting Interoperability Program. After careful consideration of the comments on our proposed approach to how high priority measures would be identified, we are finalizing it without modification.

Comment: Several commenters stated their support for aligning the eCQM reporting period for EPs in the Medicaid Promoting Interoperability Program with the corresponding performance period in MIPS, because they agreed this proposal would reduce EP burden. In addition, commenters noted that consistency with previous years will reduce confusion among EPs.

Response: We appreciate these comments and will continue to align when possible.

Comment: Several commenters urged CMS to adopt a 90-day eCQM reporting period within CY 2019 for all Medicaid EPs. A couple commenters indicated that the transition between 2014 Edition and 2015 Edition CEHRT during the year may create difficulty for Medicaid EPs to report a full year of data.

Response: We acknowledge that many Medicaid EPs might be upgrading or implementing new CEHRT in 2019. However, Medicaid EPs frequently upgrade or implement new CEHRT, regardless of the reporting year. Regardless of what CEHRT the EP used during the eCQM reporting period, the data that Medicaid EPs are required to report for eCQMs is a snapshot based on the data within the CEHRT, taken at the time of attestation, for the reporting period. Medicaid EPs are only responsible for reporting exactly the data that their CEHRT produces. As certified, 2015 Edition CEHRT should accurately calculate and report the eCQM data for the full reporting period, in accordance with the relevant certification requirements at 45 CFR 170.315(c), even if that 2015 Edition CEHRT was not implemented for the entire reporting period. Vendors should ensure that their CEHRT is performing in accordance with relevant 2015 Edition Certification requirements as defined by the Office of the National Coordinator for Health IT. The reporting process for EPs should be no different regardless of the length of the reporting period.

After careful consideration of the comments, we are finalizing without change our proposal that the eCQM reporting period for EPs in the Medicaid Promoting Interoperability Program will be a full CY in 2019 for EPs who have demonstrated meaningful use in a prior year, in order to align with the corresponding performance period in MIPS for the quality performance category. The eCQM reporting period for Medicaid EPs demonstrating meaningful use for the first time, which was established in the Stage 3 final rule, will remain any continuous 90-day period (80 FR 62892).

3. Proposed Revisions to the EHR Reporting Period and eCQM Reporting Period in 2021 for EPs Participating in the Medicaid Promoting Interoperability Program

In the July 28, 2010 final rule titled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program'' at 75 FR 44319, we established that, in accordance with section 1903(t)(4)(A)(iii) of the Act, in no case may any Medicaid EP receive an incentive after 2021 (see § 495.310(a)(2)(v)). Therefore, December 31, 2021 is the last date that states could make Medicaid Promoting Interoperability Program payments to Medicaid EPs (other than pursuant to a successful appeal related to 2021 or a prior year).

For states to make payments by that deadline, there must be sufficient time after EHR and eCQM reporting periods end for Medicaid EPs to attest to states, for states to conduct their prepayment processes, and for states to issue payments. Therefore, we proposed to amend § 495.4 to provide that the EHR reporting period in 2021 for all EPs in the Medicaid Promoting Interoperability Program would be a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that the state can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021. Similarly, we proposed to change the eCQM reporting period in 2021 for EPs in the Medicaid Promoting Interoperability Program to a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that the state can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021.

We explained that we understand that the October 31, 2021 date might not provide some states with sufficient time to process payments by December 31,

2021. We also explained that we believe that states are best positioned to determine the last possible date in CY 2021 by which the EHR or eCQM reporting periods for Medicaid EPs must end, and the deadline for receiving EP attestations, so that the state is able to issue all payments by December 31, 2021. Therefore, we proposed to allow states the flexibility to set alternative, earlier final deadlines for EHR or eCQM reporting periods for Medicaid EPs in CY 2021, with prior approval from us, through their State Medicaid HIT Plans (SMHP). If a state establishes an alternative, earlier date within CY 2021 by which all EHR or eCQM reporting periods in CY 2021 must end, Medicaid EPs in that state would continue to have a reporting period of a minimum of any continuous 90-day period within CY 2021. The end date for the reporting period would have to occur before the day of attestation, which must occur prior to the final deadline for attestations established by their state. We proposed to amend § 495.332(f) to provide for this state flexibility to identify an alternative date by which all EHR reporting periods or eCQM reporting periods for Medicaid EPs in CY 2021 must end.

We believe there is no reason why a state would need to set a date by which EHR reporting periods and eCQM reporting periods must end for Medicaid EPs that is earlier than the day before that state's attestation deadline for EPs. Doing so would restrict Medicaid EPs' ability to select EHR and eCQM reporting periods. Therefore, we proposed that any alternative deadline for CY 2021 EHR and eCQM reporting periods set by a state may not be any earlier than the day prior to the attestation deadline for Medicaid EPs attesting to that state.

The following is a summary of the comments we received regarding these proposals.

Comment: Multiple commenters stated their support for the proposal that the EHR reporting period in 2021 for all EPs in the Medicaid Promoting Interoperability Program would be a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021. They agreed that this would help ensure that states can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021. They also stated their support of the 90-day period for eCQM reporting, and for state flexibility to set earlier final deadlines for EHR or eCQM reporting periods for Medicaid EPs in CY 2021.

Response: We appreciate these comments and thank the commenters for their input.

Comment: A commenter pointed out that the earlier in the year a state sets the reporting period and attestation deadline, the more burden is put on Medicaid EPs to attest after a 90 day EHR and eCQM reporting period in 2021. They requested that we balance the burden between states and Medicaid EPs by setting a regulatory date before which a state could not set an attestation deadline.

Response: The commenters raise important questions about whether burden should be reduced on state staff and systems to the disadvantage of Medicaid EPs. Therefore, while we are finalizing the proposed policies without change, we are considering whether to propose in future rulemaking that no state may set a reporting period deadline for CY 2021 that is earlier than June 30, 2021 or an attestation deadline that is earlier than July 1, 2021. In the meanwhile, we welcome input from states and other interested parties on whether any state would need more than 6 months to process Medicaid EPs' attestations, perform the required prepayment validations, and disburse incentive payments.

Comment: One commenter requested that CMS provide outreach and educational materials to providers about the 2021 deadline, as they anticipate confusion.

Response: We will work with State Medicaid Agencies and provider communities to ensure that outreach and education are provided about the final attestation deadline and the end of the program.

Comment: Some commenters requested that CMS consider making the eCQM reporting period any 90 days within CY 2020 as well. They note that a full year reporting period may create significant backlogs of 2020 and 2021 attestations in 2021 that may create difficulty for states to issue payments by the statutory deadline.

Response: We understand that this is a concern. We will continue to monitor this issue as we develop proposed rules for the Medicaid Promoting Interoperability Program in 2020.

After careful consideration of the comments, we are finalizing our proposal to amend § 495.4 to provide that the EHR reporting period in 2021 for all EPs in the Medicaid Promoting Interoperability Program will be a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that states can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021. We are also finalizing our proposal to change the eCQM reporting period in 2021 for EPs in the Medicaid Promoting Interoperability Program to a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that states can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021.

In addition, we are finalizing our proposal to allow states the flexibility to set alternative, earlier final deadlines for EHR or eCQM reporting periods for Medicaid EPs in CY 2021, with prior approval from us, through their State Medicaid HIT Plan (SMHP). Any alternative deadline for CY 2021 EHR and eCQM reporting periods set by a state may not be any earlier than the day prior to the attestation deadline for Medicaid EPs attesting to that state.

Although we did not address reporting periods in 2021 for eligible hospitals in the proposed rule, we acknowledge that there will be a similar issue if there are still hospitals eligible to receive Medicaid Promoting Interoperability Program payments in 2021, including Medicaid-only eligible hospitals as well as ''dually-eligible'' eligible hospitals and critical access hospitals (CAHs) (those that are eligible for an incentive payment under Medicare for meaningful use of CEHRT and/or subject to the Medicare payment reduction for failing to demonstrate meaningful use of CEHRT, and are also eligible to earn a Medicaid incentive payment for meaningful use of CEHRT). However, based on attestation data and information from states' SMHPs regarding the number of years states disburse Medicaid Promoting Interoperability Program payments to hospitals, we believe that there will be no hospitals eligible to receive Medicaid Promoting Interoperability Program payments in 2021 due to the requirement that, after 2016, eligible hospitals cannot receive a Medicaid Promoting Interoperability Program payment unless they have received such a payment in the prior fiscal year. At this time, we believe that there are no hospitals that will be able to receive incentive payments in 2020 or 2021. We invited comments and suggestions on whether this belief is accurate, and if not, how we could address the issue in a manner that limits the burden on hospitals and states. The following is a summary of the comments we received on this issue.

Comment: One commenter stated that CMS's belief is accurate, and that they

do not anticipate any hospitals to participate in program years 2020 or 2021. However, the commenter requested that CMS take into consideration the audit and appeals process, which may result in payments made during those years.

Response: We acknowledge that Medicaid Promoting Interoperability Program incentive payments might still be made to hospitals after hospitals' participation years, or even after December 31, 2021, in the limited circumstance of a successful hospital appeal related to participation in the Medicaid Promoting Interoperability Program in a prior year.

We did not propose any specific policy regarding eligible hospital reporting periods for 2021 in this rule and thus are not finalizing any policy in this area now, but we expect to solicit additional comment on the issue in a future proposed rule that is more specifically related to hospital payment.

4. Revisions to Stage 3 Meaningful Use Measures for Medicaid EPs

a. Change to Objective 6 (Coordination of Care Through Patient Engagement)

In the Stage 3 final rule, we adopted a phased approach under Stage 3 for EP Objective 6 (Coordination of care through patient engagement), Measure 1 (View, Download, or Transmit) and Measure 2 (Secure Electronic Messaging). This phased approach established a 5 percent threshold for both measures 1 and 2 of this objective for an EHR reporting period in 2017. (80 FR 62848 through 62849) In the same rule, we established that the threshold for Measure 1 would rise to 10 percent, beginning with the EHR reporting period in 2018, and that the threshold for Measure 2 would rise to 25 percent, beginning with the EHR reporting period in 2018. We stated that we would continue to monitor performance on these measures to determine if any further adjustment was needed. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38493), we established a policy allowing EPs, eligible hospitals, and CAHs to use either 2014 Edition or 2015 Edition CEHRT, or a combination of 2014 Edition and 2015 Edition CEHRT, for an EHR reporting period in CY 2018, and depending on which Edition(s) they use, to attest to the Modified Stage 2 objectives and measures or the Stage 3 objectives and measures. In doing so, we also delayed the rise of the Objective 6 Measure 1 and Measure 2 thresholds until 2019.

We explained that based on feedback we have received, we understand that these two measures are the largest barrier to successfully demonstrating meaningful use, especially in rural areas and at safety net clinics. Stakeholders have reported a variety of causes that have resulted in lower patient participation than was anticipated when the Stage 3 final rule was issued. The data that we have collected via states for Medicaid EPs and at CMS from Medicare EPs for previous program years support this feedback. The primary issue is that the view, download, transmit measure requires a positive action by patients, which cannot be controlled by an EP. Medicaid populations that are at the greatest risk have lower levels of internet access, internet literacy and health literacy than the general population. Although the Secure Electronic Messaging measure does not require patient action, only that the EP send a secure message, we have received feedback that this functionality is not highly utilized by patients. Although we encourage Medicaid EPs to continue to reach out to patients via secure messaging to engage them in their health care between office visits, it is not productive for EPs to send messages to patients who are unlikely to see them or take action. Retaining the current threshold of 5 percent for both measures would continue to incentivize Medicaid EPs to engage patients in their own care without raising the requirements to unattainable thresholds for EPs who serve vulnerable Medicaid patients. Therefore, we proposed to amend § 495.24(d)(6)(i) such that the thresholds for Measure 1 (View, Download, or Transmit) and Measure 2 (Secure Electronic Messaging) of Meaningful Use Stage 3 EP Objective 6 (Coordination of care through patient engagement) would remain 5 percent for 2019 and subsequent years.

The following is a summary of the comments we received on this proposal.

Comment: The majority of commenters stated that they support CMS's proposal for the Objective 6 threshold to remain at 5 percent for the remainder of the Medicaid Promoting Interoperability Program, and that raising the thresholds would place undue burden on EPs.

Response: We thank the many commenters who stated their support.

Comment: One commenter stated that certain populations, specifically older adults, may struggle to engage with technology, which created challenges for health care providers and recommended giving special consideration to health care providers who struggle to meet this objective.

Response: We understand that some Medicaid EPs struggle to meet the objective due to factors outside of their control. However, this comment further supports our decision to keep the Objective 6 threshold at 5 percent rather than increasing it, as would happen without this rule change.

Comment: Several commenters noted that the Medicaid Promoting Interoperability Program and the Medicare Promoting Interoperability category of MIPS are still not fully aligned, and that this creates reporting burdens for providers. These commenters requested further alignment, between these two Objective 6 measures, which were proposed for removal under MIPS, as well as more broadly between the two programs.

Response: We agree that alignment of MIPS and the Medicaid Promoting Interoperability Program, to the degree practicable, is advantageous. The greater the discrepancy between the program requirements, the greater the reporting burden on health care providers who participate in both programs. We are finalizing our proposed changes to the Objective 6 measures without change, because we anticipate that doing so will reduce Medicaid EP burden. However, especially in light of these comments, we will also consider proposing further changes to the Medicaid Promoting Interoperability Program in future rulemaking, to improve alignment with the objectives and measures under the MIPS program. In the meanwhile, we welcome input from the public on this topic, and on additional ways that CMS can improve alignment between the two programs.

In addition, we note that the change from the Modified Stage 2 objectives and measures will make this objective easier for Medicaid EPs to meet. There are three measures under ''Objective 6: Coordination of Care through Patient Engagement.'' To be a meaningful EHR user, an EP must attest to all three measures, but only meet the thresholds for two of those three. Under Modified Stage 2, both Measure 1 (View, Download, or Transmit) and Measure 2 (Secure Electronic Messaging) were required (but not under the same objective) and Measure 3 was not an option. Both Measure 2 and Measure 3 do not rely on any patient action, but only require Medicaid EPs' action.

After reviewing the comments, we are finalizing without change the proposal to amend § 495.24(d)(6)(i) so that the thresholds for Measure 1 (View, Download, or Transmit) and Measure 2 (Secure Electronic Messaging) of Meaningful Use Stage 3 EP Objective 6 (Coordination of care through patient engagement) will remain 5 percent for 2019 and subsequent years.

b. Change to the Syndromic Surveillance Reporting Measure

In the proposed rule, we explained that in the Stage 3 final rule, we established that the syndromic surveillance reporting measure for EPs was limited to those who practice in urgent care settings (80 FR 62866 through 62870). Since then, we have received feedback from states and public health agencies that while many are unable to accept non-emergency or non-urgent care ambulatory syndromic surveillance data electronically, some public health agencies can and do want to receive data from health care providers in non-urgent care settings. We also explained that we believe that public health agencies that set the requirements for data submission to public health registries are in a better position to judge which health care providers can contribute useful data.

Therefore, we proposed to amend § 495.24(d)(8)(i)(B)(*2*), EP Objective 8 (Public health and clinical data registry reporting), Measure 2 (Syndromic surveillance reporting measure), to amend the language restricting the use of syndromic surveillance reporting for meaningful use only to EPs practicing in an urgent care setting. We proposed to include any EP defined by the state or local public health agency as a provider who can submit syndromic surveillance data. This change would not alter the exclusion for this measure at § 495.24(d)(8)(i)(C)(*2*)(*i*), for EPs who are not in a category of health care providers from which ambulatory syndromic surveillance data is collected by their jurisdiction's syndromic surveillance system, as defined by the state or local public health agency. Furthermore, we did not propose to create any requirements for syndromic surveillance registries to include all EPs. Additionally, we noted that under the specifications for the 2015 Edition of CEHRT for syndromic surveillance, it is possible that an EP could own CEHRT and submit syndromic surveillance in a format that is not accepted by the local jurisdiction. In this case, the EP may take an exclusion for syndromic surveillance.

The following is a summary of the comments we received on this proposal.

Comment: Several commenters stated their support of our proposal to include any EP defined by the state or local public health agency as a provider who can submit syndromic surveillance data.

Response: We thank the commenters for their support.

After careful consideration of the comments, we are finalizing without change our proposal to amend § 495.24(d)(8)(i)(B)(*2*), EP Objective 8 (Public health and clinical data registry reporting), Measure 2 (Syndromic surveillance reporting measure), to amend the language restricting the use of syndromic surveillance reporting for meaningful use only to EPs practicing in an urgent care setting. The new objective will also include any other setting from which ambulatory syndromic surveillance data are collected by the state or local public health agency. This change does not alter the exclusion for this measure at § 495.24(d)(8)(i)(C)(*2*)(*i*), for EPs who are not in a category of health care providers from which ambulatory syndromic surveillance data is collected by their jurisdiction's syndromic surveillance system, as defined by the state or local public health agency. Furthermore, this does not create any requirements for syndromic surveillance registries to include all EPs. Additionally, under the specifications for the 2015 Edition of CEHRT for syndromic surveillance, it is possible that an EP could own CEHRT and submit syndromic surveillance in a format that is not accepted by the local jurisdiction. In this case, the EP may take an exclusion for syndromic surveillance.

F. Medicare Shared Savings Program

As required under section 1899 of the Act, we established the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among health care providers to improve the quality of care for Medicare fee-for-service (FFS) beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. Eligible groups of providers and suppliers, including physicians, hospitals, and other health care providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). A subsequent major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). The final rule entitled, ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations,'' which addressed changes related to the program's financial benchmark methodology, appeared in the June 10, 2016 **Federal Register** (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule'')).

In August 2018, we issued the ''Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success'' proposed rule (hereinafter referred to as the ''August 2018 proposed rule'') which addressed a number of proposed policy changes including redesign of the participation options available under the program to encourage ACOs to transition to two-sided models; new tools to support coordination of care across settings and strengthen beneficiary engagement; revisions to ensure rigorous benchmarking; and policies promoting use of interoperable electronic health record technology among ACO providers/suppliers (83 FR 41786). In section V. of this final rule, we are finalizing the following proposals from the August 2018 proposed rule:

- A voluntary 6-month extension for existing ACOs whose participation agreements expire on December 31, 2018 and the methodology for determining financial and quality performance for this 6-month performance year from January 1, 2019, through June 30, 2019;
- Policies implementing the Bipartisan Budget Act of 2018 provisions on voluntary alignment;
- Modifications to the definition of primary care services used in assigning beneficiaries to ACOs to reflect recent code changes;
- Extension of policies providing relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances during 2017 to performance year 2018 and subsequent years; and
- Policies to promote interoperability among ACO providers/suppliers, including establishing a new program eligibility requirement regarding CEHRT use and retiring the CEHRT quality measure (ACO–11).

We expect to address the remaining proposals in the August 2018 proposed rule in a forthcoming final rule.

We have also made use of the annual calendar year (CY) PFS rules to address quality reporting for the Shared Savings Program and certain other issues. In the CY 2018 PFS final rule (82 FR 53209 through 53226), we finalized revisions to several different policies under the

Shared Savings Program, including the assignment methodology, quality measure validation audit process, use of the skilled nursing facility (SNF) 3-day waiver, and handling of demonstration payments for purposes financial reconciliation and establishing historical benchmarks. In addition, in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77255 through 77260, and 82 FR 53688 through 53706, respectively), we finalized policies related to the Alternative Payment Model (APM) scoring standard under the Merit-Based Incentive Payment System (MIPS), which reduces the reporting burden for MIPS eligible clinicians who participate in MIPS APMs, such as the Shared Savings Program, by: (1) Using the CAHPS for ACOs survey and the ACO reported CMS Web Interface quality data for purposes of assessing quality performance in the Shared Savings Program and to score the MIPS quality performance category for these eligible clinicians; (2) automatically awarding MIPS eligible clinicians participating in Shared Savings Program ACOs a minimum of one-half of the total points in the MIPS improvement activities performance category; (3) requiring ACO participants to report Advancing Care Information (ACI) data at the group practice level or solo practitioner level; and (4) not assessing MIPS eligible clinicians on the MIPS cost performance category because, through their participation in the ACO, they are already being assessed on cost and utilization under the Shared Savings Program.

As a general summary, in the CY 2019 PFS proposed rule, we proposed the following changes to the quality performance measures that will be used to assess quality performance under the Shared Savings Program for performance year 2019 and subsequent years:

- Changes to Patient Experience of Care Survey measures.
- Changes to CMS Web Interface and Claims-Based measures.

In addition, in the August 2018 proposed rule, we proposed another change to the Shared Savings Program quality measure set, which we are finalizing in section V.B.2.f. of this final rule. We proposed to remove the ACO–11—*Use of Certified EHR Technology* measure (83 FR 41908 through 41911). We refer readers to section V.B.2.f. of this final rule for a description of that proposal and a discussion of related public comments.

1. Quality Measurement

a. Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both. In the November 2011 final rule, we established a quality measure set spanning four domains: Patient experience of care, care coordination/patient safety, preventive health, and at-risk population (76 FR 67872 through 67891). Since the Shared Savings Program was established, we have updated the measures that comprise the quality performance measure set for the Shared Savings Program through the annual rulemaking in the CY 2015, 2016, and 2017 PFS final rules (79 FR 67907 through 67920, 80 FR 71263 through 71268, and 81 FR 80484 through 80489, respectively).

As we stated in the November 2011 final rule establishing the Shared Savings Program (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality health care at the individual and population levels, with a focus on outcomes. For performance year 2018, 31 quality measures will be used to determine ACO quality performance (81 FR 80488 and 80489). The information used to determine ACO performance on these quality measures will be submitted by the ACO through the CMS Web Interface, submitted by ACO participant TINs to MIPS for the Promoting Interoperability (PI) performance category (formerly Advancing Care Information), calculated by CMS from administrative claims data, and collected via a patient experience of care survey referred to as the Consumer Assessment of Healthcare Provider and Systems (CAHPS) for ACOs Survey. The CAHPS for ACOs survey is based on the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG–CAHPS) Survey and includes additional, program specific questions that are not part of the CG–CAHPS. The CG–CAHPS survey is maintained, and periodically updated, by the Agency for Healthcare Research and Quality (AHRQ) in HHS.

The quality measures collected through the CMS Web Interface in 2015 and 2016 were used to determine whether eligible professionals participating in an ACO would avoid the PQRS and automatic Physician Value-Based Payment Modifier (Value Modifier) downward payment adjustments for 2017 and 2018 and to determine if ACO participants were eligible for upward, neutral or downward adjustments based on quality measure performance under the Value Modifier. Beginning with the 2017 performance period, which impacts payments in 2019, PQRS and the Value Modifier were replaced by the MIPS. Eligible clinicians who are participating in an ACO and who are subject to MIPS (MIPS eligible clinicians) will be scored under the APM scoring standard under MIPS (81 FR 77260). These MIPS eligible clinicians include any eligible clinicians who are participating in an ACO in a track of the Shared Savings Program that is not an Advanced APM, as well as those participating in an ACO in a track that is an Advanced APM, but who do not become Qualifying APM Participants (QPs) as specified in § 414.1425, and are not otherwise excluded from MIPS. Beginning with the 2017 reporting period, measures collected through the CMS Web Interface will be used to determine the MIPS quality performance category score for MIPS eligible clinicians participating in a Shared Savings Program ACO. Starting with the 2018 performance period, the quality performance category under the MIPS APM Scoring Standard for MIPS eligible clinicians participating in a Shared Savings Program ACO will include measures collected through the CMS Web Interface and the CAHPS for ACOs survey measures.

The CAHPS for ACOs Survey includes the core questions contained in the CG–CAHPS, plus additional questions to measure access to and use of specialist care, experience with care coordination, patient involvement in decision-making, experiences with a health care team, health promotion and patient education, patient functional status, and general health. The 2018 CAHPS for ACOs Survey 3.0 incorporates updates made by AHRQ to the CG–CAHPS survey based on feedback from survey users and stakeholders, as well as analyses of multiple data sets. For a summary of the history of changes to the CAHPS for ACOs survey, please refer to the CY 2019 PFS proposed rule (83 FR 35875). Additional information on the CG–CAHPS survey update is available on the AHRQ website at *https://www.ahrq.gov/sites/default/files/wysiwyg/cahps/surveys-guidance/cg/about/proposed-changes-cahps-c&g-survey2015.pdf*.

In addition to incorporating changes based on the AHRQ survey update, CMS removed all items included in the

Summary Survey Measures (SSMs), *Helping You to Take Medications as Directed* and *Between Visit Communication* from the 2018 survey. These optional SSMs were not part of the scored measures. The update resulted in a reduction in the number of survey questions from 80 to 58. The CAHPS for ACOs SSMs that contribute to the ACO performance score for performance year 2018, as finalized in the CY 2017 PFS final rule (81 FR 80488) are as follows: Getting Timely Care, Appointments & Information; How Well Your Providers Communicate; Patients' Rating of Provider; Access to Specialists; Health Promotion and Education; Shared Decision Making; Health Status & Functional Status; and Stewardship of Patient Resources. In addition, the core survey includes SSMs on Care Coordination and Courteous & Helpful Office Staff. However, because these measures are not included in the Shared Savings Program quality measure set for 2018, scores for these measures will be provided to ACOs for informational purposes only and will not be used in determining the ACOs' quality scores.

b. Proposals for Changes to the CAHPS Measure Set

To enhance the Patient/Caregiver Experience domain and align with MIPS (82 FR 54163), we proposed to begin scoring the 2 SSMs that are currently collected with the administration of the CAHPS for ACOs survey and shared with the ACOs for informational purposes only. Under this proposal, we would add the following CAHPS for ACOs SSMs that are already collected and provided to ACOs for informational purposes to the quality measure set for the Shared Savings Program as ACO–45, *CAHPS: Courteous and Helpful Office Staff,* and ACO–46: *CAHPS: Care Coordination.* These measures would be scored and included in the ACO quality determination starting in 2019. Both of these SSMs are currently designated by AHRQ as CG CAHPS core measures.

The Courteous and Helpful Office Staff SSM, which we proposed to add as ACO–45, asks about the helpfulness, courtesy and respectfulness of office staff. This SSM has been a CG–CAHPS core measure in the previous two versions of the CG–CAHPS survey, but was previously provided for informational purposes only and not included in the ACO quality score determination. We also proposed to add the SSM, *CAHPS: Care Coordination* to the CAHPS for ACOs measures used in ACO quality score determination as ACO–46. The Care Coordination SSM asks questions about provider access to beneficiary information and provider follow-up. This SSM was designated a core measure in the most recent version of the CG–CAHPS survey.

Including these measures in the quality measure set that is used to assess the quality performance of ACOs under the Shared Savings Program would place greater emphasis on outcome measures and the voice of the patient and provide ACOs with an additional incentive to act upon opportunities for improved care coordination and communication, and would align with the MIPS measure set finalized in the CY 2018 Quality Payment Program final rule (82 FR 54163). Care Coordination and patient and caregiver engagement are goals of the Shared Savings Program. The Care Coordination SSM emphasizes the care coordination goal, while the Courteous and Helpful Office Staff SSM supports patient engagement as it addresses a topic that has been identified as important to beneficiaries in testing. For performance year 2016, the mean performance rates across all ACOs for these two measures, which were not included in the ACO quality score determination, were 87.18 for the Care Coordination SSM and 92.12 for Courteous and Helpful Office Staff SSM.

Consistent with § 425.502(a)(4), regarding the scoring of newly introduced quality measures, we proposed that these additional SSMs would be pay-for-reporting for all ACOs for 2 years (performance years 2019 and 2020). The measures would then phase into pay-for-performance in the program, according to the schedule in Table 26 beginning in performance year 2021. We solicited comment on this proposed change to the quality measure set.

The following is a summary of the comments we received on this proposed change to the CAHPS measures included in the Shared Savings Program quality measure set.

Comment: The majority of commenters supported our proposal. Several commenters noted that ACOs have had experience with these measures for some time now and that patient experience measures help to keep providers accountable for patient-centered care. A few commenters indicated support for the proposal but noted reservations, including the potentially limited ability of ACOs that include independent physician groups and hospitals as ACO participants to impact performance on ACO–45, a concern that the subjectivity of the CAHPS for ACOs measures (especially ACO–45) may put too much emphasis on aspects of care that have little effect on quality outcomes, and a recommendation to consider expanding ACO–45 (Courteous and Helpful Office Staff) to include medical assistants and nurses. Some commenters recommended delaying implementation of the proposal. A commenter suggested that we work with the Core Quality Measures Collaborative (CQMC) to re-evaluate the ACO quality measures, before implementing this proposed change. Another commenter recommended that we streamline the Shared Savings Program quality measure set. In addition, one commenter noted its support in principle for adding a quality measure to assess patients' experience with office staff, but indicated that adding a measure with a high average performance rate seems unnecessary for improving care.

Response: We believe that adding ACO–45 *CAHPS: Courteous and Helpful Office Staff* puts greater emphasis on the voice of the patient and provides ACOs with an additional incentive to act upon opportunities for improved communication. With regard to the comment that ACOs that include independent physician groups and hospitals as ACO participants may not be able to influence the outcomes of ACO–45 *CAHPS: Courteous and Helpful Office Staff,* we note that this SSM has been provided for informational purposes as part of the CAHPS for ACO survey for several years. Therefore, we believe ACOs have had sufficient experience with the SSM and have had the opportunity to monitor the survey results and make improvements, as needed. Scoring this measure would also provide ACOs with a stronger incentive to improve performance on this measure that has been identified as important by the beneficiaries they serve. We would also re-emphasize that measures newly added to the scored measures set will be pay-for-reporting for the first 2 years after inclusion, giving ACOs additional time to work toward improvement. With regard to the concern that the proposed new CAHPS measures do not impact quality outcomes, we disagree. We consider the patient's experience of care to be a quality outcome. We also note that the Courteous and Helpful Office Staff measure focuses on an issue that has been identified as important to beneficiaries in testing and that the Care Coordination SSM addresses a primary objective of the Shared Savings Program. With regard to commenters' suggestions that we delay implementation of the proposal to score these measures, including the suggestion that we work with the CQMC

to re-evaluate the ACO quality measures first, we disagree with delaying the scoring of these important SSMs. These measures assess performance in areas that the beneficiaries served by ACOs have identified as valuable and that are central to the fundamental purpose of the Shared Savings Program to promote care coordination and improve quality of care. Again, we note that the newly-scored measures would be pay-for-reporting for the first 2 years after their addition, giving ACOs additional time to become familiar with them before the performance rates are considered in scoring. In response to the commenter's suggestion that we streamline the Shared Savings Program quality measure set, we do not have plans at this time to reduce the number of CAHPS measures for which ACOs are held accountable. The two CAHPs measures we proposed to add to the quality measure set for scoring purposes are already being collected and reported to ACOs for informational purposes; thus, the addition of these measures should not result in significant additional burden on ACOs. Moreover, we note that overall, we are reducing the total number of quality measures in the ACO quality measure set, as detailed below and summarized in Table 26 of this final rule.

With regard to the comment supporting the intent of our proposal to start scoring performance on the Courteous and Helpful Office Staff measure, but stating that it is unnecessary to add a measure with a high average performance rate, we believe that this is an important area for continued measurement as beneficiaries have expressed its importance to them in testing, as noted previously. In addition, we believe it is important to continue monitoring this measure because it is an important factor in patient experience of care. By scoring this measure, we acknowledge its continued importance as a patient experience measure. With regard to the comment that we consider expanding ACO–45 to include medical assistants and nurses, we will take this comment under consideration for further analysis as part of any potential future measure refinement.

After considering the comments, we are finalizing our proposal to begin scoring ACO–45 and ACO–46 as part of the CAHPS for ACO survey beginning with quality reporting for performance years during 2019. Consistent with our existing policy regarding the scoring of newly introduced quality measures, these additional SSMs will be pay-for-reporting for all ACOs for 2 years (performance years during 2019 and performance year 2020). The measures would then phase into pay-for-performance beginning in performance year 2021 (§ 425.502(a)(4)). The phase-in schedule for the 2019 ACO quality measures set that we are finalizing in this rule is presented in Table 26.

Additionally, we solicited comment on potentially converting the Health and Functional Status SSM (ACO–7) to pay-for-performance in the future. The Health and Functional Status SSM is currently pay-for-reporting for all years. We have not scored this measure because the scores on the Health and Functional Status SSM may reflect the underlying health of beneficiaries seen by ACO providers/suppliers as opposed to the quality of the care provided by the ACO. We also sought stakeholder feedback on possible options for enhancing the collection of health and functional status data, including potentially changing our data collection procedures to collect data from the same ACO's assigned beneficiaries over time. We noted that such a change could allow for measurement of functional status changes that occurred while beneficiaries were receiving care from ACO providers/suppliers. We also solicited other recommendations regarding the potential inclusion of a functional status measure in the assessment of ACO quality performance in the future.

The following is a summary of the comments we received regarding potentially converting the Health and Functional Status SSM (ACO–7) to pay-for-performance in the future.

Comment: The majority of commenters opposed including ACO–7—*Health and Functional Status* as a pay-for-performance measure in future years, noting that the measure is largely outside of the physician's control. Some commenters were supportive of including a Health and Functional Status measure as pay-for-performance, but expressed concerns with inclusion of the measure as it is currently structured. For example, one commenter stated that the current structure of the SSM captures patient health and functional status at a single point in time but not as a change in status over time. A number of commenters emphasized this point, noting that a lack of baseline data for this measure for the ACO-assigned beneficiary population means the results cannot be attributed to ACOs. One commenter acknowledged the potential for collecting longitudinal data, but questioned the effectiveness of this approach given that ACOs may not have the same beneficiaries assigned over multiple years. Another commenter expressed concern regarding the lack of benchmark information against which ACOs might measure their performance to date. A commenter encouraged CMS to conduct analyses using existing CAHPS data to identify models that allow for a fair comparison across ACOs. Another commenter suggested an approach to scoring health and functional status using another survey instrument (such as Patient Reported Outcomes Measurement Information System), or collecting baseline data for an ACO and implementing adjustments to account for differences in patient mix across ACOs.

Response: We appreciate the comments. We agree that additional analytic work would be needed in order to assess the potential implications of adding a scored health and functional status measure to the ACO quality measure set in the future. As we plan for future updates and changes to the Shared Savings Program measure set, we will consider this feedback from commenters further before making any proposal to begin scoring ACO–7—*Health and Functional Status* or to include a different scored heath and functional status measure.

Comment: We also received a few general comments on the applicability of the CAHPS for ACOs SSM to institutional providers, including a comment that raised concerns about low response rates and low reliability of the results.

Response: We made no proposals to adjust the application of the CAHPS for ACOs survey for any specific provider types under the Shared Savings Program. The CAHPS for ACO survey is focused on beneficiaries' experience of care received from clinicians in ambulatory care settings. Consequently, we note that CMS currently excludes beneficiaries from CAHPS sampling if 100 percent of their primary care service visits were performed in an institutional setting (as determined using HCPCS codes). However, after reviewing our current CAHPS sampling process, starting with the CAHPS sample for performance year 2018, we will also begin excluding beneficiaries if their last primary care service visit (as determined using HCPCS codes) during the sampling timeframe was performed in an institutional setting. We believe this change will help to ensure that beneficiaries who are residing in institutional settings are appropriately excluded from CAHPS sampling. Patient experience is a key component of quality measurement under the Shared Savings Program, and at this time we do not have plans to provide exemptions from patient experience measures for

specific ACOs. We will monitor this issue, and may in the future consider whether additional changes to measures of patient experience would be appropriate moving forward, based on the goals and priorities of the Shared Savings Program.

c. Proposed Changes to the CMS Web Interface and Claims-Based Quality Measure Sets

In developing the proposals we made in the CY 2019 PFS proposed rule, we considered the agency's efforts to streamline quality measures, reduce regulatory burden and promote innovation as part of the agency's Meaningful Measures initiative (*see* CMS Press Release, CMS Administrator Verma Announces New Meaningful Measures Initiative and Addresses Regulatory Reform; Promotes Innovation at LAN Summit, October 30, 2017, available at *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-10-30.html*). As noted in the proposed rule, under the Meaningful Measures initiative, we have committed to assessing only those core issues that are most vital to providing high-quality care and improving patient outcomes, with the aim of focusing on outcome-based measures, reducing unnecessary burden on providers, and putting patients first. In considering the quality reporting requirements under the Shared Savings Program, we also considered the quality reporting requirements under other initiatives, such as the MIPS and Million Hearts Initiative, and consulted with the measures community to ensure that the specifications for the measures used under the Shared Savings Program are up-to-date with current clinical guidelines, focus on outcomes over process, reflect agency and program priorities, and reduce reporting burden.

Since the Shared Savings Program was first established in 2012, we have updated the quality measure set to reduce reporting burden and focus on more meaningful, outcome-based measures. The most recent updates to the Shared Savings Program quality measure set were made in the CY 2017 PFS final rule (81 FR 80484 through 80489) to adopt the ACO measure recommendations made by the Core Quality Measures Collaborative, a multi-stakeholder group with the goal of aligning quality measures for reporting across public and private initiatives to reduce provider reporting burden. Currently, more than half of the 31 Shared Savings Program quality measures are outcome-based, including:

- Patient-reported outcome measures collected through the CAHPS for ACOs Survey that strengthen patient and caregiver experience.
- Outcome measures supporting effective communication and care coordination, such as unplanned admission and readmission measures.
- Intermediate outcome measures that address the effective treatment of chronic disease, such as hemoglobin A1c control for patients with diabetes.

In the CY 2019 PFS proposed rule, we proposed to reduce the total number of measures in the Shared Savings Program quality measure set. The proposals were intended to reduce the burden on ACOs and their participating providers and suppliers by lowering the number of measures they are required to report through the CMS Web Interface and on which they are assessed using claims data. Reducing the number of measures on which ACOs are assessed would reduce the number of performance metrics that they are required to track and eliminate redundancies between measures that target similar populations. The proposed reduction in the number of measures would enable ACOs to better utilize their resources toward improving patient care. The proposed reduction in the number of measures would further reduce burden by aligning with the proposed changes to the CMS Web Interface measures that are reported under MIPS as discussed in Tables A, C, and D of Appendix 1: Proposed MIPS Quality Measures of the proposed rule. We recognize that ACOs and their participating providers and suppliers dedicate resources to performing well on our quality metrics, and we believe that reducing the number of metrics and aligning them across programs would allow them to more effectively target those resources toward improving patient care. We proposed to reduce the number of measures by minimizing measure overlap and eliminating several process measures. The proposal to remove process measures also aligns with our proposal to reduce the number of process measures within the MIPS measure set as discussed in section III.H.b.iii of this final rule and would support the CMS goal of moving toward outcome-based measurement.

We proposed to retire the following claims-based quality measures, which have a high degree of overlap with other measures that would remain in the measure set:

- ACO–35—Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM).
- ACO–36—All-Cause Unplanned Admissions for Patients with Diabetes.
- ACO–37—All-Cause Unplanned Admission for Patients with Heart Failure.

Within the claims-based quality measures, a high degree of overlap exists between measures with respect to the population being measured (the denominator), because a single admission may be counted in multiple measures. For example, ACO–35 addresses unplanned readmissions from a SNF, and the vast majority of these SNF readmissions are also captured in the numerator of ACO–8 Risk-Standardized All Condition Readmission. Similarly, ACO–36 and ACO–37 address unplanned admissions for patients with diabetes and heart failure and most of these admissions are captured in the numerator of ACO–38 *Risk-Standardized Acute Admission Rates for Patients with Multiple Chronic Conditions* (please note that the measure name has been updated to align with changes made by the measure steward). Therefore, to reduce redundancies within the Shared Savings Program measure set, we proposed to remove ACO–35, ACO–36, and ACO–37 from the measure set. However, because these measures are claims-based measures and therefore do not impose any reporting burden on ACOs, we intend to continue to provide information to ACOs on their performance on these measures for use in their quality improvement activities through a new quarterly claims-based quality outcome report that ACOs began receiving in August 2018.

We also proposed to retire claims-based measure ACO–44—*Use of Imaging Studies for Low Back Pain,* as this measure is restricted to individuals 18–50 years of age, which results in low denominator rates under the Shared Savings Program, meaning that the measure is not a meaningful reflection of the beneficiaries cared for by Shared Savings Program ACOs. Although this measure was originally added to the Shared Savings Program quality measure set in order to align with the Core Quality Measures Collaborative, we proposed to remove this measure as a result of low denominators for many ACOs. We also indicated that removing this measure would align ACO quality measurement with the MIPS requirements as this measure was removed for purposes of reporting under the MIPS program in the CY 2018 Quality Payment Program final rule (82 FR 54159). However, in recognition of the value in providing feedback to providers on potential overuse of diagnostic procedures, we noted that we intended to continue to provide ACOs feedback on performance on this

measure as part of the new quarterly claims based quality report.

We welcomed public comment on our proposal to retire these 4 claims-based measures from the quality measure set.

The following is a summary of the comments we received on our proposal to retire ACO–35—*Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM),* ACO–36—*All-Cause Unplanned Admissions for Patients with Diabetes,* and ACO–37—*All-Cause Unplanned Admission for Patients with Heart Failure* from the quality measure set.

Comment: The majority of commenters supported our proposal to remove these measures stating that they appreciated our efforts to modernize the quality measurement requirements and reduce measure overlap. However, a commenter who supported our proposal cautioned, ''that there may be a tipping point at which the choice of measures becomes too narrowed. . . .'' Another commenter expressed concern that diabetes is not included as one of the multiple chronic conditions for purposes of ACO–38—*All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions (MCC).* The commenter noted that the retirement of ACO–36—*All-Cause Unplanned Admissions for Patients with Diabetes,* without an adequate alternative to measure performance in this area could cause a potential decline in provider performance and care quality. This commenter emphasized that reducing admission rates of diabetic patients should be a shared goal and priority of CMS and ACOs. Another commenter asked if we considered adding diabetes as a qualifying condition for ACO–38.

Response: We acknowledge the concerns raised by commenters with respect to the proposed removal of ACO–36 *All-Cause Unplanned Admissions for Patients with Diabetes.* However, we disagree with the commenter who stated that without a comparable diabetes measure to replace ACO–36 there would be a decline in provider performance and care quality. An analysis of ACO data from the 2015 performance year found that, as a result of the other comorbidities included for purposes of ACO–38, 48 percent of assigned ACO beneficiaries included in the diabetes measure were also included in the MCC measure. Measure overlap was even higher when considering the number of unplanned admissions shared by the two measures. Almost three-fourths (73 percent) of the unplanned admissions for assigned ACO beneficiaries under ACO–36 were also unplanned admissions for purposes of ACO–38, and thus were counted in both measures. In addition, we note that the Shared Savings Program measure set still includes a diabetes measure that monitors Hemoglobin A1c control *(ACO–27: Diabetes Hemoglobin A1c (HbA1c) Poor Control (>9%))* which is reported via the CMS Web Interface. Consequently, we believe that removing ACO–36 will not negatively impact patients with diabetes as the majority of readmissions for these patients are captured by ACO–38. In addition, we note that we plan to continue providing metrics on ACO–36 and ACO–37 in the quarterly claims-based measure reports for informational purposes only, which will allow ACOs to continue to monitor their results for these metrics. We are not considering revisions to add diabetes as a qualifying condition for ACO–38 at this time, but we will consider any changes to the ACO–38 cohort during the annual measure update. In response to the comment that there may be a point at which the measure set becomes too narrow, we understand the concern and will continue to carefully consider the balance between burden reduction and meaningful measurement in order to retain a sufficiently robust measure set against which ACO performance can be measured.

After considering the comments, we are finalizing our proposal to remove ACO–35—*Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM),* ACO–36—*All-Cause Unplanned Admissions for Patients with Diabetes,* and ACO–37—*All-Cause Unplanned Admission for Patients with Heart Failure* from the Shared Savings Program quality measure set effective for quality reporting for performance years during 2019.

The following is a summary of the comments we received on our proposal to retire ACO–44—*Use of Imaging Studies for Low Back Pain* from the quality measure set.

Comment: A majority of commenters supported our proposal stating that they agreed the measure should be removed due to low denominators in the Medicare population and because the measure was retired from MIPS. MedPAC opposed the removal of this measure stating, ''According to our analysis, imaging for patients with nonspecific low back pain affects between 3.1 to 8.9 percent of Medicare beneficiaries.'' MedPAC encouraged CMS to consider respecifying the measure to include beneficiaries over the age of 50 and retaining the measure in the ACO quality measure set.

Response: We appreciate the recommendation to respecify the ACO *imaging for low-back pain* measure to include beneficiaries over age 50 and recognize the value of including over-utilization of care measures in the ACO quality measure set. However, we note that CMS is not the measure steward for this measure. We have raised the issue with the measure steward and will continue to coordinate with the measure owner. Additionally, we note that we proposed to remove this measure to align ACO quality measurement with the MIPS reporting requirements as this measure was removed from the quality measure set under the MIPS program in the CY 2018 Quality Payment Program final rule (82 FR 54159).

After considering the comments, we are finalizing our proposal to remove ACO–44 from the Shared Savings Program quality measure set effective for quality reporting for performance years during 2019.

Although we proposed to retire ACO–35 *Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM)* from the set of quality measures that are scored for the Shared Savings Program, we recognize the value of measuring the quality of care furnished to Medicare beneficiaries in SNFs. Therefore, we solicited comment on the possibility of adding the Skilled Nursing Facility Quality Reporting Program (SNFQRP) measure ''Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facilities'' to the Shared Savings Program quality measure set through future rulemaking. This measure differs from ACO–35—*SNFRM,* which we are removing from the quality measure set as discussed above, as the SNFQRP measure looks only at unplanned, potentially preventable readmissions for Medicare FFS beneficiaries within 30 days of discharge to a lower level of care from a SNF, while ACO–35 assesses hospital readmissions from a SNF, that occur within 30 days following discharge from a hospital for beneficiaries admitted to a SNF after hospital discharge. As a result, the SNFQRP measure would have less overlap with ACO–8 (Risk-Standardized All Cause Readmission measure) because the readmission windows for the two measures are different. Specifically, the readmission window for the SNFQRP measure is 30 days following discharge from a SNF, while the readmission window for ACO–8 is 30 days following discharge from a hospital.

The following is a summary of the comments we received on the possibility of adding the SNFQRP measure ''Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facilities''

to the Shared Savings Program quality measure set through future rulemaking.

Comment: A few commenters supported the potential inclusion of the SNFQRP measure to the Shared Savings Program quality measure set through future rulemaking stating that the SNFQRP measure would potentially add more value to the Shared Savings Program measure set than ACO–35 as it is more targeted. Additionally, a few commenters suggested that we should test the measure in the ACO population and consider risk-adjusting the measure for sociodemographic factors prior to proposing the measure for inclusion into the Shared Savings Program quality measure set. However, the majority of commenters were opposed to potentially adding this measure to the Shared Savings Program quality measure set. One commenter stated that the SNFQRP measure assumes that the ACO has input into the care processes at the SNF and has the ability to direct patients to higher quality facilities, which is not always the case. Another commenter stated that as the measure is already used in the SNFQRP, they would not support inclusion in the Shared Savings Program quality measure set because they support avoiding the use of duplicative measures across CMS programs. Some of the commenters further stated that they believed this measure would still overlap with ACO–8 *Risk-Standardized All Condition Readmission* measure.

Response: As we plan for future updates and changes to the Shared Savings Program quality measure set, we will consider this feedback prior to making any proposals regarding the SNFQRP measure.

Further, as we stated in the CY 2019 PFS proposed rule (83 FR 35877), we seek to align with changes made to the CMS Web Interface measures under the Quality Payment Program. In the 2017 PFS final rule, we stated that we do not believe it is beneficial to propose CMS Web interface measures for ACO quality reporting separately (81 FR 80499). Therefore, in order to avoid confusion and duplicative rulemaking, we adopted a policy that any future changes to the CMS Web interface measures would be proposed and finalized through rulemaking for the Quality Payment Program, and that such changes would be applicable to ACO quality reporting under the Shared Savings Program. In accordance with the policy adopted in the CY 2017 PFS final rule (81 FR 80501), we did not make any specific proposals related to changes in CMS Web Interface measures reported under the Shared Savings Program. Rather, we referred readers to Tables A, C, and D of Appendix 1: Proposed MIPS Quality Measures in the proposed rule for a complete discussion of the proposed changes to the CMS Web Interface measures. Based on the changes being finalized in Tables A, C and D of Appendix 1: Finalized MIPS Quality Measures of this final rule, ACOs will no longer be responsible for reporting the following measures for purposes of the Shared Savings Program starting with reporting for performance years during 2019:

- ACO–12 (NQF #0097) Medication Reconciliation Post-Discharge.
- ACO–15 (NQF #0043) Pneumonia Vaccination Status for Older Adults.
- ACO–16 (NQF #0421) Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow Up.
- ACO–41 (NQF #0055) Diabetes: Eye Exam.
- ACO–30 (NQF #0068) Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic.

We note that ACO–41 is one measure within a two-component diabetes composite that is currently scored as one measure. The removal of ACO–41 means that ACO–27 Diabetes Hemoglobin A1c (HbA1c) Poor Control (>9%)) will now be assessed as an individual measure. As discussed in section III.I.2.B.i of this final rule, lists of the measures being finalized for purposes of MIPS are in Tables A, C and D of Appendix 1: Finalized MIPS Quality Measures.

Additionally, we proposed to add the following measure to the CMS Web Interface for purposes of the Quality Payment Program:

- ACO–47 (NQF #0101) Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls.

Based on the policies being finalized for purposes of MIPS in Table A of Appendix 1: Finalized MIPS Quality Measures, Shared Savings Program ACOs will not be responsible for reporting this measure starting with quality reporting for performance years during 2019.

Table 26 shows the Shared Savings Program quality measure set for performance years during 2019 and subsequent performance years.

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TABLE 26: Measure Set for Use in Establishing the Shared Savings Program Quality Performance Standard, Starting with Performance Years during 2019

Domain	ACO Measure #	Measure Title	New Measure	NQF #/Measure Steward	Method of Data Submission	Pay for Performance Phase-In R – Reporting P – Performance PY1	PY2	PY3
AIM: Better Care for Individuals								
Patient/Caregiver Experience	ACO - 1	CAHPS: Getting Timely Care, Appointments, and Information		NQF N/A AHRQ	Survey	R	P	P
	ACO - 2	CAHPS: How Well Your Providers Communicate		NQF N/A AHRQ	Survey	R	P	P
	ACO - 3	CAHPS: Patients' Rating of Provider		NQF N/A AHRQ	Survey	R	P	P
	ACO - 4	CAHPS: Access to Specialists		NQF #N/A CMS/AHRQ	Survey	R	P	P
	ACO - 5	CAHPS: Health Promotion and Education		NQF #N/A AHRQ	Survey	R	P	P
	ACO - 6	CAHPS: Shared Decision Making		NQF #N/A AHRQ	Survey	R	P	P
	ACO - 7	CAHPS: Health Status/Functional Status		NQF #N/A AHRQ	Survey	R	R	R
	ACO - 34	CAHPS: Stewardship of Patient Resources		NQF #N/A AHRQ	Survey	R	P	P
	ACO - 45	CAHPS: Courteous and Helpful Office Staff	X[1]	NQF #N/A AHRQ	Survey	R	R	P
	ACO - 46	CAHPS: Care Coordination	X[1]	NQF #N/A AHRQ	Survey	R	R	P
Care Coordination/ Patient Safety	ACO - 8	Risk-Standardized, All Condition Readmission		Adapted NQF #1789 CMS	Claims	R	R	P
	ACO - 38	Risk-Standardized Acute Admission Rates for Patients with Multiple Chronic Conditions		NQF#2888 CMS	Claims	R	R	P
	ACO - 43	Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91) (version with additional Risk Adjustment)[2]		AHRQ	Claims	R	P	P
	ACO - 13	Falls: Screening for Future Falls		NQF #0101 NCQA	CMS Web Interface	R	P	P
AIM: Better Health for Populations								
Preventive Health	ACO - 14	Preventive Care and Screening: Influenza Immunization		NQF #0041 AMA-PCPI	CMS Web Interface	R	P	P
	ACO - 17	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention		NQF #0028 AMA-PCPI	CMS Web Interface	R	P	P
	ACO - 18	Preventive Care and Screening: Screening for Depression and Follow-up Plan		NQF #0418 CMS	CMS Web Interface	R	P	P
	ACO - 19	Colorectal Cancer Screening		NQF #0034 NCQA	CMS Web Interface	R	R	P
	ACO - 20	Breast Cancer Screening		NQF #2372 NCQA	CMS Web Interface	R	R	P

Domain	ACO Measure #	Measure Title	New Measure	NQF #/Measure Steward	Method of Data Submission	Pay for Performance Phase-In R – Reporting P – Performance PY1	PY2	PY3
	ACO - 42	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease		NQF #N/A CMS	CMS Web Interface	R	R	R
Clinical Care for At Risk Population - Depression	ACO - 40	Depression Remission at Twelve Months		NQF #0710 MNCM	CMS Web Interface	R	R	R
Clinical Care for At Risk Population - Diabetes	ACO-27	Diabetes Hemoglobin A1c (HbA1c) Poor Control (>9%))		NQF #0059 NCQA	CMS Web Interface	R	P	P
Clinical Care for At Risk Population - Hypertension	ACO - 28	Hypertension : Controlling High Blood Pressure		NQF #0018 NCQA	CMS Web Interface	R	P	P

[1] Measures that are currently collected as part of the administration of the CAHPS for ACO survey, but will be considered new measures for purposes of the pay-for-performance phase-in.

[2] The language in parentheses has been added for clarity and no changes have been made to the measure.

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In this section of this final rule, we are finalizing proposals to eliminate 9 measures and to add 2 measures to the Shared Savings Program quality measure set. Separately, in August 2018 proposed rule, we also proposed to remove ACO–11—*Percent of Primary Care Physicians Who Successfully Meet Meaningful Use Requirements* (83 FR 41910 and 41911). We are finalizing the removal of ACO–11 in section V.B.2.f. of this final rule and refer readers to that section for a summary of that proposal and a discussion of public comments related to it. The net result of the final policies included in this final rule is a set of 23 measures on which ACOs' quality performance will be assessed for performance years during 2019 and subsequent performance years. The 4 domains will include the following numbers of quality measures (See Table 27):

- Patient/Caregiver Experience of Care—10 measures.
- Care Coordination/Patient Safety—4 measures.
- Preventive Health—6 measures.
- At Risk Populations—3 measures.

Table 27 provides a summary of the number of measures by domain and the total points and domain weights that will be used for scoring purposes under the changes to the quality measure set finalized in this rule.

TABLE 27: Number of Measures and Total Points for Each Domain within the Shared Savings Program Quality Performance Standard, Starting with Performance Years during 2019

Domain	Number of Individual Measures	Total Measures for Scoring Purposes	Total Possible Points	Domain Weight
Patient/Caregiver Experience	10	10 individual survey module measures	20	25%
Care Coordination/ Patient Safety	4	4 measures	8	25%
Preventive Health	6	6 measures	12	25%
At-Risk Population	3	3 individual measures	6	25%
Total in all Domains	23	23	46	100%

G. Physician Self-Referral Law

1. Background

Section 1877 of the Act, also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. The statute establishes a number of specific exceptions, and grants the Secretary the authority to create regulatory exceptions for financial relationships that pose no risk of program or patient abuse. Additionally, the statute mandates refunding any amount collected under a bill for an item or service furnished under a prohibited referral. Finally, the statute imposes reporting requirements and provides for sanctions, including civil monetary penalty provisions.

Section 50404 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018) added provisions to section 1877(h)(1) of the Act pertaining to the writing and

signature requirements in certain compensation arrangement exceptions to the statute's referral and billing prohibitions. Although we believe that the newly enacted provisions in section 1877(h)(1) of the Act are principally intended merely to codify in statute existing CMS policy and regulations with respect to compliance with the writing and signature requirements, we proposed revisions to our regulations to address any actual or perceived difference between the statutory and regulatory language, to codify in regulation our longstanding policy regarding satisfaction of the writing requirement found in many of the exceptions to the physician self-referral law, and to make the Bipartisan Budget Act of 2018 policies applicable to compensation arrangement exceptions issued using the Secretary's authority in section 1877(b)(4) of the Act.

In the CY 2016 PFS final rule with comment period (80 FR 70885), we revised § 411.357(a)(7), (b)(6), and (d)(1)(vii) to permit a lease arrangement or personal service arrangement to continue indefinitely beyond the stated expiration of the written documentation describing the arrangement under certain circumstances. Section 50404 of the Bipartisan Budget Act of 2018 added substantively identical holdover provisions to section 1877(e) of the Act. Because the new statutory holdover provisions effectively mirror the existing regulatory provisions, we do not believe it is necessary to revise § 411.357(a)(7), (b)(6), and (d)(1)(vii) as a result of these statutory revisions. Therefore, we made no proposals to these provisions.

2. Special Rules on Compensation Arrangements (Section 1877(h)(1)(D) & (E) of the Act)

Many of the exceptions for compensation arrangements in § 411.357 require that the arrangements are set out in writing and signed by the parties. (See § 411.357(a)(1), (b)(1), (d)(1)(i), (e)(1)(i), (e)(4)(i), (l)(1), (p)(2), (q) (incorporating the requirement contained in § 1001.952(f)(4)), (r)(2)(ii), (t)(1)(ii) or (t)(2)(iii) (both incorporating the requirements contained in § 411.357(e)(1)(i)), (v)(7), (w)(7), (x)(1)(i), and (y)(1).)[9] As described above, section 50404 of the Bipartisan Budget Act of 2018 amended section 1877 of the Act with respect to the writing and signature requirements in the statutory compensation arrangement exceptions. As detailed in this section, we proposed a new special rule on compensation arrangements at § 411.354(e) and proposed to amend existing § 411.353(g) to codify the statutory provisions in our regulations.

a. Writing Requirement (§ 411.354(e))

In the CY 2016 PFS final rule with comment period, we stated CMS' longstanding policy that the writing requirement in various compensation arrangement exceptions in § 411.357 can be satisfied by ''a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties'' (80 FR 71315). Our guidance on the writing requirement appeared in the preamble of the CY 2016 PFS final rule with comment period but was not codified in regulations. Section 50404 of the Bipartisan Budget Act of 2018 added subparagraph D, ''Written Requirement Clarified,'' to section 1877(h)(1) of the Act. Section 1877(h)(1)(D) of the Act provides that, in the case of any requirement in section 1877 of the Act for a compensation arrangement to be in writing, such requirement shall be satisfied by such means as determined by the Secretary, including by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties involved.

In light of the recently added statutory provision at section 1877(h)(1)(D) of the Act, we proposed to add a special rule on compensation arrangements at § 411.354(e). Proposed § 411.354(e) provides that, in the case of any requirement in 42 CFR part 411, subpart J, for a compensation arrangement to be in writing, the writing requirement may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties. The proposed special rule at § 411.354(e) codifies our existing policy on the writing requirement, as previously articulated in the CY 2016 PFS final rule with comment period. (See 80 FR 71314 *et seq.*)

b. Special Rule for Certain Arrangements Involving Temporary Noncompliance With Signature Requirements (§ 411.353(g))

Many of the exceptions for compensation arrangements in § 411.357 require that the arrangement (that is, the written documentation evidencing the arrangement) is signed by the parties to the arrangement. Under our existing special rule for certain arrangements involving temporary noncompliance with signature requirements at § 411.353(g)(1), an entity that has a compensation arrangement with a physician that satisfies all the requirements of an applicable exception in § 411.355, § 411.356 or § 411.357 except the signature requirement may submit a claim and receive payment for a designated health service referred by the physician, provided that: (1) The parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant (without regard to whether any referrals occur or compensation is paid during such 90-day period); and (2) the compensation arrangement otherwise complies with all criteria of the applicable exception. Existing § 411.353(g)(1) specifies the paragraphs where the applicable signature requirements are found and existing § 411.353(g)(2) limits an entity's use of the special rule at § 411.353(g)(1) to only once every 3 years with respect to the same referring physician.

Section 50404 of the Bipartisan Budget Act of 2018 added subparagraph E, ''Signature Requirement,'' to section 1877(h)(1) of the Act. Section 1877(h)(1)(E) of the Act provides that, in the case of any requirement in section 1877 of the Act for a compensation arrangement to be in writing and signed by the parties, the signature requirement is satisfied if: (1) Not later than 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant, the parties obtain the required signatures; and (2) the compensation arrangement otherwise complies with all criteria of the applicable exception. Notably, under the newly added section 1877(h)(1)(E) of the Act, an applicable signature requirement is not limited to specific exceptions and entities are not limited in their use of the rule to only once every 3 years with respect to the same referring physician. In addition, section 1877(h)(1)(E) of the Act does not include a reference to the occurrence of referrals or the payment of compensation during the 90-day period when the signature requirement is not met.

To conform the regulations with the recently added statutory provision at section 1877(h)(1)(E) of the Act, we proposed to amend existing § 411.353(g) by: (1) Revising the reference at § 411.353(g)(1) to specific exceptions and signature requirements; (2) deleting the reference at § 411.353(g)(1) to the

[9] We note that, where the writing requirement appears in the statutory and regulatory exceptions, we interpret it uniformly, regardless of any minor differences in the language of the requirement. See 80 FR 71315. Similarly, we interpret the signature requirement uniformly where it appears, regardless of any minor differences in the language of the statutory and regulatory exceptions.

occurrence of referrals or the payment of compensation during the 90-day period when the signature requirement is not met; and (3) deleting the limitation at § 411.353(g)(2). In the alternative, we proposed to delete § 411.353(g) in its entirety and codify in proposed § 411.354(e) the special rule for signature requirements in section 1877(h)(1)(E) of the Act. We solicited comments regarding the best approach for codifying in regulation this provision of the Bipartisan Budget Act of 2018.

The following is a summary of the comments we received regarding the best approach for codifying in regulation sections 1877(h)(1)(D) & (E) of the Act.

Comment: We received a few comments in support of our proposal to codify our existing policy on the writing requirement in a special rule on compensation arrangements at § 411.354(e). No commenters opposed the proposal or suggested revisions or additions to the proposed regulatory text in § 411.354(e).

Response: We are finalizing proposed § 411.354(e) without modification. We remind readers that § 411.354(e) codifies our longstanding policy on the writing requirement in various compensation exceptions, as explained in detail in the CY 2016 PFS final rule with comment period. (See 80 FR 71314 *et seq.*)

Comment: We received a few comments expressing general support for the special rule on temporary noncompliance with signature requirements. Commenters appreciated the flexibility that the special rule affords. We received no comments in opposition to our proposal. Commenters approved of our efforts to align our regulations pertaining to temporary noncompliance with signature requirements with the statutory provision at section 1877(h)(1)(E) of the Act. Most commenters did not note if it would be better to codify section 1877(h)(1)(E) of the Act at § 411.353(g) or to delete § 411.353(g) in its entirety and codify section 1877(h)(1)(E) of the Act in the special rules on compensation arrangements at § 411.354(e). A couple of commenters acknowledged that both proposals provide clarification but expressed a preference that we delete § 411.353(g) in its entirety and codify section 1877(h)(1)(E) of the Act in proposed § 411.354(e), asserting that such a change would provide a ''clear reflection of the statute.''

Response: We believe it would be less disruptive to provider and supplier compliance efforts to amend § 411.353(g), a regulation that has been in place for over 10 years. Therefore, we are finalizing our proposal to revise the special rule for temporary noncompliance with signature requirements at § 411.353(g), thus aligning § 411.353(g) with the newly added section 1877(h)(1)(E) of the Act.

Comment: We received a few comments seeking physician self-referral law regulatory changes that were not proposed.

Response: These comments are beyond the scope of this rulemaking and are not addressed in this final rule.

Finally, we note that the effective date of section 50404 of the Bipartisan Budget Act was February 9, 2018. Thus, beginning February 9, 2018, parties who meet the requirements of section 1877(h)(1)(E) of the Act, including parties who otherwise would have been barred from relying on the special rule for certain arrangements involving temporary noncompliance with signature requirements at § 411.353(g)(1) because of the 3-year limitation at § 411.353(g)(2), may avail themselves of the new statutory provision at section 1877(h)(1)(E) of the Act.

After reviewing the comments, we are finalizing the special rule on compensation arrangements at § 411.354(e) as proposed, and we are finalizing the modifications to § 411.353(g) as proposed.

N. Physician Self-Referral Law: Annual Update to the List of CPT/HCPCS Codes

1. General

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain designated health services (DHS) to an entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless an exception applies. Section 1877 of the Act also prohibits the DHS entity from submitting claims to Medicare or billing the beneficiary or any other entity for Medicare DHS that are furnished as a result of a prohibited referral.

Section 1877(h)(6) of the Act and § 411.351 of our regulations specify that the following services are DHS:

- Clinical laboratory services.
- Physical therapy services.
- Occupational therapy services.
- Outpatient speech-language pathology services.
- Radiology services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

2. Annual Update to the Code List

a. Background

In § 411.351, we specify that the entire scope of four DHS categories is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS Level II publications. The DHS categories defined and updated in this manner are:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.

The Code List also identifies those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibition:

- EPO and other dialysis-related drugs furnished in or by an ESRD facility (§ 411.355(g)).
- Preventive screening tests, immunizations, or vaccines (§ 411.355(h)).

The definition of DHS at § 411.351 excludes services for which payment is made by Medicare as part of a composite rate (unless the services are specifically identified as DHS and are themselves payable through a composite rate, such as home health and inpatient and outpatient hospital services). Effective January 1, 2011, EPO and dialysis-related drugs furnished in or by an ESRD facility (except drugs for which there are no injectable equivalents or other forms of administration), have been reimbursed under a composite rate known as the ESRD prospective payment system (ESRD PPS) (75 FR 49030). Accordingly, EPO and any dialysis-related drugs that are paid for under ESRD PPS are not DHS and are not listed among the drugs that could qualify for the exception at § 411.355(g) for EPO and other dialysis-related drugs furnished by an ESRD facility.

ESRD-related oral-only drugs, which are drugs or biologicals with no injectable equivalents or other forms of administration other than an oral form, were scheduled to be paid under ESRD PPS beginning January 1, 2014 (75 FR 49044). However, there have been several delays of the implementation of payment of these drugs under ESRD PPS. On December 19, 2014, section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014

(ABLE) (Pub. L. 113–295) was enacted and delayed the inclusion of these oral-only drugs under the ESRD PPS until 2025. Until that time, such drugs furnished in or by an ESRD facility are not paid as part of a composite rate and thus, are DHS.

The Code List was last updated in Tables 44 and 45 of the CY 2018 PFS final rule (82 FR 53339).

b. Response to Comments

We received no comments relating to the Code List that became effective January 1, 2018.

c. Revisions Effective for CY 2019

The updated, comprehensive Code List effective January 1, 2019, is available on our website at *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html*.

Additions and deletions to the Code List conform it to the most recent publications of CPT and HCPCS Level II and to changes in Medicare coverage policy and payment status.

Tables 28 and 29 identify the additions and deletions, respectively, to the comprehensive Code List that become effective January 1, 2019. Tables 28 and 29 also identify the additions and deletions to the list of codes used to identify the items and services that may qualify for the exception in § 411.355(g) (regarding dialysis-related outpatient prescription drugs furnished in or by an ESRD facility) and in § 411.355(h) (regarding preventive screening tests, immunizations, and vaccines).

TABLE 28—ADDITIONS TO THE PHYSICIAN SELF-REFERRAL LIST OF CPT [1] HCPCS CODES

Clinical Laboratory Services:	
0018U	Onc thyr 10 microrna seq alg.
0019U	Onc rna tiss predict alg.
0020U	Rx test prsmv ur w/def conf.
0021U	Onc prst8 detcj 8 autoantb.
0022U	Trgt gen seq dna&rna 23 gene.
0023U	Onc aml dna detcj/nondetcj.
0024U	Glyca nuc mr spectrsc quan.
0025U	Tenofovir liq chrom ur quan.
0026U	Onc thyr dna&mrna 112 genes.
0027U	Jak2 gene trgt seq alys.
0028U	Cyp2d6 gene cpy nmr cmn vrnt.
0029U	Rx metab advrs trgt seq alys.
0030U	Rx metab warf trgt seq alys.
0031U	Cypia2 gene.
0032U	Comt gene.
0033U	Htr2a htr2c genes.
0034U	Tpmt nudt15 genes.
0035U	Neuro csf prion prtn qual.
0036U	Xome tum & nml spec seq alys.
0037U	Trgt gen seq rgt gen seq dna 324 genes.
0038U	Vitamin d srm microsamp quan.
0039U	Dna antb 2strand hi avidity.
0040U	Bcr/abl1 gene major bp quan.
0041U	B brgdrferi antb 5 prtn igm.
0042U	B brgdrferi antb 12 prtn igg.
0043U	Tbrg b grp antb 4 prtn igm.
0044U	Tbrf b grp antb 4 prtn igg.
0045U	Onc brst dux carc is 12 gene.
0046U	Flt3 genie itd variants quan.
0047U	Onc prst8 mrna 17 gene alg.
0048U	Onc sld org neo dna 468 gene.
0049U	Npm1 gene analysis quan.
0050U	Trgt gen seq dna 194 genes.
0051U	Rx mntr lc-ms/ms ur 31 pnl.
0052U	Lpoprtn bld w/5 maj classes.
0053U	Onc prst8 ca fish alys 4 gen.
0054U	Rx mntr 14+ drugs & sbsts.
0055U	Card hrt trnspl 96 dna seq.
0056U	Hem aml dna gene reargmt.
0057U	Onc sld org neo mrna 51 gene.
0058U	Onc merkel cll carc srm quan.
0059U	Onc merkel cll carc srm+/−.
0060U	Twn zyg gen seq alys chrms2.
0061U	Tc meas 5 bmrk sfdi m-s alys.
0011M	Onc prst8 ca mrna 12 gen alg.
0012M	Onc mrna 5 gen rsk urthl ca.
0013M	Onc mrna 5 gen recr urthl ca.
Physical Therapy, Occupational Therapy, and Outpatient Speech-Language Pathology Services:	
{No additions.}	
Radiology and Certain Other Imaging Services:	
0508T	Pls echo us b1 dns meas tib.
76391	Mr elastography.
76978	Us trgt dyn mbubb 1st les.
76979	Us trgt dyn mbubb ea addl.
76981	Use parenchyma.
76982	Use 1st target lesion.
76983	Use ea addl target lesion.
77046	Mri breast c-unilateral.
77047	Mri breast c-bilateral.
77048	Mri breast c−+ w/cad uni.
77049	Mri breast c−+ w/cad bi.
C8937	Cad breast Mri.
C9407	Iodine i-131 iobenguane, dx.
Q9950	Inj sulf hexa lipid microsph.
Radiation Therapy Services and Supplies:	
A9513	Lutetium Lu 177 dotatat ther.
C9408	Iodine i-131 iobenguane, tx.
Drugs Used by Patients Undergoing Dialysis:	
{No additions.}	
Preventive Screening Tests, Immunizations and Vaccines:	
81528	Oncology colorectal scr.
90689	Vacc IIv4 no prsrv 0.25ml im.

[1] CPT codes and descriptions only are copyright 2018 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

TABLE 29—DELETIONS FROM THE PHYSICIAN SELF-REFERRAL LIST OF CPT [1] HCPCS CODES

Clinical Laboratory Services:	
78270	Vit B-12 absorption exam.
78271	Vit B-12 absrp exam int fac.
78272	Vit B-12 absorp combined.
Physical Therapy, Occupational Therapy, and Outpatient Speech-Language Pathology Services:	
64550	Appl surface neurostimulator.
96111	Developmental testing.
Radiology and Certain Other Imaging Services:	
0159T	Cad breast mri.
0346T	Ultrasound elastography.
C9744	Abd us w/contrast.
77058	Mri one breast.
77059	Mri both breasts.
77776	Apply interstit radiat simpl.
77785	HDR brachytx 1 channel.
77786	HDR brachytx 2-12 channel.
C9457	Lumason contrast agent.
C9461	Choline C 11, diagnostic.
G0173	Linear acc stereo radsur com.
G0251	Linear acc based stero radio.
Radiation Therapy Services and Supplies:	
0190T	Place intraoc radiation src.
Drugs Used by Patients Undergoing Dialysis:	
{No deletions}.	
Preventive Screening Tests, Immunizations and Vaccines:	
G0389	Ultrasound exam AAA screen.
G0464	Colorec CA scr, sto bas DNA.

[1] CPT codes and descriptions only are copyright 2018 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

I. CY 2019 Updates to the Quality Payment Program

1. Executive Summary

a. Overview

This final rule will make payment and policy changes to the Quality Payment Program starting January 1, 2019, except as noted for specific provisions elsewhere in this final rule. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015) amended title XVIII of the Act to repeal the Medicare sustainable growth rate (SGR) formula, to reauthorize the Children's Health Insurance Program, and to strengthen Medicare access by improving physician and other clinician payments and making other improvements. The MACRA advances a forward-looking, coordinated framework for clinicians to successfully participate in the Quality Payment Program, which rewards value in one of two ways:

- The Merit-based Incentive Payment System (MIPS).
- Advanced Alternative Payment Models (Advanced APMs).

As we move into the third year of the Quality Payment Program, we have taken all stakeholder input into consideration, including recommendations made by the Medicare Payment Advisory Commission (MedPAC), an independent congressional agency established by the Balanced Budget Act of 1997 (Pub. L. 105–33, enacted on August 5, 1997) to advise the U.S. Congress on issues

affecting the Medicare program, such as payment policies under Medicare, the factors affecting expenditures for the efficient provision of services, and the relationship of payment policies to access and quality of care for Medicare beneficiaries. We will continue to implement the Quality Payment Program as required, smoothing the transition where possible and offering targeted educational resources for program participants. A few examples of how we are working to address stakeholder input are evident in our work around burden reduction and reshaping our focus of interoperability. We have heard the concern about process-based measures, and we are continuing to move towards the development and use of more outcome measures by way of removing process measures that are topped out and funding new quality measure development, as required by section 102 of MACRA. We have also developed new episode-based cost measures, with stakeholder feedback, for inclusion in the cost performance category beginning in 2019, with additional measure development occurring for potential inclusion in future years.

Additionally, we have also received feedback from stakeholders regarding the added value of the Quality Payment Program. To that point, CMS has begun a series of strategic planning sessions to (1) assess the current value of the program for clinicians and beneficiaries alike and (2) implement the program in a way that is understandable to beneficiaries, as they are the core of the Medicare program.

As a priority for the Quality Payment Program Year 3, we are committed to continue using the framework established by the Patients over Paperwork initiative to assist in reducing clinician burden, implementing the Meaningful Measures Initiative, promoting interoperability, continuing our support of small and rural practices, empowering patients, and promoting price transparency.

Reducing Clinician Burden

We are committed to reducing clinician burden by simplifying and streamlining the program for participating clinicians. Examples include:

- Implementing the Meaningful Measures Initiative, which is a framework that applies a series of cross-cutting criteria to identify and utilize the most meaningful measures with the least amount of burden and greatest impact on patient outcomes;
- Promoting advances in interoperability; and
- Establishing an automatic extreme and uncontrollable circumstances policy for MIPS eligible clinicians.

Improving Patient Outcomes and Reducing Burden Through Meaningful Measures

Regulatory reform and reducing regulatory burden are high priorities for CMS. To reduce the regulatory burden on the healthcare industry, lower health care costs, and enhance patient care, we launched the Meaningful Measures Initiative in October 2017.[10] This initiative is one component of our agency-wide Patients Over Paperwork Initiative,[11] which is aimed at evaluating and streamlining regulations with a goal to reduce unnecessary cost and burden, increase efficiencies, and improve beneficiary experience. The Meaningful Measures Initiative is aimed at identifying the highest priority areas for quality measurement and quality improvement to assess the core quality of care issues that are most vital to advancing our work to improve patient outcomes. The Meaningful Measures Initiative represents a new approach to quality measures that fosters operational efficiencies, and reduces cost associated with collection and reporting burden, while producing quality measurement that is more focused on meaningful outcomes.

The Meaningful Measures Framework has the following principles for identifying measures that:

- Address high-impact measure areas that safeguard public health;
- Patient-centered and meaningful to patients;
- Outcome-based where possible;
- Fulfill each program's statutory requirements;
- Minimize the level of burden for health care providers (for example, through a preference for EHR-based measures where possible, such as electronic clinical quality measures);
- Significant opportunity for improvement;
- Address measure needs for population based payment through alternative payment models; and
- Align across programs and/or with other payers.

To achieve these objectives, we have identified 19 Meaningful Measures areas and mapped them to six overarching quality priorities as shown in Table 30.

TABLE 30—MEANINGFUL MEASURES FRAMEWORK DOMAINS AND MEASURE AREAS

Quality priority	Meaningful measure area
Making Care Safer by Reducing Harm Caused in the Delivery of Care	Healthcare-Associated Infections. Preventable Healthcare Harm.
Strengthen Person and Family Engagement as Partners in Their Care	Care is Personalized and Aligned with Patient's Goals. End of Life Care according to Preferences. Patient's Experience of Care. Patient Reported Functional Outcomes.
Promote Effective Communication and Coordination of Care	Medication Management. Admissions and Readmissions to Hospitals. Transfer of Health Information and Interoperability.
Promote Effective Prevention and Treatment of Chronic Disease	Preventive Care. Management of Chronic Conditions. Prevention, Treatment, and Management of Mental Health. Prevention and Treatment of Opioid and Substance Use Disorders. Risk Adjusted Mortality.
Work with Communities to Promote Best Practices of Healthy Living	Equity of Care. Community Engagement.

[10] Meaningful Measures web page: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

[11] See Remarks by Administrator Seema Verma at the Health Care Payment Learning and Action Network (LAN) Fall Summit, as prepared for delivery on October 30, 2017, *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html.*

TABLE 30—MEANINGFUL MEASURES FRAMEWORK DOMAINS AND MEASURE AREAS—Continued

Quality priority	Meaningful measure area
Make Care Affordable	Appropriate Use of Healthcare. Patient-focused Episode of Care. Risk Adjusted Total Cost of Care.

By including Meaningful Measures in our programs, we believe that we can also address the following cross-cutting measure criteria:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
- Safeguarding public health;
- Achieving cost savings;
- Improving access for rural communities; and
- Reducing burden.

We believe that the Meaningful Measures Initiative will improve outcomes for patients, their families, and health care providers while reducing burden and costs for clinicians and providers and promoting operational efficiencies.

In the quality performance category under MIPS, clinicians have the flexibility to select and report the measures that matter most to their practice and patients. However, we have received feedback that some clinicians find the performance requirements confusing, and the program makes it difficult for them to choose measures that are meaningful to their practices and have more direct benefit to beneficiaries. For the 2019 MIPS performance period, we are finalizing the following updates: (1) Adding 8 new MIPS quality measures that include 4 patient reported outcome measures, 6 high priority measures, and 2 measures on important clinical topics in the Meaningful Measures framework; and (2) removing 26 quality measures.

In addition to having the right measures, we want to ensure that the collection of information is valuable to clinicians and worth the cost and resources of collecting the information.

Promoting Interoperability Performance Category

As required by MACRA, the Quality Payment Program includes a MIPS performance category that focuses on meaningful use of certified EHR technology, referred to in the CY 2017 and CY 2018 Quality Payment Program final rules as the ''advancing care information'' performance category. As part of our approach to promoting and prioritizing interoperability of healthcare data, in Quality Payment Program Year 2, we changed the name of the performance category to the Promoting Interoperability performance category.

We have prioritized interoperability, which we define as health information technology, that enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable law; and does not constitute information blocking as defined by the 21st Century Cures Act (Pub. L. 114–255, enacted December 13, 2016). We are committed to working with the Office of the National Coordinator for Health IT (ONC) on implementation of the interoperability provisions of the 21st Century Cures Act to have seamless but secure exchange of health information for clinicians and patients, ultimately enabling Medicare beneficiaries to get their claims information electronically. In addition, we are prioritizing quality measures and improvement activities that support interoperability.

To further CMS' commitment to implementing interoperability, at the 2018 Healthcare Information and Management Systems Society (HIMSS) conference, CMS Administrator Seema Verma announced the launching of the MyHealthEData initiative.[12] This initiative aims to empower patients by ensuring that they control their healthcare data and can decide how their data is going to be used, all while keeping that information safe and secure. The overall government-wide initiative is led by the White House Office of American Innovation with participation from HHS—including its CMS, ONC, and the National Institutes of Health (NIH)—as well as the U.S. Department of Veterans Affairs (VA). MyHealthEData aims to break down the barriers that prevent patients from having electronic access and true control of their own health records from the device or application of their choice. This effort will approach the issue of healthcare data from the patient's perspective.

For the Promoting Interoperability performance category, we require MIPS eligible clinicians to use 2015 Edition certified EHR technology beginning with the 2019 MIPS performance period to make it easier for:

- Patients to access their data.
- Patient information to be shared between doctors and other health care providers.

Continuing To Support Small and Rural Practices

We understand that the Quality Payment Program is a big change for clinicians, especially for those in small and rural practices. We intend to continue to offer tailored flexibilities to help these clinicians to participate in the program. For example, in this rule we are finalizing our proposal to retain a small practice bonus under MIPS by moving it to the quality performance category. We will also continue to support small and rural practices by offering free and customized resources available within local communities, including direct, one-on-one support from the Small, Underserved, and Rural Support Initiative along with our other no-cost technical assistance.

Further, we note that we are finalizing our proposal to amend our regulatory text to allow small practices to continue using the Medicare Part B claims collection type. We are also finalizing our proposal to revise the regulatory text to allow a small practice to submit quality data for covered professional services through the Medicare Part B claims submission type for the quality performance category, as discussed further in section III.I.3.h. of this final rule. Finally, in the CY 2018 Quality Payment Program final rule, we finalized a policy to allow small practices to continue to choose to participate in MIPS as a virtual group (82 FR 53598).

Empowering Patients Through the Patients Over Paperwork Initiative

Our Patients Over Paperwork initiative establishes an internal process to evaluate and streamline regulations with a goal to reduce unnecessary burden, to increase efficiencies, and to

[12] *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-03-06.html.*

improve the beneficiary experience.[13] This administration is dedicated to putting patients first, empowering consumers of healthcare to have the information they need to be engaged and active decision-makers in their care. As a result of this consumer empowerment, clinicians will gain competitive advantage by delivering coordinated, high-value quality care.

The policies for the Quality Payment Program in this final rule promote competition and empower patients. We are consistently listening, and we are committed to using data-driven insights, increasingly aligned and meaningful quality measures, and technology that empowers patients and clinicians to make decisions about their healthcare.

In conjunction with development of the Patients Over Paperwork initiative, we are making progress toward developing a patient-centered portfolio of measures for the Quality Payment Program, including 7 new outcome measures included on the 2017 CMS Measures Under Consideration List,[14] 5 of which are directly applicable to the prioritized specialties of general medicine/crosscutting and orthopedic surgery. Finally, on September 21, 2018, CMS awarded seven organizations new cooperative agreements to partner with the agency in developing, improving, updating, or expanding quality measures for Medicare's Quality Payment Program. Awardees will work to establish more appropriate measures for clinical specialties underrepresented in the current measure set with the goal of improving patient care, and focus on outcome measures, including patient-reported and functional-status measures, to better reflect what matters most to patients.[15]

b. Summary of the Major Provisions

In May 2018, CMS announced that 91 percent of MIPS eligible clinicians participated in the 2017 transition year. (See *https://www.cms.gov/blog/quality-payment-program-exceeds-year-1-participation-goal*.) This CY 2017 performance period data were incorporated for this final rule when estimating eligibility and payment adjustment for the CY 2019 MIPS performance period. One important finding is that many more clinicians than reported in the CY 2019 PFS proposed rule are expected to participate in MIPS using the group reporting option. This increase means more clinicians are covered in MIPS and are measured on their performance.

(1) Quality Payment Program Year 3

During the first 2 years of the program, we have heard concerns from clinicians that were not eligible to participate. Under MIPS, for year 3, we are expanding in this final rule the opportunities to participate, while still understanding the burden required to participate, to include physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dietitians or nutrition professionals in the list of MIPS eligible clinicians. We also are finalizing an opt-in policy that allows some clinicians, who otherwise would have been excluded under the low-volume threshold, the option to participate in MIPS.

We believe the third year of the Quality Payment Program should build upon the foundation that has been established in the first 2 years, which provides a trajectory for clinicians moving to a performance-based payment system. This trajectory provides clinicians the ability to participate in the program through two pathways: MIPS and Advanced APMs.

(2) Payment Adjustments

As discussed in section VII.F.8. of this final rule, for the 2021 payment year and based on Advanced APM participation during the 2019 MIPS performance period, we estimate that between 165,000 and 220,000 clinicians will become Qualifying APM Participants (QP). As a QP, an eligible clinician is not subject to the MIPS reporting requirements and payment adjustment, and qualifies for a lump sum APM incentive payment equal to 5 percent of their aggregate payment amounts for covered professional services for the year prior to the payment year. We estimate that the total lump sum APM incentive payments will be approximately $600–800 million for the 2021 Quality Payment Program payment year.

Again, we estimate that approximately 798,000 clinicians would be MIPS eligible clinicians in the 2019 MIPS performance period, an increase of almost 148,000 from the estimate we provided in the CY 2019 PFS proposed rule, which reflects growth in group reporting and our ability to better capture group reporting. The final number will depend on several factors, including the number of eligible clinicians excluded from MIPS based on their status as QPs or Partial QPs, the number that report as groups, and the number that elect to opt-in to MIPS. In the 2021 MIPS payment year, MIPS payment adjustments, which only apply to covered professional services, will be applied based on MIPS eligible clinicians' performance on specified measures and activities within four integrated performance categories. We estimate that MIPS payment adjustments will be approximately equally distributed between negative MIPS payment adjustments ($390 million) and positive MIPS payment adjustments ($390 million) to MIPS eligible clinicians, as required by the statute to ensure budget neutrality. Positive MIPS payment adjustments will also include up to an additional $500 million for exceptional performance to MIPS eligible clinicians whose final score meets or exceeds the additional performance threshold of 75 points that we are establishing in this final rule. However, the distribution will change based on the final population of MIPS eligible clinicians for the 2021 MIPS payment year and the distribution of final scores under the program.

2. Definitions

At § 414.1305, subpart O—

- We are revising in this final rule the regulation to define the following terms:
  - ++ Ambulatory Surgical Center (ASC)-based MIPS eligible clinician.
  - ++ Collection type.
  - ++ Health IT vendor.
  - ++ MIPS determination period.
  - ++ Submission type.
  - ++ Submitter type.
  - ++ Third party intermediary.
- We are revising in this final rule the definitions of the following terms:
  - ++ High priority measure.
  - ++ Hospital-based MIPS eligible clinician
  - ++ Low-volume threshold.
  - ++ MIPS eligible clinician.
  - ++ Non-patient facing MIPS eligible clinician.
  - ++ Qualified clinical data registry (QCDR).
  - ++ Qualifying APM Participant (QP).
  - ++ Small practice.

These terms and definitions are discussed in detail in relevant sections of this final rule.

[13] Patients Over Paperwork web page available at *https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/PatientsOverPaperwork.html*.

[14] Centers for Medicare & Medicaid Services. *List of Measures Under Consideration for December 1, 2017*. Baltimore, MD: US Department of Health and Human Services; 2017. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/Measures-under-Consideration-Listfor2017.pdf*. Accessed May 4, 2018.

[15] CMS Awards Funding for Quality Measure Development, *https://www.cms.gov/newsroom/press-releases/cms-awards-funding-quality-measure-development*.

3. MIPS Program Details

a. MIPS Eligible Clinicians

Under § 414.1305, a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, is defined as any of the following (excluding those identified at § 414.1310(b)): A physician (as defined in section 1861(r) of the Act); a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); and a group that includes such clinicians. Section 1848(q)(1)(C)(II) of the Act provides the Secretary with discretion, beginning with the 2021 MIPS payment year, to specify additional eligible clinicians (as defined in section 1848(k)(3)(B) of the Act) as MIPS eligible clinicians. Such clinicians may include physical therapists, occupational therapists, or qualified speech-language pathologists; qualified audiologists (as defined in section 1861(ll)(3)(B) of the Act); certified nurse-midwives (as defined in section 1861(gg)(2) of the Act); clinical social workers (as defined in section 1861(hh)(1) of the Act); clinical psychologists (as defined by the Secretary for purposes of section 1861(ii) of the Act); and registered dietitians or nutrition professionals.

As discussed in the CY 2019 PFS proposed rule (83 FR 35883 through 35884), we received feedback from non-physician associations representing each type of additional eligible clinician through listening sessions and meetings with various stakeholder entities and through public comments discussed in the CY 2017 Quality Payment Program final rule (81 FR 77038). Commenters generally supported the specification of such clinicians as MIPS eligible clinicians beginning with the 2021 MIPS payment year. In order to assess whether these additional eligible clinicians could successfully participate in MIPS, we evaluated whether there would be sufficient measures and activities applicable and available for each of the additional eligible clinician types. We finalized in the CY 2018 Quality Payment Program final rule (82 FR 53780), that having sufficient measures for the quality performance category, means having sufficient measures applicable and available means that we can calculate a quality performance category percent score for the MIPS eligible clinician because at least one quality measure is applicable and available to the clinician. For the improvement activities performance category, we stated the belief that all MIPS eligible clinicians will have sufficient activities applicable and available. We focused our analysis on the quality and improvement activities performance categories because these performance categories require submission of data. We did not focus on the Promoting Interoperability performance category because there is extensive analysis regarding who can participate in the Promoting Interoperability performance category under the current exclusion criteria. In addition, in section III.I.3.h.(5) of this final rule, we are finalizing a policy to automatically assign a zero percent weighting for the Promoting Interoperability performance category for these new types of MIPS eligible clinicians. We did not focus as part of our analysis on the cost performance category because we are only able to assess cost performance for a subset of eligible clinicians—specifically, those who are currently eligible as a result of not meeting any of the current exclusion criteria. So the impact of the cost performance category for these additional eligible clinicians will continue to be considered but is currently not a decisive factor for successful participation in MIPS. From our analysis, we found that improvement activities would generally be applicable and available for each of the additional eligible clinician types. However, for the quality performance category, we found that not all of the additional eligible clinician types would have sufficient MIPS quality measures applicable and available. As discussed in section III.I.3.h.(2)(b)(iii) of this final rule, for the quality performance category, we are finalizing our proposals to remove several MIPS quality measures. In the CY 2019 PFS proposed rule (83 FR 35883 through 35884), we explained that if those measures were finalized for removal, we anticipated that qualified speech-language pathologists, qualified audiologists, certified nurse-midwives, and registered dietitians or nutrition professionals would each have less than 6 MIPS quality measures applicable and available to them. However, if the quality measures were not finalized for removal, we would reassess whether these eligible clinicians would have an adequate amount of MIPS quality measures available to them. We proposed to include these additional clinicians in the MIPS eligible clinician definition if we found that they do have at least 6 MIPS quality measures available to them. As discussed in ''Appendix 1: Finalized MIPS Quality Measures'', TABLE Group C. of this final rule, we are retaining one of the MIPS quality measures that was proposed for removal: ''Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use'' (Quality #185). We do not believe that this measure is applicable to any of the proposed additional eligible clinicians. Therefore, it does not affect the number of available measures for these clinicians. We refer readers to section III.I.3.h.(2) of this final rule for more information regarding quality measures.

We focused on the quality performance category because the quality and improvement activities performance categories require submission of data. We believed there would generally be applicable and available improvement activities for each of the additional eligible clinician types, but that not all of the additional eligible clinician types would have sufficient MIPS quality measures applicable and available if the proposed MIPS quality measures were removed from the program. In our analysis, we did find QCDR measures approved for the CY 2018 performance period that are either high priority and/or outcome measures that, if approved for the CY 2019 performance period, may be applicable to these additional eligible clinicians. However, this would necessitate that the clinician utilize a QCDR in order to be successful in MIPS. Further, we have heard some concerns from the non-physician associations, through written correspondence, that since their clinicians would be joining the program 2 years after its inception, we should consider several ramp-up policies in order to facilitate an efficient integration of these clinicians into MIPS. We note that the MIPS program is still ramping up, and we will continue to increase the performance threshold to ensure a gradual and incremental transition to the performance threshold that will be used in the Quality Payment Program Year 6. Therefore, if specified as MIPS eligible clinicians beginning with the 2021 MIPS payment year, the additional eligible clinicians would have 4 years in the program in order to ramp up. Conversely, if specified as MIPS eligible clinicians beginning in a future year, they would be afforded less time to ramp up the closer the program gets to Quality Payment Program Year 6.

We requested comments on our proposal to amend § 414.1305 to modify the definition of a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, to mean any of

the following (excluding those identified at § 414.1310(b)): A physician (as defined in section 1861(r) of the Act); a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); beginning with the 2021 MIPS payment year, a physical therapist, occupational therapist, a clinical social worker (as defined in section 1861(hh)(1) of the Act), a clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act); and a group that includes such clinicians. Alternatively, we proposed that if the quality measures proposed for removal were not finalized, then we would include additional eligible clinician types in the definition of a MIPS eligible clinician beginning with the 2021 MIPS payment year (specifically, qualified speech-language pathologists, qualified audiologists, certified nurse-midwives, and registered dietitians or nutrition professionals), provided that we determine that each applicable eligible clinician type would have at least 6 MIPS quality measures available to them. In addition, we requested comments on: (1) Specifying qualified speech-language pathologists, qualified audiologists, certified nurse-midwives, and registered dietitians or nutrition professionals as MIPS eligible clinicians beginning with the 2021 MIPS payment year; and (2) delaying the specification of one or more additional eligible clinician types as MIPS eligible clinicians until a future MIPS payment year.

The following is a summary of the public comments received on our proposals and our responses:

Comment: Many commenters supported our proposal to expand the definition of MIPS eligible clinicians to physical therapists, occupational therapists, clinical social workers, and clinical psychologists. A few commenters encouraged us to ensure that a reasonable number of measures are maintained for these newly eligible clinicians. Other commenters specifically discussed adding qualified audiologist and qualified speech-language pathologists as MIPS eligible clinicians, stating that there are enough discipline-specific measures for these clinicians to be included in the program. One commenter specifically stated that registered dietitians have seven quality measures on which to report, and, therefore should be included in the program. A few commenters requested that we include the following additional clinicians as MIPS eligible clinicians: Nurse navigators, oncology staff nurses, and clinical pharmacists, stating that adding more clinicians would enable better understanding of healthcare data across other specialties.

Response: We appreciate the additional information provided regarding the quality measures available to the additional eligible clinicians. After review of the additional information regarding quality measures we revisited our findings and found support for the comments. We were persuaded by the arguments of the specialties who requested to be included in the program including: Physical therapists, occupational therapists, speech-language pathologists, audiologists, clinical psychologists, and dieticians or nutrition professionals. However, we believe that clinical social workers may not have six applicable quality measures to report. For example, some measures may contain CPT codes utilized by clinical social workers, but may not be applicable to their practice. We do believe that there is at least one quality measure that clinical social workers could report for MIPS. We encourage the clinicians within the specialty provide feedback during the specialty measure set solicitation process to create a measure set applicable to clinical social workers for implementation in future rulemaking. This will ensure proper scoring based on applicable measures and will not hold clinical social workers accountable for measures that are outside their scope. Therefore, we are modifying our proposal by removing clinical social workers from our proposed list and including qualified speech-language pathologists, qualified audiologists, and registered dieticians who were not in our proposed list but have requested inclusion as MIPS eligible clinicians. We are finalizing to modify § 414.1305 the definition of a MIPS eligible clinician to include: Beginning with the 2021 MIPS payment year, a physical therapist, occupational therapist, qualified speech-language pathologist; a qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act); clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act); and registered dietician or nutrition professional; and a group that includes such clinicians. We note that we do not have discretion under the statute to include clinicians other than those specified in section 1848(q)(1)(C)(II) of the Act. Thus, nurses and pharmacists would not be able to participate in MIPS.

Comment: A few commenters requested that clinical social workers not be included in MIPS. They stated several reasons why they believe that clinical social workers should not be included in MIPS: (1) Many of their clinicians are solo or small group practices and do not have the technology infrastructure in place to effectively meet expectations in the Promoting Interoperability performance category; (2) many are in private practice and have limited ability to influence the overall care of patients limiting their ability to manage the overall cost of the beneficiary; (3) while there are more than six measures available in the mental/behavioral health measure set there are only four claims measures appropriate for use by clinical social workers as determined by eligible CPT codes and scope of practice; and (4) some of the available MIPS CQM measures are limited by patient diagnosis, such as dementia, which may further limit a clinical social workers ability to effectively report on six quality measures, as there are only two outcome measures in the Mental/Behavioral health measure set for clinical social workers and they require the utilization of the PHQ–9 measure which is only reportable via EHR. When a clinical social worker does not utilize EHR technology there may be further limitations to reporting adequate measures.

Response: After review of the additional information regarding quality measures, we revisited our findings and found support for the comments. We were persuaded by the arguments of the specialties who requested to be included in the program including: Physical therapists; occupational therapists; speech-language pathologists; audiologists; clinical psychologists; and dieticians or nutrition professionals. We understand the issues that have been highlighted by the commenters and believe that some clinical social workers may have a difficult time successfully participating in MIPS. Therefore, we agree that clinical social workers should not be added as a MIPS eligible clinician at this time. However, we do believe that they may be able to participate at some point in the future. From our analysis, clinical social workers may not have six applicable quality measures to report at this time. For example, some measures may contain CPT codes utilized by clinical social workers, but may not be applicable to their practice. We do believe that there is at least one quality measure that clinical social workers

could report for MIPS. Therefore, we are modifying our proposal by removing clinical social workers and certified nurse-midwives from our proposed list and including qualified speech-language pathologists, qualified audiologists, and registered dieticians who were not in our proposed list but have requested inclusion as MIPS eligible clinicians. We are finalizing to modify § 414.1305 the definition of a MIPS eligible clinician to include, beginning with the 2021 MIPS payment year, a physical therapist, occupational therapist, qualified speech-language pathologist; a qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act); clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act); and registered dietician or nutrition professional; and a group that includes such clinicians. We encourage clinicians who are not eligible to participate in MIPS to voluntarily report on applicable measures and activities for MIPS. The data received will not be used to assess performance for the purpose of the MIPS payment adjustment; however, these clinicians will have the opportunity to access feedback on their submitted MIPS data. We agree that the two outcome measures within the mental/behavioral health specialty measure set do require the utilization of the PHQ–9 to measure the depression outcome; however, we disagree with the commenter as this is not restricted to EHR and available by MIPS CQMs Specification.

Comment: One commenter recommended that we adopt a standard definition of a Quality Payment Program eligible provider, eligible clinician and/or an eligible professional as it continues to expand the list of eligible clinicians. The commenter recommended the word ''physician'' be replaced with provider and/or clinician, stating that this terminology better reflects the collaboration of the current inter-professional healthcare team.

Response: We understand the commenter to be suggesting that we unify the definitions of eligible clinician and MIPS eligible clinician. While we agree that a unified definition might have certain benefits, we believe that two separate definitions are necessary as the two tracks of the Quality Payment Program (MIPS and APM) have distinctly different requirements for participation and the term eligible clinicians reflects, a broader set of clinician types than the term MIPS eligible clinicians. We note that both terms already refer to clinicians.

Comment: Some commenters stated that inclusion of these additional eligible clinicians in the program with just two months' notice is overly burdensome and would ultimately prove counterproductive. One commenter stated that because of the limited scope of MIPS reporting that is applicable to these specialties, we should carefully evaluate whether the expense and added burden of reporting for these specialties is commensurate with the benefits. Another commenter noted that these clinicians tend to have a high patient turnover rate, which could make certain measures challenging. Several commenters opposed expanding the definition of eligible clinician to the proposed clinician types, stating that the clinician types do not, as a general rule, encompass the same types of workflows as current MIPS eligible clinicians, and, therefore, adding these clinicians could increase the cost, time, and effort for reporting and documentation. Many commenters requested we create ramp-up policies for the additional eligible clinicians, such as a pick-your-pace approach or a 1-year delayed effective date. Likewise, a few commenters requested that we allow the additional clinicians to opt-in for the first year in which they are eligible to participate. A few commenters requested that we consider a one-time bonus payment for voluntary reporting, and requested modified quality benchmarks, performance thresholds, reporting requirements, and data completeness requirements.

Response: We acknowledge that adding these additional clinicians will require some adaptation to the current systems and processes and will take careful consideration by measure stewards to determine the appropriateness of adding clinician encounters to align with measure intent. However, we believe the benefits outweigh the costs as these clinicians are an integral part of the health care delivery team. We believe that all eligible clinicians benefit from participation in quality reporting under MIPS and help reach one of our strategic objectives to improve beneficiary outcomes and engage and empower consumers by providing healthcare information useful for driving value and making healthcare decisions. Regarding measures that are considered challenging, the additional clinicians should choose measures and activities that are applicable and meaningful to them. As noted in the proposed rule (83 FR 35884), the MIPS program is still ramping up, and we will continue to increase the performance threshold to ensure a gradual and incremental transition to the performance threshold that will be used in the Quality Payment Program Year 6. Therefore, if specified as MIPS eligible clinicians beginning with the 2021 MIPS payment year, the additional eligible clinicians would have 4 years in the program in order to ramp up. Conversely, if specified as MIPS eligible clinicians beginning in a future year, they would be afforded less time to ramp up the closer the program gets to Quality Payment Program Year 6. In addition, for the first 2 years of MIPS, clinicians who are not MIPS eligible had the opportunity to voluntarily report to become familiar with MIPS measures and reporting. For these reasons, we do not believe we should adopt policies such as those suggested by the commenters. We note that additional eligible clinicians that exceed at least one, but not all, of the low-volume threshold criteria will have the opportunity to opt-in to participate in MIPS as discussed in section III.I.3.c.(5) of this final rule. We do not agree with offering a one-time bonus payment for voluntary reporting as section 1848(q)(1)(C)(vi) of the Act precludes the application of a MIPS adjustment factor (or additional MIPS adjustment factor) to an individual who is not a MIPS eligible clinician. Finally, as these additional clinicians will be defined as MIPS eligible clinicians, they will be subject to the same requirements as other MIPS eligible clinicians, including quality benchmarks, performance thresholds, reporting requirements, and data completeness requirements.

Comment: Several commenters requested that we provide targeted education on program requirements to additional eligible clinicians. Specifically, the commenters urged us to provide compliance support to small practices, by creating an industry pathway to EHR reporting. A few commenters requested that we convene a Technical Expert Panel (TEP) comprised of individuals representing the additional eligible clinician types to inform adaptation of the Quality Payment Program to meet their needs.

Response: We have consistently provided targeted education on program requirements in the past and intend to continue doing so through various means including: Webinars, national provider calls, virtual office hours, speaking engagements, and tailored educational resources for the additional clinicians. No cost technical assistance is also available by contacting the Quality Payment Program Service Center by phone at 1–866–288–8292, (TTY) 1–877–715–6222 or by email at *QPP@cms.hhs.gov*. We will also continue to support small and rural

practices by offering free and customized resources available within local communities, including direct, one-on-one support from the Small, Underserved, and Rural Support Initiative along with our other no-cost technical assistance. We appreciate the suggestion to convene a TEP comprised of the additional clinicians. We will continue to explore additional opportunities for this type of engagement in the future.

Comment: Many commenters noted their concern regarding whether the Quality Payment Program could be utilized for these new clinician types, asking us to consider if these clinicians are able to meet MIPS reporting requirements across all performance categories before expanding the list of MIPS-eligible clinicians. Specifically, some commenters stated that the Promoting Interoperability performance category would be difficult to meet without a change in meaningful use guidelines, noting that because these clinicians rarely bill the clinician group directly and may not be integrated with the clinician group's EHR, interoperability remains a material issue. These commenters requested that we weight the Promoting Interoperability performance category at zero percent or allow new eligible clinicians to opt-in to this performance category. Another commenter requested clarification on whether the proposal to automatically assign a zero percent weighting for the Promoting Interoperability performance category for these new types of MIPS eligible clinicians applies to both individual clinicians and groups. Another commenter asked for clarification regarding if they could continue to report as a group. One commenter questioned whether the additional clinicians would be removed from the denominator for these measures. Other commenters asked for clarification on how quality measures will be captured as most of these clinicians may not have electronic medical records (EMRs).

Response: In the CY 2019 PFS proposed rule (83 FR 35883 through 35884) to assess whether these additional eligible clinicians could successfully participate in MIPS, we evaluated whether there would be sufficient measures and activities applicable and available for each of the additional eligible clinician types. We did not focus on the Promoting Interoperability performance category because for CY 2019 we are finalizing to automatically assign a zero percent weighting for the Promoting Interoperability performance category which will be reweighted to the quality performance category for these new types of MIPS eligible clinicians. In response to the comment, the proposal to automatically assign a zero percent weighting for the Promoting Interoperability performance category does apply to both individual clinicians and groups. Clinicians may choose to report for MIPS as an individual or as part of a group. If the clinician chooses to report as part of a group, then under the policy we established previously (82 FR 53687), all of the MIPS eligible clinicians in the group must qualify for a zero percent weighting in order for the Promoting Interoperability performance category to be reweighted in the final score. We refer readers to section III.I.3.h.(5)(h)(ii) of this final rule for further details on the policy that we are finalizing in this rule to automatically assign a zero percent weighting for the Promoting Interoperability performance category. Regarding data submission requirements for quality measures, the additional eligible clinicians may submit their quality data through the same data collection types available to all MIPS eligible clinicians including eCQMs, MIPS Clinical Quality Measures (MIPS CQMs), QCDR measures, Medicare Part B claims measures, CMS Web Interface measures, the CAHPS for MIPS survey, and administrative claims measures which may be submitted via one of the submission types including: Direct; log in and upload; log in and attest; Medicare Part B claims; and the CMS Web Interface. We refer readers to section III.I.3.h.(1) in this final rule for further information regarding performance category measures and reporting.

Comment: A few commenters requested that we be certain that we are operationally prepared to support reporting and scoring for the additional eligible clinician types, as clinicians have experienced operational data submissions issues in the past.

Response: We intend to have our Quality Payment Program portal ready to accept and process data for all MIPS eligible clinicians for 2021 MIPS payment year.

Comment: Several commenters requested clarification on how our proposal would apply to eligible clinicians billing under a hospital- or facility-based TIN. A few commenters stated that the rule does not indicate whether hospitals should report the NPI of these clinicians on the UB–04 claims used by hospitals and cautioned that adding these clinician types to UB–04 claims would entail significant administrative burden to hospitals. One commenter also stated that the majority of facility-based outpatient therapy claims do not contain the rendering NPI and usually contain just a facility NPI; therefore, most facility-based outpatient therapy claims will not be eligible for MIPS. A few commenters said that due to a technicality in how facility-based claims (such as those submitted by inpatient rehabilitation facilities) are submitted, only independently rendered, private practice outpatient therapy services will be included in MIPS, and facility-based outpatient therapy will generally not be included. One commenter recommended that we operationalize the inclusion of facility-based clinicians in MIPS by treating the facility NPI as a MIPS-participating NPI and allow the facility to report measures under MIPS like a group. Another commenter argued that facility-based outpatient therapy clinicians should be included in the program. A few commenters sought clarification of how clinicians of therapy services in skilled-nursing facilities will be treated, stating that assessing individual clinicians for quality and adjusting payment poses unique challenges in this setting.

Response: These additional clinicians will be defined as MIPS eligible clinicians and will be subject to the same requirements as other MIPS eligible clinicians billing under a hospital- or facility-based TIN. MIPS eligible clinician may report as an individual or as part of a group. We finalized at § 414.1380(e)(2)(i) and (ii) the determination of a facility-based individual and facility-based group. A facility-based individual is a MIPS eligible clinician that furnishes 75 percent or more of his or her covered professional services in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital or emergency room setting based on claims for a period prior to the performance period as specified by CMS. A facility-based group is a group in which 75 percent or more of its eligible clinician NPIs billing under the group's TIN meet the facility-based individual determination. Therefore, if a MIPS eligible clinician is submitting their data as part of a facility-based group their NPI number would need to be annotated on the claim which is part of normal billing practices. We refer readers to section III.I.3.h.(2)(a)(iv) of this final rule for further details regarding the application of facility-based measures. The definition of a hospital-based clinician finalized at § 414.1410 is primarily applicable to the Promoting Interoperability performance category. We refer readers to the CY 2018 Quality Payment Program final rule (82 FR

53684) for details on a hospital-based clinician. We are aware that facility-based outpatient therapy and skilled nursing facility claims do not contain the rendering NPI and usually contain just a facility NPI; therefore, facility-based outpatient therapy and skilled nursing facility claims will not be eligible for MIPS. For those billed Medicare Part B allowed charges we are able to associate with a MIPS eligible clinician at an NPI level, such covered professional services furnished by such clinicians would be included for purposes of applying any MIPS payment adjustment. It is our intention to provide clinicians with their eligibility status prior to the performance period through the Quality Payment Program portal eligibility determination tool. This should allow clinicians to know ahead of time whether they are included in MIPS or not. We will take these comments into consideration in future rulemaking.

Comment: A few commenters noted that adding physical and occupational therapists would affect the determination of practice size. One commenter expressed concern that groups may lose their small group status even though the composition of the practice did not change.

Response: We do not anticipate that the small practice size determination will be affected by adding additional clinicians to the definition of MIPS eligible clinician. Small practice is defined at § 414.1305 to mean a practice consisting of 15 or fewer eligible clinicians. Thus, the definition of small practice already accounts for all eligible clinicians in the practice, including those that we are adding to the definition of MIPS eligible clinician.

Comment: One commenter requested clarification regarding how the additional MIPS eligible clinicians would be subject to payment reductions if they do not meet the performance requirements under MIPS.

Response: The additional eligible clinicians, who are not otherwise excluded, will be included in the performance requirements for a MIPS eligible clinician for CY 2021 payment year. In addition, MIPS eligible clinicians are subject to the MIPS payment adjustment factor. Clinicians who are considered MIPS eligible and who do not report under MIPS may receive a final score of zero and an associated negative payment adjustment of 7 percent during the CY 2021 payment year.

Comment: Some commenters stated that the additional clinician types could water down the performance pool, and increasing the number of participants will create increased competition for an additional performance threshold, making it more difficult for disadvantaged clinicians to meaningfully participate in MIPS.

Response: Although the number of MIPS eligible clinicians will increase, we do not anticipate that the additional clinicians will substantially change the total number of MIPS eligible clinicians or make it more difficult for other clinicians to meaningfully participate in MIPS. Regarding the additional performance threshold, we note that the eligible clinician must first qualify for the additional performance threshold for exceptional performance. We do not believe that the addition of new clinician types to be MIPS eligible implies they are going to perform at a level that qualifies for the additional performance threshold. We refer readers to Table 98 in section VII (Regulatory Impact Analysis) of this final rule for information regarding the impact of expanding the definition of MIPS eligible clinicians on the total number of MIPS eligible clinicians and the total estimated PFS amount paid.

Comment: One commenter believed it was unnecessary to include the proposed additional eligible clinicians as they would more than likely be ineligible because they would fall below the low-volume threshold.

Response: We understand that some of the additional eligible clinicians may not exceed the low-volume threshold. However, as discussed in section III.I.3.c.(5) of this final rule, we are also finalizing an opt-in option that will allow eligible clinicians to opt-in to MIPS if the eligible clinician or group meets or exceeds at least one, but not all, of the low-volume threshold criteria. In addition, MIPS eligible clinicians may participate in MIPS as part of a group or virtual group which should improve their ability to exceed the low-volume threshold. We believe this option would allow the additional eligible clinicians the opportunity to participate in MIPS if they desired to do so.

Comment: Several commenters suggested that there is misalignment between the proposed expanded list of eligible clinician types for the MIPS and the scope of clinician types for the Advanced Alternative Payment Model path under the Quality Payment Program. Specifically, a few commenters noted that, currently, a number of clinician types (for example, clinical psychologists and certified nurse midwives) could be in an Advanced APM, but that we are proposing to include clinician types for MIPS that may not be eligible for the Advanced APM path under the Quality Payment Program. Thus, commenters suggested that we standardize the included clinician types across the Quality Payment Program unless there are appropriate clinical reasons for differences. One commenter requested clarification as to whether physical, occupational, and speech therapists, as eligible clinicians, can participate in the Advanced APMs path under the Quality Payment Program. Another commenter requested that we provide guidance on how APM entities, ACOs, and other health care organizations should identify these clinician types on their clinician participation lists.

Response: We note that the proposed expanded list of eligible clinician types for the MIPS is not misaligned with the scope of eligible clinicians for the Advanced APMs path under the Quality Payment Program. In accordance with section 1848(q)(1)(C)(i)(I) of the Act, we defined MIPS eligible clinician for the 2019 and 2020 MIPS payment years to include only physicians (as defined under section 1861(r) of the Act), physician assistants, nurse practitioners, clinician nurse specialists, and certified registered nurse anesthetists (and groups that include these clinicians). In contrast, we explained in the CY 2017 Quality Payment Program final rule (81 FR 77405 through 77406), for the Advanced APM path under the Quality Payment Program, the term ''eligible clinician'' is defined in section 1833(z)(3)(B) of the Act (by cross-reference to the definition of ''eligible professional'' in section 1848(k)(3)(B) of the Act), and includes: Physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, clinical psychologists, registered dietitians or nutrition professionals, physical or occupational therapists, qualified speech-language pathologists, and qualified audiologists, and a group that includes these professionals. Our proposed expansion of the list of MIPS eligible clinician types would actually align with the current scope of eligible clinicians under the Advanced APM path of the Quality Payment Program. Currently, any of those eligible clinicians who participate sufficiently in Advanced APMs can become QPs for a year and receive the associated APM Incentive Payment. We note that each APM has its own focus, and many offer participation opportunities for a broad scope of eligible clinicians. Although the design of existing or future APMs is beyond the scope of this final rule, we welcome ideas on how to further engage

the full scope of eligible clinicians as we work hard to develop more APM opportunities. Additionally, we finalized in the CY 2017 Quality Payment Program final rule (81 FR 77442) that the eligible clinicians for whom we would make QP determinations would be all the eligible clinicians participating in an APM Entity in an Advanced APM, as identified at each of three snapshot dates, during a QP Performance Period. The eligible clinicians for whom we make QP determinations are those identified on an Advanced APM's Participation List or Affiliated Practitioner List on one of those three dates. Lastly, we note that decisions about the eligible clinicians that are included on the Participation List or Affiliated Practitioner List for any particular Advanced APM are made based on the specific terms and conditions of the Advanced APM, which can vary based on the model test, entities involved, payment arrangements, and other factors.

After consideration of the public comments received, we are finalizing a modification of our proposal to amend § 414.1305 to revise the definition of a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, to mean any of the following (excluding those identified at § 414.1310(b)): A physician (as defined in section 1861(r) of the Act); a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); beginning with the 2021 MIPS payment year, a physical therapist, occupational therapist, qualified speech-language pathologist; qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act); clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act); and registered dietician or nutrition professional; and a group that includes such clinicians.

b. MIPS Determination Period

As discussed in the proposed rule (83 FR 35884 through 35886), currently MIPS uses various determination periods to identify certain MIPS eligible clinicians for consideration for certain applicable policies. For example, the low-volume threshold, non-patient facing, small practice, hospital-based, and ambulatory surgical center (ASC)-based determinations are on the same timeline with slight differences in the claims run-out policies, whereas the facility-based determinations has a slightly different determination period. The virtual group eligibility determination requires a separate election process. We proposed to add a virtual group eligibility determination period beginning in CY 2020 as discussed in section III.I.3.f.(2)(a) of this final rule. In addition, the rural and HPSA determinations do not utilize a determination period.

Under § 414.1305, the low-volume threshold determination period is described as a 24-month assessment period consisting of an initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding the performance period, and a second 12-month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible clinician or group that is identified as not exceeding the low-volume threshold during the initial 12-month segment will continue to be excluded under § 414.1310(b)(1)(iii) for the applicable year regardless of the results of the second 12-month segment analysis. For the 2020 MIPS payment year and future years, each segment of the low-volume threshold determination period includes a 30-day claims run out.

Under § 414.1305, the non-patient facing determination period is described as a 24-month assessment period consisting of an initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding the performance period and a second 12-month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible MIPS clinician, group, or virtual group that is identified as non-patient facing during the initial 12-month segment will continue to be considered non-patient facing for the applicable year regardless of the results of the second 12-month segment analysis. For the 2020 MIPS payment year and future years, each segment of the non-patient facing determination period includes a 30-day claims run out.

In the CY 2018 Quality Payment Program final rule (82 FR 53581), we finalized that for the small practice size determination period, we would utilize a 12-month assessment period, which consists of an analysis of claims data that spans from the last 4 months of a calendar year 2 years prior to the performance period followed by the first 8 months of the next calendar year and includes a 30-day claims run out.

In the CY 2017 Quality Payment Program final rule (81 FR 77238 through 77240), we finalized that to identify a MIPS eligible clinician as hospital-based we would use claims with dates of service between September 1 of the calendar year 2 years preceding the performance period through August 31 of the calendar year preceding the performance period, but in the event it is not operationally feasible to use claims from this time period, we would use a 12-month period as close as practicable to this time period.

In the CY 2018 Quality Payment Program final rule (82 FR 53684 through 53685), we finalized that to identify a MIPS eligible clinician as ASC-based, we would use claims with dates of service between September 1 of the calendar year 2 years preceding the performance period through August 31 of the calendar year preceding the performance period, but in the event it is not operationally feasible to use claims from this time period, we would use a 12-month period as close as practicable to this time period.

In the CY 2018 Quality Payment Program final rule (82 FR 53760), we discussed, but did not finalize, our proposal or the alternative option for how an individual clinician or group would elect to use and be identified as using facility-based measurement for the MIPS program. Because we were not offering facility-based measurement until the 2019 MIPS performance period, we did not need to finalize either of these for the 2018 MIPS performance period. However, as discussed in section III.I.3.i.(1)(d) of this final rule, we proposed to amend § 414.1380(e)(2)(i)(A) to specify a criterion for a clinician to be eligible for facility-based measurement. Specifically, that is, the clinician furnishes 75 percent or more of his or her covered professional services in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, or emergency room setting based on claims for a 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period with a 30-days claims run out. We did not propose to utilize the MIPS determination period for purposes of the facility-based determination because for the facility-based determination, we are only using the first segment of the MIPS determination period. We are using the

first segment because the performance period for measures in the hospital value-based purchasing program overlapped in part with that determination period. If we were to use the second segment, we could not be assured that the clinician actually worked in the hospital on which their MIPS score would be based during that time. We believe this approach provides clarity and is a cleaner than providing a special exception for the facility-based determination in the MIPS determination period for the second segment. We refer readers to section III.I.3.i.(1)(d) for further details on the facility-based determinations and the time periods that are applicable to those determinations.

In the CY 2018 Quality Payment Program final rule (82 FR 53602 through 53604), we finalized that for the virtual group eligibility determination period, we would utilize an analysis of claims data during an assessment period of up to 5 months that would begin on July 1 and end as late as November 30 of the calendar year prior to the applicable performance period and include a 30-day claims run out. To capture a real-time representation of TIN size, we finalized that we would analyze up to 5 months of claims data on a rolling basis, in which virtual group eligibility determinations for each TIN would be updated and made available monthly. We noted that an eligibility determination regarding TIN size is based on a relative point in time within the 5-month virtual group eligibility determination period, and not made at the end of such 5-month determination period. Beginning with the 2019 performance period, we proposed to amend § 414.1315(c)(1) to establish a virtual group eligibility determination period to align with the first segment of the MIPS determination period, which includes an analysis of claims data during a 12-month assessment period (fiscal year) that would begin on October 1 of the calendar year 2 years prior to the applicable performance period and end on September 30 of the calendar year preceding the applicable performance period and include a 30-day claims run out. We refer readers to section III.I.3.f.(2)(a) of this final rule for further details on this proposal.

In addition, we have established other special status determinations, including rural area and HPSA. Rural area is defined at § 414.1305 as a ZIP code designated as rural, using the most recent Health Resources and Services Administration (HRSA) Area Health Resource File data set available. HPSAs are defined at § 414.1305 as areas designated under section 332(a)(1)(A) of the Public Health Service Act.

We understand that the current use of various MIPS determination periods is complex and causes confusion. Therefore, beginning with the 2021 MIPS payment year, we proposed to consolidate several of these policies into a single MIPS determination period that would be used for purposes of the low-volume threshold and to identify MIPS eligible clinicians as non-patient facing, a small practice, hospital-based, and ASC-based, as applicable. We did not propose to include the facility-based or virtual group eligibility determination periods or the rural and HPSA determinations in the MIPS determination period, as they each require a different process or timeline that does not align with the other determination periods, or do not utilize determination periods. We invited public comments on the possibility of incorporating these determinations into the MIPS determination period in the future.

There are several reasons we believe a single MIPS determination period for most of the eligibility criteria is the most appropriate. First, it would simplify the program by aligning most of the MIPS eligibility determination periods. Second, it would continue to allow us to provide eligibility determinations as close to the beginning of the performance period as feasible. Third, we believe a timeframe that aligns with the fiscal year is easier to communicate and more straightforward to understand compared to the current determination periods. Finally, it would allow us to extend our data analysis an additional 30 days.

It is important to note that during the final 3 months of the calendar year in which the performance period occurs, in general, we do not believe it would be feasible for many MIPS eligible clinicians who join an existing practice (existing TIN) or join a newly formed practice (new TIN) to participate in MIPS as individuals. We refer readers to section III.I.3.i.(2)(b) of this final rule for more information on the proposed reweighting policies for MIPS eligible clinicians who join an existing practice or who join a newly formed practice during this timeframe.

We requested comments on our proposal that beginning with the 2021 MIPS payment year, the MIPS determination period would be a 24-month assessment period including a two-segment analysis of claims data consisting of: (1) An initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period; and (2) a second 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs. The first segment would include a 30-day claims run out. The second segment would not include a claims run out, but would include quarterly snapshots for informational use only, if technically feasible. For example, a clinician could use the quarterly snapshots to understand their eligibility status between segments. Specifically, we believe the quarterly snapshots would be helpful for new TIN/NPIs and TINs created between the first segment and the second segment allowing them to see their preliminary eligibility status sooner. Without the quarterly snapshots, these clinicians would not have any indication of their eligibility status until just before the submission period. An individual eligible clinician or group that is identified as not exceeding the low-volume threshold, or a MIPS eligible clinician that is identified as non-patient facing, a small practice, hospital-based, or ASC-based, as applicable, during the first segment would continue to be identified as such for the applicable MIPS payment year regardless of the second segment. For example, for the 2021 MIPS payment year, the first segment would be October 1, 2017 through September 30, 2018, and the second segment would be October 1, 2018 through September 30, 2019. However, based on our experience with the Quality Payment Program, we believe that some eligible clinicians, whose TIN or TIN/NPIs are identified as eligible during the first segment and do not exist in the second segment, are no longer utilizing these same TIN or TIN/NPI combinations. Therefore, because those TIN or TIN/NPIs would not exceed the low-volume threshold in the second segment, they would no longer be eligible for MIPS. For example, in the 2019 performance period a clinician exceeded the low-volume threshold during the first segment of the determination period (data from the end of CY 2017 to early 2018) under one TIN; then in CY 2019 the clinician switches practices under a new TIN and during segment two of the determination period. Therefore, it is determined that the clinician is not eligible (based on CY 2019 data) under either TIN. This clinician would not be eligible to participate in MIPS based on either segment of the determination

period because the TIN that was assessed for the first segment of the determination period no longer exists. So there are no charges or services that would be available to assess in the second segment for that TIN and the new TIN assessed during the second segment was not eligible. In this scenario, though the clinician exceeded the low-volume threshold criteria initially, the clinician is not required to submit any data based on TIN eligibility determinations. However, it is important to note that if a TIN or TIN/NPI did not exist in the first segment but does exist in the second segment, these eligible clinicians could be eligible for MIPS. For example, the eligible clinician may not find their TIN or TIN/NPI in the Quality Payment Program lookup tool but may still be eligible if they exceed the low-volume threshold in the second segment. We proposed to incorporate this policy into our proposed definition of MIPS determination period at § 414.1305. We also requested comments on our proposals to define MIPS determination period at § 414.1305 and modify the definitions of low-volume threshold, non-patient facing, a small practice, hospital-based, and ASC-based at § 414.1305 to incorporate references to the MIPS determination period.

The following is a summary of the public comments received on our proposals and our responses:

Comment: Several commenters supported our proposal, noting that the varying determination periods add unnecessary confusion and this policy would reduce complexity. One commenter recommended we continue our efforts to align the determination period with facility-based, virtual groups, and rural and HPSA eligibility determinations.

Response: We appreciate the commenters' support.

Comment: Some commenters stated that in order for clinicians to successfully perform over a 12-month period for the cost and quality performance categories, the clinician must know before the start of the performance period their full eligibility status for MIPS.

Response: We understand that it is important for clinicians to know their eligibility status prior to the performance period. It is our intention to provide eligibility determinations as close to the beginning of the performance period as feasible. We would like to assure commenters that we are working diligently to provide clinicians with this information at the earliest time possible.

Comment: A few commenters supported using quarterly snapshots for the second segment of the MIPS determination period to show preliminary eligibility status. One commenter recommended that the first quarterly snapshot for the second segment be mandated to be available in the look-up tool no later than January 1, 2019, the first day of the CY 2019 performance period. One commenter recommended that if a clinician does not exceed the low-volume threshold during the quarterly snapshots, then they should be automatically excluded from MIPS unless further snapshots allow for an opt-in similar to the proposed low-volume threshold opt-in policy.

Response: While the statute does not require the use of quarterly snapshots, we believe the snapshots may provide useful information for eligible clinicians. Therefore, we are working to provide the quarterly snapshots, if feasible. In addition, it is important to note that the quarterly snapshots are being provided for informational use only and are not final until after the second segment of the MIPS determination period closes and a reconciliation between the segments occurs. Since the quarterly snapshots are not final this information is subject to change and should not be considered the final eligibility determination. The eligibility determination will be made after a reconciliation of the first and second segment of the MIPS determination period.

Comment: Several commenters did not support the proposed 24-month MIPS determination period, with most arguing for a single determination period. These commenters recommended that the MIPS determination period be a single, 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs. Another commenter stated that a preliminary assessment for the exclusions would be useful, but the final decision should be made only based on performance period data. One commenter stated that the two segments lead to confusion and uncertainty about participation status and requested that the second segment have an end date and notification date prior to the start of the performance year. Another commenter opposed the shift in determination period dates unless the eligibility tool on the Quality Payment Program website is updated in a timely fashion prior to the performance year.

Response: If we had a singular eligibility determination period we would not be able to identify eligible clinicians who switch practices between the first and second segments of the MIPS determination period. We estimate that this would affect approximately 13 percent of MIPS eligible clinicians who may switch practices between the first and second determination periods. If we did not conduct the first segment analyses then there would be no way to inform clinicians of their eligibility status prior to the performance period. The second segment accounts for the identification of additional, previously unidentified individual eligible clinicians and groups who do not exceed the low-volume threshold or meet other special circumstances. It is our intention that the eligibility tool on the Quality Payment Program website will be updated to provide eligibility determinations prior to the start of the performance period.

Comment: A few commenters noted the challenge for clinicians who exceeded the low-volume threshold during the first segment of the MIPS determination period and then discovered late in the performance period, after the second segment of the MIPS determination period that they are no longer eligible. One commenter suggested that if a clinician exceeds the low-volume threshold during the second segment of MIPS eligibility determination period, the clinician should remain excluded unless the clinician opts-in. One commenter noted that these issues may be less of a problem if the opt-in proposal is finalized. Another commenter requested the definition of the MIPS determination period be expanded to account for scenarios when an eligible clinician or group exceeded the low-volume threshold during the first segment but falls below the low-volume threshold during the second segment or when a eligible clinician or group is not categorized as a special status (such as non-patient facing) during the first segment but gains special status during the second segment.

Response: We agree that the issues identified by the commenters may be alleviated with the opt-in policy. If an eligible clinician finds out following the second segment of the MIPS determination period that they are no longer eligible to participate in MIPS and they meet the requirements of the opt-in policy they may choose to participate in MIPS by opting-in to MIPS. Regarding changing statuses between the two segments of the MIPS determination period, we are finalizing

the definition of the MIPS determination period at § 414.1305(2) that subject to § 414.1310(b)(1)(iii), an individual eligible clinician or group that is identified as not exceeding the low-volume threshold or as having special status during the first segment of the MIPS determination period will continue to be identified as such for the applicable MIPS payment year regardless of the results of the second segment of the MIPS determination period. An individual eligible clinician or group for which the unique billing TIN and NPI combination is established during the second segment of the MIPS determination period will be assessed based solely on the results of that segment. While we would like to ensure that there is as much flexibility as possible within the MIPS program, we believe it is important that MIPS eligible clinicians choose how they will participate in MIPS as a whole, either as an individual or as a group. Whether MIPS eligible clinicians participate in MIPS as an individual or group, it is critical for us to assess the performance of individual MIPS eligible clinicians or groups across the four performance categories collectively as either an individual or group in order for the final score to reflect performance at a true individual or group level and to ensure the comparability of data.

After consideration of the public comments received, we are finalizing our proposal to define MIPS determination period at § 414.1305 beginning with the 2021 MIPS payment year, as a 24-month assessment period including a two-segment analysis of claims data consisting of: (1) An initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period; and (2) a second 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs. The first segment would include a 30–day claims run out. The second segment would not include a claims run out, but would include quarterly snapshots for informational use only, if technically feasible. In addition, we are finalizing that subject to § 414.1310(b)(1)(iii), an individual eligible clinician or group that is identified as not exceeding the low-volume threshold or as having special status during the first segment of the MIPS determination period will continue to be identified as such for the applicable MIPS payment year regardless of the results of the second segment of the MIPS determination period. An individual eligible clinician or group for which the unique billing TIN and NPI combination is established during the second segment of the MIPS determination period will be assessed based solely on the results of that segment. Finally, at § 414.1305 we are finalizing our proposal to modify the definitions of low-volume threshold, non-patient facing MIPS eligible clinician, a small practice, hospital-based MIPS eligible clinician, and ASC-based MIPS eligible clinician at § 414.1305 to incorporate references to the MIPS determination period.

c. Low-Volume Threshold

(1) Overview

As discussed in the CY 2019 PFS proposed rule (83 FR 35886), section 1848(q)(1)(C)(iv) of the Act, as amended by section 51003(a)(1)(A)(ii) of the Bipartisan Budget Act of 2018, provides that, for performance periods beginning on or after January 1, 2018, the low-volume threshold selected by the Secretary may include one or more or a combination of the following (as determined by the Secretary): (1) The minimum number of part B-enrolled individuals who are furnished covered professional services (as defined in section 1848(k)(3)(A) of the Act) by the eligible clinician for the performance period involved; (2) the minimum number of covered professional services furnished to part B-enrolled individuals by such clinician for such performance period; and (3) the minimum amount of allowed charges for covered professional services billed by such clinician for such performance period.

Under § 414.1310(b)(1)(iii), for a year, eligible clinicians who do not exceed the low-volume threshold for the performance period with respect to a year are excluded from MIPS. Under § 414.1305, the low-volume threshold is defined as, for the 2019 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician or group that, during the low-volume threshold determination period, has Medicare Part B allowed charges less than or equal to $30,000 or provides care for 100 or fewer Part B-enrolled Medicare beneficiaries. In addition, for the 2020 MIPS payment year and future years, the low-volume threshold is defined as the low-volume threshold that applies to an individual eligible clinician or group that, during the low-volume threshold determination period, has Medicare Part B allowed charges less than or equal to $90,000 or provides care for 200 or fewer Part B-enrolled Medicare beneficiaries. The low-volume threshold determination period is a 24-month assessment period consisting of: (1) An initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding the performance period; and (2) a second 12-month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible clinician or group that is identified as not exceeding the low-volume threshold during the initial 12-month segment will continue to be excluded under § 414.1310(b)(1)(iii) for the applicable year regardless of the results of the second 12-month segment analysis. For the 2019 MIPS payment year, each segment of the low-volume threshold determination period includes a 60-day claims run out. For the 2020 MIPS payment year, each segment of the low-volume threshold determination period includes a 30-day claims run out.

(2) Amendments To Comply With the Bipartisan Budget Act of 2018

In the CY 2019 PFS proposed rule (83 FR 35887), we proposed to amend § 414.1305 to modify the definition of low-volume threshold in accordance with section 1848(q)(1)(C)(iv) of the Act, as amended by section 51003(a)(1)(A)(ii) of the Bipartisan Budget Act of 2018. Specifically, we requested comments on our proposals that for the 2020 MIPS payment year, we will utilize the minimum number (200 patients) of Part B-enrolled individuals who are furnished covered professional services by the eligible clinician or group during the low-volume threshold determination period or the minimum amount ($90,000) of allowed charges for covered professional services to Part B-enrolled individuals by the eligible clinician or group during the low-volume threshold determination period.

The following is a summary of the public comments received on our proposals and our responses:

Comment: A few commenters supported the technical amendments passed by Congress in the Bipartisan Budget Act of 2018, specifically noting support for the proposal to not use Part B drugs for the low-volume threshold determinations, and to rely instead on covered professional services (instead of all Medicare Part B items and services) to determine MIPS eligibility. Other commenters supported that items or services beyond the PFS, especially Part B drugs, would not be subject to the

MIPS payment adjustment factor or the MIPS additional payment adjustment factor.

Response: We appreciate the commenters' support.

Comment: One commenter expressed concern about using covered professional services for low-volume threshold determinations because it could make it difficult for eligible clinicians and groups to predict whether they are subject or excluded from MIPS. Additionally, the commenter recommended that we provide timely notification based on the results of the first determination period.

Response: We understand that utilizing covered professional services rather than all Medicare Part B items and services is a different approach to calculating the low-volume threshold. For the CY 2018 and CY 2019 MIPS payment years, we have utilized two calculations in order to make low-volume threshold determinations: The number of patients and the amount of allowed charges for each eligible clinician or group. These calculations were based on the patients who were furnished any Part B item or service, and on the allowed charges for all Part B items and services. Beginning for the 2020 MIPS payment year, the calculations will instead be based only on covered professional services. A clinician may identify and monitor a claim to distinguish covered professional services from Part B items and services by calculating one professional claim line with positive allowed charges to be considered one covered professional service. In addition, we believe the quarterly snapshots will be helpful for new TIN/NPIs and TINs created between the first segment and the second segment allowing them to see their preliminary eligibility status sooner. In addition, we believe these policies will allow clinicians to understand their eligibility determination as close to the beginning of the performance period as feasible.

After consideration of the public comments received, we are finalizing our proposal to amend § 414.1305 to modify the definition of low-volume threshold to mean for the 2020 MIPS payment year, we will utilize the minimum number (200 patients) of Part B-enrolled individuals who are furnished covered professional services by the eligible clinician or group during the low-volume threshold determination period or the minimum amount ($90,000) of allowed charges for covered professional services to Part B-enrolled individuals by the eligible clinician or group during the low-volume threshold determination period.

(3) MIPS Program Details

In the CY 2019 PFS proposed rule (83 FR 35887), we requested comments on our proposal to modify § 414.1310 to specify in paragraph (a), Program Implementation, that except as specified in paragraph (b), MIPS applies to payments for covered professional services furnished by MIPS eligible clinicians on or after January 1, 2019. We also requested comments on our proposal to revise § 414.1310(b)(1)(ii) to specify that for a year, a MIPS eligible clinician does not include an eligible clinician that is a Partial Qualifying APM Participant (as defined in § 414.1305) and does not elect, as discussed in section III.I.4.e. of this final rule, to report on applicable measures and activities under MIPS. Finally, we requested comments on our proposal to revise § 414.1310(d) to specify that, in no case will a MIPS payment adjustment factor (or additional MIPS payment adjustment factor) apply to payments for covered professional services furnished during a year by eligible clinicians (including those described in paragraphs (b) and (c) of this section) who are not MIPS eligible clinicians, including those who voluntarily report on applicable measures and activities under MIPS.

We did not receive any comments regarding these proposals.

We are finalizing our proposal to modify § 414.1310 to specify in paragraph (a), Program Implementation, that except as specified in paragraph (b), MIPS applies to payments for covered professional services furnished by MIPS eligible clinicians on or after January 1, 2019. We are also finalizing our proposal to revise § 414.1310(b)(1)(ii) to specify that for a year, a MIPS eligible clinician does not include an eligible clinician that is a Partial Qualifying APM Participant (as defined in § 414.1305) and does not elect, as discussed in section III.I.4.e. of this final rule, to report on applicable measures and activities under MIPS. Finally, we are finalizing our proposal to revise § 414.1310(d) to specify that, in no case will a MIPS payment adjustment factor (or additional MIPS payment adjustment factor) apply to payments for covered professional services furnished during a year by eligible clinicians (including those described in paragraphs (b) and (c) of this section) who are not MIPS eligible clinicians, including those who voluntarily report on applicable measures and activities under MIPS.

(4) Addition of Low-Volume Threshold Criterion Based on Number of Covered Professional Services

In the CY 2018 Quality Payment Program final rule (82 FR 53591), we received several comments in response to the proposed rule regarding adding a third criterion of items and services for defining the low-volume threshold. We refer readers to that rule for further details.

As discussed in the CY 2019 PFS proposed rule (83 FR 35887) for the 2021 MIPS payment year and future years, we proposed to add one additional criterion to the low-volume threshold determination—the minimum number of covered professional services furnished to Part B-enrolled individuals by the clinician. Specifically, we requested comments on our proposal, for the 2021 MIPS payment year and future years, that eligible clinicians or groups who meet at least one of the following three criteria during the MIPS determination period will not exceed the low-volume threshold: (1) Those who have allowed charges for covered professional services less than or equal to $90,000; (2) those who provide covered professional services to 200 or fewer Part B-enrolled individuals; or (3) those who provide 200 or fewer covered professional services to Part B-enrolled individuals.

For the third criterion, we proposed to set the threshold at 200 or fewer covered professional services furnished to Part B-enrolled individuals for several reasons. First, in the CY 2018 Quality Payment Program final rule (82 FR 53589 through 53590), although we received positive feedback from stakeholders on the increased low-volume threshold, we also heard from some stakeholders that they would like to participate in the program. Second, setting the third criterion at 200 or fewer covered professional services, combined with our proposed policy with respect to opting in to MIPS, allows us to ensure that a significant number of eligible clinicians have the ability to opt-in if they wish to participate in MIPS. Finally, when we considered where to set the low-volume threshold for covered professional services, we examined two options: 100 or 200 covered professional services. For 100 covered professional services, there is some historical precedent. In the CY 2017 Quality Payment Program final rule (81 FR 77062), we finalized a low-volume threshold that excluded individual eligible clinicians or groups that have Medicare Part B allowed charges less than $30,000 or that provide care for 100 or fewer Part B-

enrolled Medicare beneficiaries; we believe the latter criterion is comparable to 100 covered professional services. Conversely for 200 covered professional services, in the CY 2018 Quality Payment Program final rule with comment period (82 FR 53588), we discussed that based on our data analysis, excluding individual eligible clinicians or groups that have Medicare Part B allowed charges less than or equal to $90,000 or that provide care for 200 or fewer Part B-enrolled Medicare beneficiaries decreased the percentage of MIPS eligible clinicians that come from small practices. In addition, in the CY 2018 Quality Payment final rule (82 FR 53955), we codified at § 414.1380(b)(1)(iv) that the minimum case requirements for quality measures are 20 cases, which both services thresholds being considered (100 or 200) exceed. We also codified at § 414.1380(b)(1)(v) that the minimum case requirement for the all-cause hospital readmission measure is 200 cases, which only the 200 services threshold consideration exceeds. We believe that setting a threshold of 200 services for the third criterion, combined with our proposed policy for opting in to MIPS, strikes the appropriate balance between allowing a significant number of eligible clinicians the ability to opt-in (as described in this section) to MIPS and consistency with the previously established low-volume threshold criteria. In section VII.F.8.b. of this final rule, we estimated no additional clinicians would be excluded if we add the third criterion because a clinician that cares for at least 200 beneficiaries would have at least 100 or 200 services; however, we estimate 27,903 clinicians would opt-in with the low-volume threshold at 200 services, as compared to 12,242 clinicians if we did not add the third criterion. If we set the third criterion at 100 services, then we estimate 32,828 clinicians would opt-in.

The following is a summary of the public comments received on our proposals and our responses:

Comment: Many commenters supported the low-volume threshold criteria and the newly proposed criterion based on number of covered professional services. Many commenters noted this policy will reduce burden, will help mitigate adverse effects on solo and small or rural practices, and combined with the opt-in policy, allow practices to transition into MIPS. Commenters specifically noted that the addition of the third criteria and the proposed opt-in policy will permit clinicians who are ready to participate if they had been previously excluded. Several commenters also mentioned the newly proposed criterion would increase the number of eligible clinicians that are able to participate in MIPS.

Response: We appreciate the commenters' support.

Comment: One commenter noted concern that MIPS reporting requirements may place significant financial, administrative, and operational burdens on clinicians treating a low volume of Medicare patients.

Response: It is important to note that clinicians who treat a low-volume of Part B Medicare beneficiaries may be excluded from MIPS if they fall below the low-volume threshold.

Comment: Many commenters opposed the low-volume threshold criteria because they noted the thresholds for the individual criteria are too high and excluded too many clinicians and added complexity. Many of these commenters stated that the proposed low-volume threshold limits the number of clinicians in the budget neutral pool and effectively precludes MIPS eligible clinicians with good performance from earning more than a nominal payment adjustment. Several commenters expressed concern that eligible clinicians who make large financial commitments and organizational infrastructure modifications to obtain designation as exceptional performers would be adversely affected. A few commenters noted that practices with these types of clinicians do not have large compliance staff and other resources that larger groups have, and therefore, it may be difficult for these clinicians to report and navigate the program with short notice. Many commenters also stated the proposed low-volume threshold would not move the Quality Payment Program toward value and could jeopardize clinicians, particularly those in small or rural practices, by leaving them unprepared should they become MIPS eligible. One commenter expressed concerned that the threshold could make it difficult to benchmark data because fewer practices would be expected to participate in the program. One commenter requested lowering the performance threshold to the $30,000 in Part B claims or 100 Part B patients threshold that we utilized for 2017 MIPS performance period or lowering the criteria for the opt-in policy. A few commenters recommended that we consider revisiting the low-volume thresholds to increase the percentage of clinicians that are eligible.

Response: We believe that the proposed low-volume threshold strikes the correct balance by including a sufficient number of clinicians, while excluding those who are not quite ready to participate and need additional time to prepare, such as clinicians in small and rural practices. The addition of the third criterion for covered professional services, in conjunction with the opt-in policy, creates a highly-desired opportunity to join MIPS and provides new flexibility for clinicians otherwise excluded to drive value and improve patient outcomes when they are prepared to meaningfully participate. We have heard feedback from many clinicians indicating the desire to participate in MIPS. This feedback was especially prominent from clinicians in small practices who were initially included in the 2017 performance year, but excluded in 2018 due to the increase in the low-volume threshold. The addition of the third criterion for covered professional services, in conjunction with the opt-in policy, provides new flexibilities to participate in MIPS, which creates opportunities for clinicians to drive value and improve patient outcomes. While we understand that the inclusion of any new element may add complexity, we believe that this enhancement will benefit both clinicians and beneficiaries. We will work closely with the clinician and stakeholder community to develop educational resources to help clarify the requirements and reduce any potential confusion. Further, we do not believe that the addition of the third criterion for covered professional services will exclude more clinicians, as clinicians who are currently treating over 200 beneficiaries would likely also be furnishing over 200 covered professional services. As discussed, in section III.I.3.j. of this final rule, we are finalizing our proposal to increase the MIPS performance threshold to 30 points and the exceptional performance bonus to 75 points in 2019. We believe that this will likely result in an evolving distribution of payment adjustments for high performing clinicians who have made the investments to advance quality improvement, enhance clinical practice, and improve outcomes for beneficiaries.

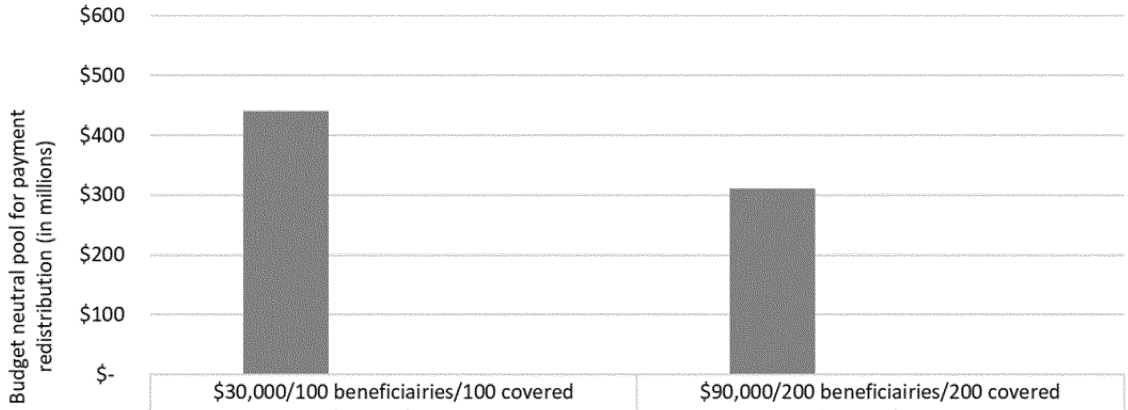
We understand that some MIPS eligible clinicians may work in small group practices and may not have the same resources as a large group. As discussed in the proposed rule (83 FR 35882) we intend to continue to offer tailored flexibilities to help these clinicians to participate in the program. For example, we are finalizing to retain a small practice bonus under MIPS by moving it to the quality performance category. We will also continue to

support small and rural practices by offering free and customized resources available within local communities, including direct, one-on-one support from the Small, Underserved, and Rural Support Initiative along with our other no-cost technical assistance. Further, we note that we are finalizing to amend our regulatory text to allow small practices to continue using the Medicare Part B claims collection type and submission types, either as an individual or as a group. Finally, small practices may continue to choose to participate in MIPS as a virtual group. In addition, we will continue offering the voluntary reporting option, and encourage clinicians to pursue this pathway so that they can familiarize themselves with the program requirements and prepare to participate in future years. We clarify that for the first several years of MIPS, which we view as transitional, we anticipate that the distribution of MIPS payment adjustments will be spread across many more clinicians and groups due to the moderate performance thresholds and not necessarily because clinicians are excluded by the low-volume threshold. For example, in 2017, the performance threshold was set at 3 points, which resulted in an estimated participation rate of 91 percent of MIPS eligible clinicians. As discussed in section III.I.3.j. of this final rule, we are finalizing our proposal to increase the MIPS performance threshold to 30 points and the exceptional performance bonus to 75 points in 2019, which we anticipate will likely result in an evolving distribution of payment adjustments for high performing clinicians who have made the investments to advance quality improvement, enhance clinical practice, and improve outcomes for beneficiaries.

We do not believe that the total amount of dollars available for the payment adjustments is low because too many clinicians are excluded from the program. After incorporating the data submitted for the 2017 MIPS performance period (which we refer to as Quality Payment Program Year 1 data) to estimate the CY 2021 MIPS payment year, an estimated three-quarters (approximately $66.6B) of all PFS dollars will be included in the CY 2021 MIPS payment year. Of the remaining one-quarter (approximately $23.2B), only 2 percent (or less than 1 percent of total PFS dollars) were associated with clinicians who did not meet the low-volume threshold. The remaining clinicians excluded from the budget neutral payment adjustments were Qualifying APM Participants, clinicians with ineligible specialties, and newly enrolled clinicians (11 percent of total PFS dollars). We considered the impact of lowering the low-volume threshold to $30,000/100 beneficiaries/100 covered professional services from the finalized low-volume threshold of this final rule based on the budget neutrality distributions and the size of the total payments. As seen in Figure 1, reducing the low-volume threshold to $30,000/100 beneficiaries/100 covered professional services) [16] leads to an increase in the number of MIPS eligible clinicians (by approximately 73,000 clinicians) and on the dollars available in the budget neutral pool ($131M), but has minimal impact on the maximum possible positive payment adjustment. The majority of clinicians excluded from MIPS with the higher low-volume threshold are clinicians in small practices with fewer than 15 clinicians. We understand the importance of ensuring meaningful participation in the program. We will continue to strike a balance between ensuring sufficient participation in MIPS while also addressing the needs of small practices that may find it difficult to meet the program requirements.

[16] The estimated values when the threshold is set to $30,000/100 beneficiaries/100 covered professional services are not reflective of actual MIPS results for the 2019 MIPS payment year. There are slight differences in data sources and methods compared to the 2019 MIPS payment year such as the low-volume threshold in this model is based on covered PFS services and the model assumes a 33 percent opt-in assumption and uses the QP thresholds for the 2019 QP performance period.

FIGURE 1: Budget neutral pool for redistribution and maximum payment adjustment for different low-volume thresholds. (Estimates apply CY2019 MIPS performance period final policies)*



	$30,000/100 beneficiairies/100 covered professional services	$90,000/200 beneficiairies/200 covered professional services
Budget neutral pool for redistribution	$441	$310
Maximum payment adjustment	5.0%	4.7%
Number of MIPS Eligible Clinicians	871,238	797,990

Data: CY 2019 Quality Payment Program Final Rule Regulatory Impact Analysis data; with 33 percent opt-in assumption.
**The estimates presented only reflect the impact of lowering the low-volume threshold. All other model specifications are reflective of CY 2019 performance period finalized policies and the data sources described in the regulatory impact analysis of this final rule.*

Comment: One commenter encouraged us to continue reviewing the low-volume threshold annually to ensure that the low-volume threshold serves the purpose of excluding those for which the work of MIPS reporting would outweigh the number of Medicare beneficiaries impacted. A few commenters stated that the burden and cost of reporting for those who do not exceed the low-volume threshold far exceeds any possible benefit.

Response: We are committed to continuing program simplification and burden reduction as we move into future years, including identifying additional opportunities to help clinicians successfully participate. We will continue to assess the low-volume threshold, as needed, to help reduce burden for clinicians, especially those in small and rural practices, who still find participation challenging. We believe that it is important to implement the low-volume threshold in a way that provides more time for clinicians to familiarize themselves with the performance requirements under MIPS and, most importantly, prepare to drive clinical quality improvement and improved outcomes for all Medicare beneficiaries. We refer readers to the regulatory impact analysis in section VII.F.8.b. of this final rule for further details on the burden and cost of reporting.

Comment: A few commenters requested that we clarify how a covered professional service would count when calculating the low-volume threshold. Other commenters supported defining the concept of a covered professional service as a single billing of a CPT code. One commenter suggested 15-minute increments as the defining characteristic of a professional service.

Response: For the CY 2018 and CY 2019 MIPS payment years, we have utilized two calculations in order to make low-volume threshold determinations: The number of patients and the amount of allowed charges for each eligible clinician or group. These calculations were based on the patients who were furnished any Part B item or service, and on the allowed charges for all Part B items and services. Beginning for the 2020 MIPS payment year, the calculations will instead be based on covered professional services rather than all Part B items and services.

Comment: One commenter requested clarification on the definition of allowed charges for the low-volume threshold. The commenter asked if allowed charges is equivalent to the full PFS amount or the PFS amount minus the 20 percent co-pay. The commenter also asked about the applicable Multiple Procedure Payment Reduction for a given session. The commenter noted that each option would result in a different dollar amount.

Response: In general, allowed charges refers to the maximum amount Medicare will pay for a covered professional service under the PFS, which is the PFS fee schedule amount reduced by the applicable beneficiary co-payment. For purposes of MIPS low-volume threshold determinations, allowed charges are calculated before any Multiple Procedure Payment Reduction is applied. We refer readers to the CY 2018 Quality Payment Program final rule with comment period (82 FR 53578 through 53579) where we discuss the items and services to which the MIPS payment adjustment could be applied under Part B.

Comment: A few commenters requested we outline a plan for the low-volume threshold, such as a roadmap approach in which we propose and adopt lower thresholds for several performance years at a time.

Additionally, the commenters requested that we describe if CMS has plans to include currently excluded clinicians in the MIPS program in the future. A few commenters asked for a report on the number of low-volume clinicians that elect to be eligible and for us to use this experience to modify the low-volume threshold criteria in future years to move more clinicians into value-based programs.

Response: We agree that providing more clarity and stability into the future of MIPS would be helpful and are interested in working with stakeholders on what such future changes should look like. We are working to provide as much consistency as possible for the low-volume threshold while being flexible and considering changing needs. We note that we are finalizing the low-volume threshold for the 2021 MIPS payment year and future years, as well. Regarding a report on the number of clinicians who are excluded due to the low-volume threshold but elect to opt-in to MIPS, we will consider this suggestion for our MIPS Experience Report.

After consideration of the public comments received, we are finalizing our proposal to modify the definition of low-volume threshold at § 414.1305, to mean that for the 2021 MIPS payment year and future years, that eligible clinicians or groups who meet at least one of the following three criteria during the MIPS determination period will not exceed the low-volume threshold: (1) Those who have allowed charges for covered professional services less than or equal to $90,000; (2) those who provide covered professional services to 200 or fewer Part B-enrolled individuals; or (3) those who provide 200 or fewer covered professional services to Part B-enrolled individuals.

(5) Low-Volume Threshold Opt-In

In the CY 2018 Quality Payment Program proposed rule (82 FR 30026), we proposed the option to opt-in to MIPS participation if clinicians might otherwise be excluded under the low-volume threshold. We received general support from comments received on that final rule (82 FR 53589). However, we did not finalize the proposal for the 2019 MIPS performance period at that time. We were concerned that we would not be able to operationalize this policy in a low-burden manner to MIPS eligible clinicians as it was proposed.

After consideration of operational and user experience implications of an opt-in policy, we proposed an approach we believed could be implemented in a way that provides the least burden to clinicians. As discussed in the CY 2019 PFS proposed rule (83 FR 35887 through 35890), we proposed to modify § 414.1310(b)(1)(iii) to provide that beginning with the 2021 MIPS payment year, if an eligible clinician or group meets or exceeds at least one, but not all, of the low-volume threshold determinations, including as defined by dollar amount (less than or equal to $90,000) or number of beneficiaries (200 or fewer), or number of covered professional services (200 or fewer), then such eligible individual or group may choose to opt-in to MIPS.

This policy would apply to individual eligible clinicians and groups who exceed at least one, but not all, of the low-volume threshold criteria and would otherwise be excluded from MIPS participation as a result of the low-volume threshold. We believed that it would be beneficial to provide, to the extent feasible, such individual eligible clinicians and groups with the ability to opt-in to MIPS. Conversely, this policy would not apply to individual eligible clinicians and groups who exceed all of the low-volume threshold criteria, who unless otherwise excluded, are required to participate in MIPS. In addition, this policy would not apply to individual eligible clinicians and groups who do not exceed any of the low-volume threshold criteria, who would be excluded from MIPS participation without the ability to opt-in to MIPS. Although we believe we proposed the appropriate balance for the low-volume threshold elements and the opt-in policy, we requested comments on other low-volume threshold criteria and supporting justification for the recommended criteria.

Under the proposed policies, we estimated clinician eligibility based on the following (we refer readers to the regulatory impact analysis in section VII.F.8.b. of this final rule for further details on our assumptions): (1) Eligible because they exceed all three criteria of the low-volume threshold and are not otherwise excluded (estimated 770,000 based on our assumptions of who did individual and group reporting); (2) eligible because they exceed at least one, but not all, of the low-volume threshold criteria and elect to opt-in (estimated 28,000 for a total MIPS eligible clinician population of approximately 798,000); (3) potentially eligible if they either did group reporting or elected to opt-in [17] (estimated 390,000); (4) excluded because they do not exceed any of the low-volume threshold criteria (estimated 78,000); and (5) excluded due to non-eligible specialty, newly enrolled, or QP status (estimated 209,000).

We proposed that applicable eligible clinicians who meet one or two, but not all, of the criteria to opt-in and are interested in participating in MIPS would be required to make a definitive choice to either opt-in to participate in MIPS or choose to voluntarily report before data submission (83 FR 35888). If they do not want to participate in MIPS, they will not be required to do anything and will be excluded from MIPS under the low-volume threshold. For those who do want to participate in MIPS, we considered the option of allowing the submission of data to signal that the clinician is choosing to participate in MIPS. However, we anticipated that some clinicians who utilize the quality data code (QDC) claims submission type may have their systems coded to automatically append QDCs on claims for eligible patients. We were concerned that they could submit a QDC code and inadvertently opt-in when that was not their intention.

For individual eligible clinicians and groups to make an election to opt-in or voluntarily report to MIPS, they will make an election via the Quality Payment Program portal by logging into their account and simply selecting either the option to opt-in (positive, neutral, or negative MIPS adjustment) or to remain excluded and voluntarily report (no MIPS adjustment). Once the eligible clinician has elected to participate in MIPS, the decision to opt-in to MIPS will be irrevocable and cannot be changed for the applicable performance period. Clinicians who opt-in will be subject to the MIPS payment adjustment during the applicable MIPS payment year. Clinicians who do not decide to opt-in to MIPS will remain excluded and may choose to voluntarily report. Such clinicians will not receive a MIPS payment adjustment factor. To assist commenters in providing pertinent comments, we developed a website that provided design examples of the different approaches to MIPS participation in CY 2019. The website utilized wireframe (schematic) drawings to illustrate the three different approaches to MIPS participation: Voluntary reporting to MIPS, opt-in reporting to MIPS, and required to

[17] A clinician may be in a group that we estimated would not elect group reporting, however, the group would exceed the low-volume threshold on all three criteria if the group elected group reporting. Similarly, an individual or group may exceed at least one but not all of the low-volume threshold criteria, but we estimated the clinician or group would not elect to opt-in to MIPS. In both cases, these clinicians could be eligible for MIPS if the group or individual makes choices that differ from our assumptions.

participate in MIPS. The website provided specific matrices illustrating potential stakeholder experiences when opting-in or voluntarily reporting.

The option to opt-in to participate in the MIPS as a result of an individual eligible clinician or group exceeding at least one, but not all, of the low-volume threshold elements differs from the option to voluntarily report to the MIPS as established at § 414.1310(b)(2) and (d). Individual eligible clinicians and groups opting-in to participate in MIPS will be considered MIPS eligible clinicians, and therefore subject to the MIPS payment adjustment factor; whereas, individual eligible clinicians and groups voluntarily reporting measures and activities for the MIPS are not considered MIPS eligible clinicians, and therefore not subject to the MIPS payment adjustment factor. MIPS eligible clinicians and groups that made an election to opt-in will be able to participate in MIPS at the individual, group, or virtual group level for that performance period. Eligible clinicians and groups that are excluded from MIPS, but voluntarily report, are able to report measures and activities at the individual or group level; however, such eligible clinicians and groups are not able to voluntarily report for MIPS at the virtual group level.

In Table 31, we provided possible scenarios regarding which eligible clinicians may be able to opt-in to MIPS depending upon their beneficiary count, dollars, and covered professional services if the proposed opt-in policy was finalized.

TABLE 31—LOW-VOLUME THRESHOLD DETERMINATION OPT-IN SCENARIOS

Beneficiaries	Dollars	Covered professional services	Eligible for opt-in
≤200	≤90K	≤200	Excluded not eligible to Opt-in.
≤200	≤90K	>200	Eligible to Opt-in, Voluntarily Report, or Not Participate.
≤200	>90K	≤200	Eligible to Opt-in, Voluntarily Report, or Not Participate.
>200	≤90K	>200	Eligible to Opt-in, Voluntarily Report, or Not Participate.
>200	>90K	>200	Not eligible to Opt-in, Required to Participate.

We recognize that the low-volume threshold opt-in option may expand MIPS participation at the individual, group, and virtual group levels. For solo practitioners and groups with 10 or fewer eligible clinicians (including at least one MIPS eligible clinician) that exceed at least one, but not all, of the elements of the low-volume threshold and are interested in participating in MIPS via the opt-in and doing so as part of a virtual group, such solo practitioners and groups will need to make an election to opt-in to participate in the MIPS. Therefore, beginning with the 2021 MIPS payment year, we proposed that a virtual group election would constitute a low-volume threshold opt-in for any prospective member of the virtual group (solo practitioner or group) that exceeds at least one, but not all, of the low-volume threshold criteria. As a result of the virtual group election, any such solo practitioner or group will be treated as a MIPS eligible clinician for the applicable MIPS payment year.

During the virtual group election process, the official virtual group representative of a virtual group submits an election to participate in the MIPS as a virtual group to CMS prior to the start of a performance period (82 FR 53601 through 53604). The submission of a virtual group election includes TIN and NPI information, which is the identification of TINs composing the virtual group and each member of the virtual group. As part of a virtual group election, the virtual group representative is required to confirm through acknowledgement that a formal written agreement is in place between each member of the virtual group (82 FR 53604). A virtual group may not include a solo practitioner or group as part of a virtual group unless an authorized person of the TIN has executed a formal written agreement.

For a solo practitioner or group that exceeds only one or two elements of the low-volume threshold, an election to opt-in to participate in the MIPS as part of a virtual group would be represented by being identified as a TIN that is included in the submission of a virtual group election. Such solo practitioners and groups opting-in to participate in the MIPS as part of a virtual group would not need to independently make a separate election to opt-in to participate in the MIPS. We note that being identified as a TIN in a submitted virtual group election, any such TIN (represented as a solo practitioner or group) that exceeds at least one, but not all, of the low-volume threshold elements during the MIPS determination period is signifying an election to opt-in to participate in MIPS as part of a virtual group and recognizing that a MIPS payment adjustment factor would be applied to any such TIN based on the final score of the virtual group. For a virtual group election that includes a TIN determined to exceed at least one, but not all, of the low-volume threshold elements during the MIPS determination period, such election would have a precedence over the eligibility determination made during the MIPS determination period pertaining to the low-volume threshold and as a result, any such TIN would be considered MIPS eligible and subject to a MIPS payment adjustment factor due the virtual group election. Furthermore, we note that a virtual group election would constitute an election to opt-in to participate in MIPS and any low-volume threshold determinations that result from segment 2 data analysis of the MIPS determination period would not have any bearing on the virtual group election. Thus, a TIN included as part of a virtual group election that submitted prior to the start of the applicable performance period and does not exceed at least one element of the low-volume threshold during segment 2 of the MIPS determination period, such TIN would be considered MIPS eligible and a virtual group participant by virtue of the virtual group's election to participate in MIPS as a virtual group that was made prior to the applicable performance period. For virtual groups with a composition that may only consist of solo practitioners and groups that exceed at least one, but not all of the low-volume threshold elements, such virtual groups are encouraged to form a virtual group that would include a sufficient number of TINs to ensure that such virtual groups are able to meet program requirements such as case minimum criteria that would allow measures to be scored. For example, if a virtual group does not have a sufficient number of cases to report for quality measures (minimum of 20 cases per measures), a virtual group would

not be scored on such measures (81 FR 77175).

We further noted that APM Entities in MIPS APMs, which meet one or two, but not all, of the low-volume threshold elements to opt-in and are interested in participating in MIPS under the APM scoring standard, would be required to make a definitive choice at the APM Entity level to opt-in to participate in MIPS. For such APM Entities to make an election to opt-in to MIPS, they would make an election via a similar process that individual eligible clinicians and groups will use to make an election to opt-in. Once the APM Entity has elected to participate in MIPS, the decision to opt-in to MIPS is irrevocable and cannot be changed for the performance period in which the data was submitted. Eligible clinicians in APM Entities in MIPS APMs that opt-in would be subject to the MIPS payment adjustment factor. APM Entities in MIPS APMs that do not decided to opt-in to MIPS cannot voluntarily report.

Additionally, we proposed for applicable eligible clinicians participating in a MIPS APM, whose APM Entity meets one or two, but not all, of the low-volume threshold elements rendering the option to opt-in and does not decide to opt-in to MIPS, that if their TIN or virtual group does elect to opt-in, it does not mean that the eligible clinician is opting-in on his/her own behalf, or on behalf of the APM Entity, but that the eligible clinician is still excluded from MIPS participation as part of the APM Entity even though such eligible clinician is part of a TIN or virtual group. This is necessary because low-volume threshold determinations are currently conducted at the APM Entity level for all applicable eligible clinicians in MIPS APMs, and therefore, the low-volume threshold opt-in option should similarly be executed at the APM Entity level rather than at the individual eligible clinician, TIN, or virtual group level. Thus, in order for an APM Entity to opt-in to participate in MIPS at the APM Entity level and for eligible clinicians within such APM Entity to be subject to the MIPS payment adjustment factor, an election would need to be made at the APM Entity level in a similar process that individual eligible clinicians and groups would use to make an election to opt-in to participate in MIPS.

We requested comments on our proposals: (1) To modify § 414.1305 for the low-volume threshold definition at paragraph (3) to specify that, beginning with the 2021 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician or group that, during the MIPS determination period, has allowed charges for covered professional services less than or equal to $90,000, furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare Part B-enrolled individuals; (2) that a clinician who is eligible to opt-in would be required to make an affirmative election to opt-in to participate in MIPS, elect to be a voluntary reporter, or by not submitting any data the clinician is choosing to not report; and (3) to modify § 414.1310(b)(1)(iii) under Applicability to specify exclusions as follows: Beginning with the 2021 MIPS payment year, if an individual eligible clinician, group, or APM Entity group in a MIPS APM exceeds at least one, but not all, of the low-volume threshold criteria and elects to report on applicable measures and activities under MIPS, the individual eligible clinician, group, or APM Entity group is treated as a MIPS eligible clinician for the applicable MIPS payment year. For APM Entity groups in MIPS APMs, only the APM Entity group election can result in the APM Entity group being treated as MIPS eligible clinicians for the applicable payment year.

The following is a summary of the public comments received on our proposals and our responses:

Comment: Many commenters supported the opt-in policy as proposed. Many commenters supported that clinicians electing to opt-in may have either a negative or positive payment adjustment. One commenter stated the opportunity for clinicians to opt-in to MIPS will help to offset the additional exclusions resulting from the addition of a third low-volume criterion. A few commenters noted the opt-in provides a participation opportunity for clinicians who bill low-cost services and would not otherwise exceed the low-volume threshold based on allowed charges. Other commenters noted that MIPS is the only way for MIPS eligible clinicians to earn a meaningful MIPS payment adjustment factor and opt-in is the only way for eligible clinicians who do not exceed the low-volume threshold to participate. Many commenters noted the policy provides flexibility and may encourage those clinicians who are not ready to have their payment affected by MIPS performance to test their ability to gather and submit performance data and gain experience with MIPS.

Response: We appreciate the commenters' support. We note that if an eligible clinician chooses to opt-in to MIPS then they will be subject to the MIPS payment adjustment during the applicable MIPS payment year. If a clinician is eligible to opt-in but does not want to participate in MIPS, and be subject to the MIPS payment adjustment, then we would encourage clinicians to voluntarily report.

Comment: Many commenters opposed the opt-in policy. A few commenters noted concern that the opt-in will reduce incentives to participate in MIPS, with one specifically stating it does not align with the agency's stated goal for MIPS to be a pathway to eventual participation in APMs. Some commenters also noted concern with how the opt-in may affect the overall scores, stating that (1) the additional clinicians who voluntarily opt-in are likely to be above the MIPS threshold, and therefore may reduce the amount of positive MIPS payment adjustment factors for clinicians who are required to participate, (2) the opt-in will likely continue to flatten the clinician's final score, lowering the overall aggregate increase, and (3) if too many eligible clinicians are excluded, positive payment adjustments would be insufficient to help offset the investments practices health systems must make to succeed under MIPS. Another commenter stated that CMS should identify a core set of data on MIPS and its various exclusions to be updated annually in conjunction with the proposed rule to allow stakeholders to follow the impacts of those exclusions longitudinally.

Response: While we encourage clinicians who are excluded to opt-in to the program once they are prepared to meaningfully participate as a means of driving value and improving outcomes for more Medicare beneficiaries, we believe that the opt-in policy does not undermine APM participation or the transition of clinicians from MIPS to APMs because the opt-in policy is applied at the APM Entity level for clinicians and groups participating in APMs. For this final rule, we analyzed the impact of the opt-in policy by running models which incorporate the Quality Payment Program Year 1 submissions data. The models include eligibility without opt-in, opt-in based on a random sample of 33 percent of clinicians who can elect to opt-in, and opt-in where only high performers (that is, clinicians who can anticipate a positive adjustment) elect to opt-in. To model the situation where only high performers would opt-in to MIPS, we assumed 100 percent of clinicians with final scores above the additional performance threshold would opt-in and 50 percent of clinicians above the performance threshold but below the additional performance threshold would

opt-in. We observed a very modest impact to the payment adjustment irrespective of the opt-in assumption used. Please see Figure 2 for the model by opt-in assumption. Lastly, we appreciate the request for additional core data to be made available, we will continue to work with stakeholders to identify the information that is valuable and release it accordingly.

Comment: Many commenters supported an opt-in policy, but believed the policy should be available to more clinicians. Of these commenters, most believed that the opt-in should be available even if the clinician did not exceed any of the low-volume criteria. A few commenters indicated that MIPS should be voluntary for all clinicians. One commenter requested that we make the opt-in policy retroactive to the MIPS 2018 performance period for year-to-year consistency, simplification, and to improve overall participation. Another commenter stated that the clinicians who switch practices in the last three months of MIPS performance period should be able to opt-in.

Response: We do not believe that we have the flexibility to allow any clinician who wishes to participate in MIPS to opt-in nor to retroactively apply the opt-in policy to the 2018 MIPS performance period. Finally, as discussed in the section III.I.3.b. of this final rule, during the final 3 months of the calendar year in which the performance period occurs, in general, we do not believe it would be feasible for many MIPS eligible clinicians who join an existing practice (existing TIN) or join a newly formed practice (new TIN) to participate in MIPS as individuals. To clarify if an eligible clinician switches to an existing TIN or a new TIN they may be able to participate in MIPS as a group. However, they would not be able to participate as an individual.

Comment: Several commenters supported the proposal that eligible clinicians who are eligible to opt-in would be required to make an affirmative election to opt-in to participate in MIPS. One commenter agreed that an affirmative election to report is necessary to avoid confusion and possible inadvertent claims submissions that might involuntarily opt-in a clinician to MIPS.

Response: We agree that even eligible clinicians submitting MIPS data via claims must make an affirmative election.

Comment: Several commenters sought clarification on the deadline to opt-in. A few commenters wondered if clinicians can choose to wait until the data submission deadline for a performance year, or whether they must elect to opt-in sooner than that. One commenter recommended that clinicians should have a deadline of no later than the last day in the month of February, or perhaps the 15th of March, for the performance period in which they intend to participate. This commenter stated that allowing the choice to opt-in at any point during the performance period will only increase participatory rates among clinicians or groups who have knowledge of favorable outcomes and will excuse those whose outcomes were undesirable. One commenter encouraged us to allow clinicians to opt-in at the time of data submission, as this would create the least amount of burden on clinicians who wish to opt-into the program. Another commenter urged us to allow an opt-in decision at any point during the data submission window and to provide confirmation of the decision to opt-in. Another commenter stated that we should not make the opt-in decision irrevocable.

Response: We would like to create a process for eligible clinicians who wish to opt-in to MIPS that is the least burdensome but also provides the clinician with the most flexibility. We are exploring if we can operationally allow clinicians to opt-in at any time prior to the submission period and will provide further guidance via subregulatory guidance if this becomes available. We are finalizing at § 414.1310(b)(1)(iii) under Applicability to specify exclusions as follows: Beginning with the 2021 MIPS payment year, if an individual eligible clinician, group, or APM Entity group in a MIPS APM exceeds at least one, but not all, of the low-volume threshold criteria and elects to report on applicable measures and activities under MIPS, the individual eligible clinician, group, or APM Entity group is treated as a MIPS eligible clinician for the applicable MIPS payment year. We agree that allowing clinicians the choice to opt-in at any point during the performance period may increase the potential that only high performers will opt-in, but we believe that this policy accounts for clinicians who identified in the second segment of the MIPS determination period. Also, we plan to monitor this issue and will address it through future rulemaking if necessary. Finally, regarding the opt-in decision being irrevocable, we believe it is necessary for the clinician to make a definitive decision regarding their participation in MIPS. If the decision to opt-in was not definitive then we believe the potential for a clinician to have an unfair advantage is increased by their ability to review their final feedback and scoring information available at submissions and subsequently alter their participation decision.

Comment: One commenter noted that with the manual election to indicate opt-in, the need for a low-volume threshold criterion based on professional services should not make a difference in a clinician's ability to opt-in. Other commenters opposed the requirement for the eligible clinician to manually opt-in, noting that it would add administrative burden. Another commenter stated that it is unnecessary to create a MIPS opt-in policy for some low-volume clinicians as they may not meet the case minimums for measures.

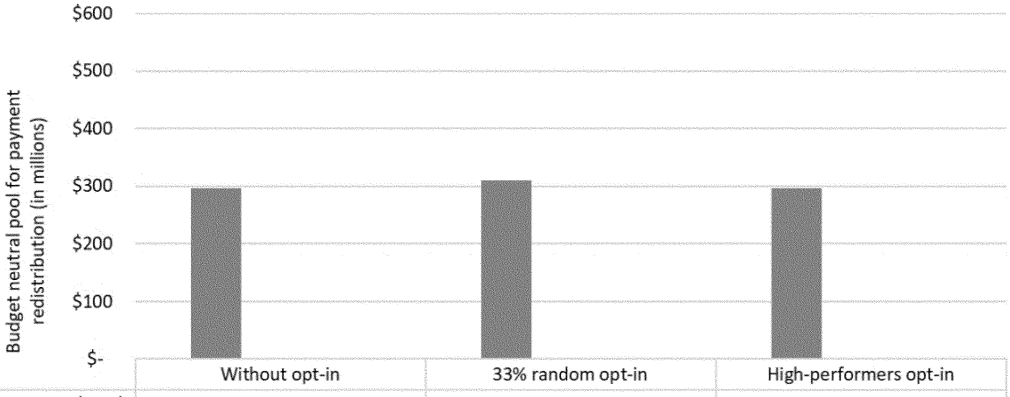
Response: We do not believe that the manual election to opt-in has relevance to the clinician's covered professional services. We are providing the third criterion of covered professional services to expand the number of clinicians eligible to opt-in to the program. Regarding the manual election to opt-in, we believe this is the least burdensome approach to ensuring that clinicians are making an informed decision regarding their MIPS participation. We believe that most MIPS eligible clinicians that provide at least 200 covered professional service will be able to meet the case minimums for measures.

Comment: A few commenters requested additional clarification on the implication of the opt-in policy on the MIPS payment adjustment and on how we estimated the number of opt-in clinicians.

Response: We described our approach to estimating the opt-in policy in the regulatory impact analysis of the CY 2019 PFS proposed rule (83 FR 36057 through 36068). We sought comment on this approach and refer readers to the Regulatory Impact Analysis (RIA) in section VII. of this final rule for additional information. The RIA for this final rule examined the impact of the opt-in policy on payment adjustments by using two alternate opt-in assumptions: (1) If only clinicians with scores above the performance threshold opt-in (the actual opt-in is likely to be lower than this estimated number of clinicians opting-in); and (2) if none of the clinicians elected to opt-in. See Figure 2 for a summary of the results. As shown in Figure 2, the opt-in policy was found to have a small impact on the budget neutral pool when we assumed a random 33 percent of clinicians would opt-in irrespective of their performance and a minimal impact on payment adjustments regardless of the opt-in assumption used. Given these findings, we chose to use the 33 percent opt-in

assumption for all CY 2019 performance period estimates.

FIGURE 2: Budget Neutral Pool for Redistribution and Maximum Payment Adjustment for Different Opt-in Assumptions



	Without opt-in	33% random opt-in	High-performers opt-in
Budget neutral pool for redistribution	$296	$310	$296
Maximum payment adjustment	4.7%	4.7%	4.6%
Number of MIPS Eligible Clinicians	770,087	797,990	787,928

Data: CY 2019 Quality Payment Program Final Rule Regulatory Impact Analysis data.

Comment: A few commenters supported the proposal to only allow APM entities to opt-in as a group. One commenter urged us to explain in-depth the application of the low-volume threshold opt-in option for MIPS APM TINs.

Response: We explained the application of the low-volume threshold for APM Entities in MIPS APMs in detail in the CY 2019 PFS proposed rule (83 FR 35889) and refer readers to that discussion.

Comment: One commenter did not agree that performance category data submitted by a third party intermediary needed a separate opt-in election. The commenter stated that in these instances, the clinician or group has chosen to engage a third party intermediary for MIPS reporting which the commenter believed is an affirmative event demonstrating intent to participate in the MIPS program. The commenter also noted that for clinicians or small-groups submitting quality data via QDC codes on claims, if those clinicians and/or small groups also submit any category data via a third-party intermediary, the Quality Payment Program portal, or the CMS Web Interface, that should be considered as an opt-in decision. One commenter requested that we provide a technical interface/API which allows clinicians and groups to opt-in through the service of third party intermediaries.

Response: We want to ensure that clinicians are making an informed decision regarding opting-in to participate in MIPS. It is imperative that they make a definitive decision since clinicians who opt-in will be subject to the MIPS payment adjustment during the applicable MIPS payment year. We believe that an election to opt-in to MIPS must be made by the clinician or group through a definitive opt-in decision to participate in MIPS regardless of the way in which the data is submitted. In addition, in response to public comments, in instances where a third party intermediary is representing a MIPS eligible clinician, the third party intermediary must be able to transmit the clinician's opt-in decision to CMS. We refer readers to section III.I.3.k. of this final rule for more information regarding third party intermediary requirements.

Comment: A few commenters requested information for clinicians and groups to make an informed choice about the opt-in. One commenter urged us to make it clear as to whether a clinician and group is eligible to opt-in to MIPS, what this decision could mean in terms of reducing or increasing their Medicare payments, and when the decision would be final. A few commenters requested the eligibility information prior to the start of the performance period, so that MIPS eligible clinicians and groups who want to opt-in to MIPS have the information necessary to make an informed choice about their participation options. Other commenters requested information on how the two MIPS determination periods work with the opt-in policy.

Response: We understand that it is important for clinicians to know their eligibility status prior to the performance period. We are working to provide quarterly snapshots, if feasible. We believe these quarterly snapshots will provide important information to clinicians so that they may make informed decisions regarding whether they should opt-in to participate in MIPS. It is important to note that the quarterly snapshots are being provided for informational use only and not final until after the second segment of the MIPS determination period closes (which is September 30 of the calendar year in which the applicable performance period occurs) and a reconciliation occurs. Since the quarterly snapshots are not final this information is subject to change and should not be considered the final eligibility determination. The eligibility determination will be made after a reconciliation of the first and second segment of the MIPS determination period. We are finalizing at § 414.1310(b)(1)(iii) under Applicability to specify exclusions that include, beginning with the 2021 MIPS payment year, if an individual eligible clinician, group, or APM Entity group in a MIPS APM exceeds at least one, but not all,

of the low-volume threshold criteria and elects to report on applicable measures and activities under MIPS, the individual eligible clinician, group, or APM Entity group is treated as a MIPS eligible clinician for the applicable MIPS payment year.

Comment: One commenter recommended that we change the name of the voluntary participation option to ensure that clinicians do not confuse that option with opt-in participation. Since a voluntary participant is only reporting data, they suggested changing that category to Voluntary Reporting to ensure this is not confused with opt-in Participation.

Response: We agree and are modifying the participation terms on the Quality Payment Program website to provide clear directions. Therefore, we note that when clinicians are reporting for MIPS they may enter the Quality Payment Program portal to choose the appropriate MIPS participation. For those eligible clinicians or groups who exceed all three criteria of the low-volume threshold their participation will be automatically selected as they are required to participate. For individual eligible clinicians and groups who are qualified they may make an election to by choosing to either: Agree to opt-in participation or to voluntarily report to MIPS, the clinician would make an election via the Quality Payment Program portal by logging into their account and simply selecting either the option to opt-in participation (positive, neutral, or negative MIPS adjustment) or to remain excluded and voluntarily report (no MIPS adjustment). So the three options when reporting data through the Quality Payment Program portal are: Voluntary reporting, opt-in participation, and required to participate in MIPS. We referred readers to the Quality Payment Program at *qpp.cms.gov/design-examples* to review the finalized wireframe drawings.

After consideration of the public comments received, we are finalizing our proposals: (1) To modify § 414.1305 for the low-volume threshold definition at paragraph (3) to specify that, beginning with the 2021 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the MIPS determination period, has allowed charges for covered professional services less than or equal to $90,000, furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare Part B-enrolled individuals; (2) that a clinician who is eligible to opt-in would be required to make an affirmative election to opt-in to participate in MIPS, elect to be a voluntary reporter, or by not submitting any data the clinician is choosing to not report; and (3) to modify § 414.1310(b)(1)(iii) under Applicability to specify exclusions as follows: Beginning with the 2021 MIPS payment year, if an individual eligible clinician, group, or APM Entity group in a MIPS APM exceeds at least one, but not all, of the low-volume threshold criteria and elects to report on applicable measures and activities under MIPS, the individual eligible clinician, group, or APM Entity group is treated as a MIPS eligible clinician for the applicable MIPS payment year. For such solo practitioners and groups that elect to participate in MIPS as a virtual group (except for APM Entity groups in MIPS APMs), the virtual group election under § 414.1315 constitutes an election under this paragraph and results in the solo practitioners and groups being treated as MIPS eligible clinicians for the applicable MIPS payment year. For such APM Entity groups in MIPS APMs, only the APM Entity group election can constitute an election under this paragraph and result in the APM Entity group being treated as MIPS eligible clinicians for the applicable MIPS payment year. We note that a virtual group election does not constitute a Partial QP election under revised § 414.1310(b)(1)(ii). In order for an individual eligible clinician or APM Entity with a Partial QP status to explicitly elect to participate in MIPS and be subject to the MIPS payment adjustment factor, such individual eligible clinician or APM Entity would make such election during the applicable performance period as a Partial QP status becomes applicable and such option for election is warranted.

(6) Part B Services Subject to MIPS Payment Adjustment

Section 1848(q)(6)(E) of the Act, as amended by section 51003(a)(1)(E) of the Bipartisan Budget Act of 2018, provides that the MIPS adjustment factor and, as applicable, the additional MIPS adjustment factor, apply to the amount otherwise paid under Part B with respect to covered professional services (as defined in subsection (k)(3)(A) of the Act) furnished by a MIPS eligible clinician during a year (beginning with 2019) and with respect to the MIPS eligible clinician for such year.

In the CY 2019 PFS proposed rule (83 FR 35890), we requested comments on our proposal to amend § 414.1405(e) to modify the application of both the MIPS adjustment factor and, if applicable, the additional MIPS adjustment factor so that beginning with the 2019 MIPS payment year, these adjustment factors will apply to Part B payments for covered professional services (as defined in section 1848(k)(3)(A) of the Act) furnished by the MIPS eligible clinician during the year. We are making this change beginning with the first MIPS payment year and note that these adjustment factors will not apply to Part B drugs and other items furnished by a MIPS eligible clinician, but will apply to covered professional services furnished by a MIPS eligible clinician. We refer readers to section III.I.3.j. of this final rule for further details on this modification.

The following is a summary of the public comments received on our proposals and our responses:

Comment: One commenter stated that they support the technical amendment made by Congress in the Bipartisan Budget Act of 2018 to clarify that items or services beyond the PFS, especially Part B drugs, should not be included when determining MIPS eligibility and applying the MIPS payment adjustment.

Response: We appreciate the commenters' support.

After consideration of the public comments received, we are finalizing our proposal to amend § 414.1405(e) to modify the application of both the MIPS adjustment factor and, if applicable, the additional MIPS adjustment factor so that beginning with the 2019 MIPS payment year, these adjustment factors will apply to Part B payments for covered professional services (as defined in section 1848(k)(3)(A) of the Act) furnished by the MIPS eligible clinician during the year. We are making this change beginning with the first MIPS payment year and note that these adjustment factors will not apply to Part B drugs and other items furnished by a MIPS eligible clinician, but will apply to covered professional services furnished by a MIPS eligible clinician.

d. Partial QPs

(1) Partial QP Elections Within Virtual Groups

In the CY 2017 Quality Payment Program final rule, we finalized that following a determination that eligible clinicians in an APM Entity group in an Advanced APM are Partial QPs for a year, the APM Entity will make an election whether to report on applicable measures and activities as required under MIPS. If the APM Entity elects to report to MIPS, all eligible clinicians in

the APM Entity would be subject to the MIPS reporting requirements and payment adjustments for the relevant year. If the APM Entity elects not to report, all eligible clinicians in the APM Entity group will be excluded from the MIPS reporting requirements and payment adjustments for the relevant year (81 FR 77449).

We also finalized that in cases where the Partial QP determination is made at the individual eligible clinician level, if the individual eligible clinician is determined to be a Partial QP, the eligible clinician will make the election whether to report on applicable measures and activities as required under MIPS and, as a result, be subject to the MIPS reporting requirements and payment adjustments (81 FR 77449). If the individual eligible clinician elects to report to MIPS, he or she would be subject to the MIPS reporting requirements and payment adjustments for the relevant year. If the individual eligible elects not to report to MIPS, he or she will be excluded from the MIPS reporting requirements and payment adjustments for the relevant year.

We also clarified how we consider the absence of an explicit election to report to MIPS or to be excluded from MIPS. We finalized that for situations in which the APM Entity is responsible for making the decision on behalf of all eligible clinicians in the APM Entity group, the group of Partial QPs will not be considered MIPS eligible clinicians unless the APM Entity opts the group into MIPS participation, so that no actions other than the APM Entity's election for the group to participate in MIPS would result in MIPS participation (81 FR 77449). For eligible clinicians who are determined to be Partial QPs individually, we finalized that we will use the eligible clinician's actual MIPS reporting activity to determine whether to exclude the Partial QP from MIPS in the absence of an explicit election. Therefore, if an eligible clinician who is individually determined to be a Partial QP submits information to MIPS (not including information automatically populated or calculated by CMS on the Partial QP's behalf), we will consider the Partial QP to have reported, and thus to be participating in MIPS. Likewise, if such an individual does not take any action to submit information to MIPS, we will consider the Partial QP to have elected to be excluded from MIPS (81 FR 77449).

In the CY 2018 Quality Payment Program final rule, we clarified that in the case of an eligible clinician participating in both a virtual group and an Advanced APM who has achieved Partial QP status, that the eligible clinician would be excluded from the MIPS payment adjustment unless the eligible clinician elects to report under MIPS (82 FR 53615). As discussed in the CY 2019 PFS proposed rule (83 FR 35890 through 35891), we incorrectly stated that affirmatively agreeing to participate in MIPS as part of a virtual group prior to the start of the applicable performance period would constitute an explicit election to report under MIPS for all Partial QPs. As such, we also incorrectly stated that all eligible clinicians who participate in a virtual group and achieve Partial QP status would remain subject to the MIPS payment adjustment due to their virtual group election to report under MIPS, regardless of their Partial QP election. We note that an election made prior to the start of an applicable performance period to participate in MIPS as part of a virtual group is separate from an election made during the performance period that is warranted as a result of an individual eligible clinician or APM Entity achieving Partial QP status during the applicable performance period. A virtual group election does not equate to an individual eligible clinician or APM Entity with a Partial QP status explicitly electing to participate in MIPS. In order for an individual eligible clinician or APM Entity with a Partial QP status to explicitly elect to participate in MIPS and be subject to the MIPS payment adjustment factor, such individual eligible clinician or APM Entity would make such election during the applicable performance period as a Partial QP status becomes applicable and such option for election is warranted. Thus, we are restating that affirmatively agreeing to participate in MIPS as part of a virtual group prior to the start of the applicable performance period does not constitute an explicit election to report under MIPS as it pertains to making an explicit election to either report to MIPS or be excluded from MIPS for individual eligible clinicians or APM Entities that have Partial QP status.

Related to this clarification, we are finalizing in section III.I.4.e.(3) of this final rule to clarify that beginning with the 2021 MIPS payment year, when an eligible clinician is determined to be a Partial QP for a year at the individual eligible clinician level, the individual eligible clinician has the option to make an election whether to report to MIPS. If the eligible clinician elects to report to MIPS, he or she will be subject to MIPS reporting requirements and payment adjustments. If the eligible clinician elects to not report to MIPS, he or she will not be subject to MIPS reporting requirements and payment adjustments. If the eligible clinician does not make any affirmatively election to report to MIPS, he or she will not be subject to MIPS reporting requirements and payment adjustments. As a result, beginning with the 2021 MIPS payment year, for eligible clinicians who are determined to be Partial QPs individually, we will not use the eligible clinician's actual MIPS reporting activity to determine whether to exclude the Partial QP from MIPS in the absence of an explicit election.

Therefore, the finalized policy in section III.I.4.e.(3) of this final rule eliminates the scenario in which affirmatively agreeing to participate in MIPS as part of a virtual group prior to the start of the applicable performance period will constitute an explicit election to report under MIPS for eligible clinicians who are determined to be Partial QPs individually and make no explicit election to either report to MIPS or be excluded from MIPS. We believe this change is necessary because QP status and Partial QP status, achieved at the APM Entity level or eligible clinician level, is applied to an individual and all of his or her TIN/NPI combinations, whereas virtual group participation is determined at the TIN level. Therefore, we do not believe that it is appropriate that the actions of the TIN in joining the virtual group should deprive the eligible clinician who is a Partial QP, whether that status was achieved at APM Entity level or eligible clinician level, of the opportunity to elect whether or not to opt-in to MIPS.

e. Group Reporting

We refer readers to § 414.1310(e) and the CY 2018 Quality Payment Program final rule (82 FR 53592 through 53593) for a description of our previously established policies regarding group reporting.

In the CY 2018 Quality Payment Program final rule (82 FR 53593), we clarified that we consider a group to be either an entire single TIN or portion of a TIN that: (1) Is participating in MIPS according to the generally applicable scoring criteria while the remaining portion of the TIN is participating in a MIPS APM or an Advanced APM according to the MIPS APM scoring standard; and (2) chooses to participate in MIPS at the group level. We further clarify that we consider a group to be an entire single TIN that chooses to participate in MIPS at the group level. However, individual eligible clinicians (TIN/NPIs) within that group may receive a MIPS payment adjustment

based on the APM scoring standard if they are on the participant list of a MIPS APM. We proposed to amend §§ 414.1310(e) and 414.1370(f)(2) to codify this policy and more fully reflect the scoring hierarchy as discussed in section III.I.3.h.(6) of this final rule.

As discussed in the CY 2018 Quality Payment Program final rule (82 FR 53593), one of the overarching themes we have heard from stakeholders is that we make an option available to groups that would allow a portion of a group to report as a separate sub-group on measures and activities that are more applicable to the sub-group and be assessed and scored accordingly based on the performance of the sub-group. We stated that in future rulemaking, we intend to explore the feasibility of establishing group-related policies that would permit participation in MIPS at a sub-group level and create such functionality through a new identifier. In the CY 2018 Quality Payment Program proposed rule (82 FR 30027), we solicited public comments on the ways in which participation in MIPS at the sub-group level could be established. In addition, in the CY 2018 Quality Payment Program final rule (82 FR 53593), we sought comment on additional ways to define a group, not solely based on a TIN. Because there are several operational challenges with implementing a sub-group option, we did not propose any such changes to our established reporting policies in this final rule. Rather, we are considering facilitating the use of a sub-group identifier in the Quality Payment Program Year 4 through future rulemaking, as necessary. In addition, it has come to our attention that providing a sub-group option may provide potential gaming opportunities. For example, a group could manipulate scoring by creating sub-groups that are comprised of only the high performing clinicians in the group. Therefore, we requested comment on implementing sub-group level reporting through a separate sub-group sub-identifier in the Quality Payment Program Year 4 and possibly future years of the program.

In the CY 2019 PFS proposed rule (83 FR 35891) we requested comments on the following: (1) Whether and how a sub-group should be treated as a separate group from the primary group: For example, if there is 1 sub-group within a group, how would we assess eligibility, performance, scoring, and application of the MIPS payment adjustment at the sub-group level; (2) whether all of the sub-group's MIPS performance data should be aggregated with that of the primary group or should be treated as a distinct entity for determining the sub-group's final score, MIPS payment adjustments, and public reporting, and eligibility be determined at the whole group level; (3) possible low burden solutions for identification of sub-groups: For example, whether we should require registration similar to the CMS Web Interface or a similar mechanism to the low-volume threshold opt-in that we proposed and is discussed in section III.I.3.c.(5) of this final rule; and (4) potential issues or solutions needed for sub-groups utilizing submission mechanisms, measures, or activities, such as APM participation, that are different than the primary group. We also welcomed comments on other approaches for sub-group reporting that we should consider. We received many comments on group reporting and will take them into consideration for future rulemaking.

f. Virtual Groups

(1) Background

We refer readers to § 414.1315 and the CY 2018 Quality Payment Program final rule (82 FR 53593 through 53617) for our previously established policies regarding virtual groups.

(2) Virtual Group Election Process

We refer readers to § 414.1315(c) and the CY 2018 Quality Payment Program final rule (82 FR 53601 through 53604) for our previously established policies regarding the virtual group election process.

We proposed to amend § 414.1315(c) to continue to apply the previously established policies regarding the virtual group election process for the 2022 MIPS payment year and future years, with the exception of the proposed policy modification discussed below (83 FR 35891 through 35892).

Under § 414.1315(c)(2)(ii), an official designated virtual group representative must submit an election on behalf of the virtual group by December 31 of the calendar year prior to the start of the applicable performance period. In the CY 2018 Quality Payment Program final rule (82 FR 53603), we stated that such election will occur via email to the Quality Payment Program Service Center using the following email address for the 2018 and 2019 performance periods: *MIPS_VirtualGroups@cms.hhs.gov*. Beginning with the 2022 MIPS payment year, we proposed to amend § 414.1315(c)(2)(ii) to provide that the election would occur in a manner specified by CMS. We anticipate that a virtual group representative would make an election on behalf of a virtual group by registering to participate in MIPS as a virtual group via a web-based system developed by CMS. We believe that a web-based system would be less burdensome for virtual groups given that the interactions stakeholders would have with the Quality Payment Program are already conducted via the Quality Payment Program portal, and would provide stakeholders with a seamless user experience. Stakeholders would be able to make a virtual group election in a similar manner to all other interactions with the Quality Payment Program portal and would no longer need to separately identify the appropriate email address to submit such an election and email an election outside of the Quality Payment Program portal. The Quality Payment Program portal is the gateway and source for interaction with MIPS that contains a range of information on topics including eligibility, data submission, and performance reports. We believe that using the same web-based platform to make a virtual group election would enhance the one-stop MIPS interactive experience and eliminate the potential for stakeholders to be unable to identify or erroneously enter the email address.

We solicited public comment on this proposal, which would provide for an election to occur in a manner specified by CMS such as a web-based system developed by CMS.

The following is a summary of the public comments received regarding the proposal to continue to apply the previously established policies regarding the virtual group election process for the 2022 MIPS payment year and future years, with the exception of providing for an election to occur in a manner specified by CMS, such as a web-based system developed by CMS, and our responses.

Comment: Several commenters supported the proposal to facilitate virtual group elections through the Quality Payment Program portal, as opposed to email, and indicated that the use of portal would be less burdensome for virtual groups and facilitate a more seamless user experience. A few commenters noted that the web-based system linked to the existing portal could give interested participants an easier means of connecting with other possible virtual group members. The commenters recommended that CMS explore the inclusion/development of a platform within the portal that would facilitate interactions and connections between parties interested in forming or joining a virtual group. Additionally, the commenters requested that CMS clearly outline and provide additional guidance on the election process via the

Quality Payment Program website. Another commenter recommended that CMS devise, as part of the portal, a direct way for clinicians to confirm their virtual group-eligibility status with 100 percent reliability, and eliminate potential human errors when using a Quality Payment Program representative as an intermediary.

Response: We will consider various means for providing information and guidance to virtual groups regarding the election process, and explore options for facilitating and supporting virtual group formation and providing virtual group eligibility via the Quality Payment Program portal in future years. It should be noted that all necessary information pertaining to virtual groups will be published on the CMS website prior to the virtual group election period, which occurs during the calendar before the start of the applicable performance period.

After consideration of the public comments, we are finalizing our proposal at § 414.1315(c) to continue to apply the previously established policies regarding the virtual group election process for the 2022 MIPS payment year and future years, with the exception of providing for an election to occur in a manner specified by CMS, such as a web-based system developed by CMS.

(a) Virtual Group Eligibility Determinations

For purposes of determining TIN size for virtual group participation eligibility for the CY 2018 and 2019 performance periods, we coined the term ''virtual group eligibility determination period'' and defined it to mean an analysis of claims data during an assessment period of up to 5 months that would begin on July 1 and end as late as November 30 of the calendar year prior to the applicable performance period and includes a 30-day claims run out (82 FR 53602). We proposed to modify the virtual group eligibility determination period beginning with the 2019 performance period (83 FR 35892 through 35893). We proposed to amend § 414.1315(c)(1) to establish a virtual group eligibility determination period to mean an analysis of claims data during a 12-month assessment period (fiscal year) that would begin on October 1 of the calendar year 2 years prior to the applicable performance period and end on September 30 of the calendar year preceding the applicable performance period and include a 30-day claims run out. The virtual group eligibility determination period aligns with the first segment of data analysis under the MIPS eligibility determination period. As part of the virtual group eligibility determination period, TINs would be able to inquire about their TIN size prior to making an election during a 5-month timeframe, which would begin on August 1 and end on December 31 of a calendar year prior to the applicable performance period. TIN size inquiries would be made through the Quality Payment Program Service Center. For TINs that inquire about their TIN size during such 5-month timeframe, it should be noted that any TIN size information provided is only for informational purposes and may be subject to change; official eligibility regarding TIN size and all other eligibility pertaining to virtual groups would be determined in accordance with the MIPS determination period and other applicable special status eligibility determination periods. The proposed modification would provide stakeholders with real-time information regarding TIN size for informational purposes instead of TIN size eligibility determinations on an ongoing basis (between July 1 and November 30 of the calendar year prior to the applicable performance period) due to technical limitations.

For the 2018 and 2019 performance periods, TINs could determine their status by contacting their designated TA representative as provided at § 414.1315(c)(1); otherwise, the TIN's status would be determined at the time that the TIN's virtual group election is submitted. We proposed to amend § 414.1315(c)(1) to remove this provision since the inquiry about TIN size would be for informational purposes only and may be subject to change.

We believe that the utilization of the Quality Payment Program Service Center, versus the utilization of designated TA representatives, as the means for stakeholders to obtain information regarding TIN size provides continuity and a seamless experience for stakeholders. We note that the TA resources already available to stakeholders would continue to be available. The following describes the experience a stakeholder would encounter when interacting with the Quality Payment Program Service Center to obtain information pertaining to TIN size. For example, the applicable performance period for the 2022 MIPS payment year would be CY 2020. If a group contacted the Quality Payment Program Service Center on September 20, 2019, the claims data analysis would include the months of October of 2018 through August of 2019. If another group contacted the Quality Payment Program Service Center on November 20, 2019, the claims data analysis would include the months of October of 2018 through September of 2019 with a 30-day claims run out.

We believe this virtual group eligibility determination period provides a real-time representation of TIN size for purposes of determining virtual group eligibility and allows solo practitioners and groups to know their real-time virtual group eligibility status and plan accordingly for virtual group implementation. Beginning with the 2022 MIPS payment year, it is anticipated that starting in August of each calendar year prior to the applicable performance period, solo practitioners and groups would be able to contact the Quality Payment Program Service Center and inquire about their TIN size. TIN size determinations would be based on the number of NPIs associated with a TIN, which may include clinicians (NPIs) who do not meet the definition of a MIPS eligible clinician at § 414.1305 or who are excluded from MIPS under § 414.1310(b) or (c).

We proposed to continue to apply the aforementioned previously established virtual group policies for the 2022 MIPS payment year and future years, with the exception of the following policy modifications:

- The virtual group eligibility determination period would align with the first segment of the MIPS determination period, which includes an analysis of claims data during a 12-month assessment period (fiscal year) that would begin on October 1 of the calendar year 2 years prior to the applicable performance period and end on September 30 of the calendar year preceding the applicable performance period and include a 30-day claims run out. As part of the virtual group eligibility determination period, TINs would be able to inquire about their TIN size prior to making an election during a 5-month timeframe, which would begin on August 1 and end on December 31 of a calendar year prior to the applicable performance period.
- MIPS eligible clinicians would be able to contact their designated technical assistance representative or, beginning with the 2022 MIPS payment year, the Quality Payment Program Service Center, as applicable, to inquire about their TIN size for informational purposes in order to assist MIPS eligible clinicians in determining whether or not to participate in MIPS as part of a virtual group. We anticipate that starting in August of each calendar year prior to the applicable performance period, solo practitioners and groups would be able to contact the Quality Payment Program

Service Center and inquire about virtual group participation eligibility.

• A virtual group representative would make an election on behalf of a virtual group by registering to participate in MIPS as a virtual group in a form and manner specified by CMS. We anticipate that a virtual group representative would make the election via a web-based system developed by CMS.

We also proposed updates to § 414.1315 in an effort to more clearly and concisely capture previously established policies. These proposed updates are not intended to be substantive in nature, but rather to bring more clarity to the regulatory text.

The following is a summary of the public comments received on these proposals and our responses.

Comment: One commenter requested that CMS revisit the virtual group definition's current limit of ten clinicians because the definition of eligible clinician will be expanded. The commenter recommended revising the definition and measure virtual groups by setting an attributed membership floor to improve reporting validity.

Response: In regard to determining TIN size for purposes of virtual group eligibility, we count each NPI associated with a TIN in order to determine whether or not a TIN exceeds the threshold of 10 NPIs, which includes clinicians who are eligible and not eligible for MIPS. We believe that such an approach provides continuity over time if the definition of a MIPS eligible clinician is expanded in future years under section 1848(q)(1)(C)(i)(II) of the Act to include other eligible clinicians (82 FR 53596). As discussed in the 2018 Quality Payment Program final rule (82 FR 53596 through 53597), we considered an alternative approach for determining TIN size, which would determine TIN size for virtual group eligibility based on NPIs who are MIPS eligible clinicians. However, as we conducted a comparative assessment of the application of such alternative approach with the current definition of a MIPS eligible clinician (as defined at § 414.1305) and a potential expanded definition of a MIPS eligible clinician, we found that such an approach could create confusion as to which factors determine virtual group eligibility and cause the pool of virtual group eligible TINs to significantly be reduced once the definition of a MIPS eligible clinician would be expanded, which may impact a larger portion of virtual groups that intend to participate in MIPS as a virtual group for consecutive performance periods. Such impact would be the result of the current definition of a MIPS eligible clinician being narrower than the potential expanded definition of a MIPS eligible clinician. We did not pursue such an approach given that it did not align with our objective of establishing virtual group eligibility policies that are simplistic in understanding and provide continuity.

Furthermore, we note that given that the TIN size is already based on the total number of NPIs within a TIN, the expanded definition of a MIPS eligible clinician will not impact the population of TINs eligible to form or join a virtual group. In regard to increasing the TIN size threshold of 10, section 1848(q)(5)(I)(ii) of the Act establishes a threshold of 10 and as a result, we do not have discretion to expand virtual group participation to TINs with more than 10 NPIs.

Comment: A few commenters supported our proposal to align the virtual group eligibility determination period with the first segment of the MIPS determination period for consistency. The commenters also supported the availability of TIN size information that can be considered by groups prior to submitting a virtual group election. One commenter requested that CMS provide notification regarding the timeframe for the virtual group election process each year.

Response: In regard to the virtual group election period, we publish the timeframe for virtual groups to make an election in subregulatory guidance (that is, materials published and posted on the CMS website and information disseminated via a listserv) each year on the CMS website in advance of the start of the election period. Each year, the virtual group election period will occur prior to the start of an applicable performance period and have an end date of December 31.

Comment: One commenter requested clarification as to why a virtual group election must be made prior to the performance period and recommended that CMS postpone the deadline to the third quarter of the performance year.

Response: Section 1848(q)(5)(I)(iii)(I) of the Act provides that the virtual group election process must include the following requirement: An individual MIPS eligible clinician or group electing to be in a virtual group must make their election prior to the start of the performance period and cannot change their election during the performance period.

After consideration of the public comments, we are finalizing our proposals to continue to apply the aforementioned previously established virtual group policies for the 2022 MIPS payment year and future years, with the exception of the following:

• The virtual group eligibility determination period is the first segment of the MIPS determination period (proposal finalized at § 414.1315(c)(1)(ii)), which consists of an analysis of claims data during a 12-month assessment period (fiscal year) that begins on October 1 of the calendar year 2 years prior to the applicable performance period and ends on September 30 of the calendar year preceding the applicable performance period and includes a 30-day claims run out. As part of the virtual group eligibility determination period, TINs will be able to inquire about their TIN size prior to making an election during a 5-month timeframe, which will begin on August 1 and end on December 31 of a calendar year prior to the applicable performance period. We refer readers to section III.I.3.b. of this final rule for more information regarding the MIPS determination period.

• MIPS eligible clinicians will be able to contact their designated technical assistance representative or, beginning with the 2022 MIPS payment year, the Quality Payment Program Service Center, as applicable, to inquire about their TIN size for informational purposes in order to assist MIPS eligible clinicians in determining whether or not to participate in MIPS as part of a virtual group. We anticipate that starting in August of each calendar year prior to the applicable performance period, solo practitioners and groups would be able to contact the Quality Payment Program Service Center and inquire about virtual group participation eligibility.

• A designated virtual group representative must submit an election, on behalf of the solo practitioners and groups that compose a virtual group, to participate in MIPS as a virtual group for a performance period in a form and manner specified by CMS by the election deadline specified at § 414.1315(b) (proposal finalized at § 414.1315(c)(2)(ii)) We anticipate that a virtual group representative will make the election via a web-based system developed by CMS.

Also, we are finalizing updates to § 414.1315 in an effort to more clearly and concisely capture previously established policies. The updates are not intended to be substantive in nature, but rather to bring more clarity to the regulatory text.

We note that we are further revising § 414.1315 to consolidate paragraphs (c)(2)(ii) and (iii) and redesignate paragraph (c)(2)(iv) as paragraph (c)(2)(iii) for clarity. Additionally, we are revising redesignated paragraph

(c)(2)(iii) to refer to ''the start of data submission'' rather than ''the start of an applicable submission period'' because ''submission period'' is not an expressly defined term.

g. MIPS Performance Period

In the CY 2018 Quality Payment Program final rule (82 FR 53617 through 53619), we finalized at § 414.1320(c)(1) that for purposes of the 2021 MIPS payment year, the performance period for the quality and cost performance categories is CY 2019 (January 1, 2019 through December 31, 2019). We did not finalize the performance period for the quality and cost performance categories for purposes of the 2022 MIPS payment year or future years. We also redesignated § 414.1320(d)(1) and finalized at § 414.1320(c)(2) that for purposes of the 2021 MIPS payment year, the performance period for the Promoting Interoperability and improvement activities performance categories is a minimum of a continuous 90-day period within CY 2019, up to and including the full CY 2019 (January 1, 2019 through December 31, 2019).

As noted in the CY 2018 Quality Payment Program final rule, we received comments that were not supportive of a full calendar year performance period for the quality and cost performance categories. However, we continue to believe that a full calendar year performance period for the quality and cost performance categories will be less confusing for MIPS eligible clinicians. As discussed in the CY 2019 PFS proposed rule (83 FR 35893), we believe that a longer performance period for the quality and cost performance categories will likely include more patient encounters, which will increase the denominator of the quality and cost measures. Statistically, larger sample sizes provide more accurate and actionable information. Additionally, a full calendar year performance period is consistent with how many of the measures used in our program were designed to be performed and reported. We also noted that the Bipartisan Budget Act of 2018 (Pub. L. 115–119, enacted February 9, 2018) has provided further flexibility to the 3rd, 4th, and 5th years of MIPS to help continue the gradual transition to MIPS.

Regarding the Promoting Interoperability performance category, we have heard from stakeholders through public comments, letters, and listening sessions that they oppose a full year performance period, indicating that it is very challenging and may add administrative burdens (83 FR 35893). Some stated that a 90-day performance period is necessary in order to enable clinicians to have a greater focus on the objectives and measures that promote patient safety, support clinical effectiveness, and drive toward advanced use of health IT. They also noted that as this performance category requires the use of CEHRT, a 90-day performance period will help relieve pressure on clinicians to quickly implement changes and updates from their CEHRT vendors and developers so that patient care is not compromised. Others cited the challenges associated with reporting on a full calendar year for clinicians newly employed by a health system or practice during the course of a program year, switching CEHRT, vendor issues, system downtime, cyber-attacks, difficulty getting data from old places of employment, and office relocation. Most stakeholders stated that the performance period should be 90 days in perpetuity, as this would greatly reduce the reporting burden (83 FR 35893).

In the CY 2019 PFS proposed rule (83 FR 35893), in an effort to provide as much transparency as possible so that MIPS eligible clinicians and groups may plan for participation in the program, we requested comments on our proposals at § 414.1320(d)(1) that for purposes of the 2022 MIPS payment year and future years, the performance period for the quality and cost performance categories would be the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year. For example, for the 2022 MIPS payment year, the performance period would be 2020 (January 1, 2020 through December 31, 2020), and for the 2023 MIPS payment year, the performance period would be CY 2021 (January 1, 2021 through December 31, 2021).

In addition, we requested comments on our proposal at § 414.1320(d)(2) that for purposes of the 2022 MIPS payment year and future years, the performance period for the improvement activities performance category would be a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. For example, for the 2022 MIPS payment year, the performance period for the improvement activities performance category would be a minimum of a continuous 90-day period within CY 2020, up to and including the full CY 2020 (January 1, 2020 through December 31, 2020). For the 2023 MIPS payment year, the performance period for the improvement activities performance category would be a minimum of a continuous 90-day period within CY 2021, up to and including the full CY 2021 (January 1, 2021 through December 31, 2021) that occurs 2 years before the MIPS payment year (83 FR 35893).

Finally, we requested comments on our proposal to add § 414.1320(e)(1) that for purposes of the 2022 MIPS payment year, the performance period for the Promoting Interoperability performance category would be a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. Thus, for the 2022 MIPS payment year, the performance period for the Promoting Interoperability performance category would be a minimum of a continuous 90-day period within CY 2020, up to and including the full CY 2020 (January 1, 2020 through December 31, 2020) (83 FR 35893).

The following is a summary of the public comments received on these proposals and our responses:

Comment: Several commenters agreed with our proposal to maintain the quality and cost performance periods as a full calendar year that occurs 2 years prior to the applicable MIPS payment year, noting that this proposal provides some of the stability needed for MIPS. One commenter supported a full calendar year for the cost performance category as this allows for a greater number of cases to be included in each measure, which will give a more reliable performance result. Another commenter supported a full calendar year for the quality and cost performance categories because they stated that it is in the best interest of patients encouraging clinicians to evolve in their approach to delivering care.

Response: We appreciate the commenters' support.

Comment: Several commenters opposed a full calendar-year performance period for the quality and cost performance categories and urged CMS to establish a minimum 90-day performance period, consistent with the other performance categories. Commenters noted that a minimum of 90-day performance period would reduce the administrative burden in MIPS, align the performance period across MIPS performance categories and allow the agency to shorten the 2-year lag between performance and payment. Other commenters requested that clinicians be allowed to choose between 90 days up to a full year of reporting. Another commenter urged CMS to consider adopting a 90-day performance period to capture eligible clinicians who may join a group in the middle of a performance year. One commenter agreed with the challenges CMS

outlined in the proposed rule (83 FR 35893) regarding the Promoting Interoperability performance category and stated that these various challenges create obstacles outside the control of the clinician, which inhibits their ability to collect and report 12 months of MIPS data for the quality performance category as well.

Response: We do not believe that it would be in the best interest of MIPS eligible clinicians to have less than a full calendar year performance period for the quality and cost performance categories for the 2022 MIPS payment year and future years, as we are maintaining consistency with the performance period established for the first 3 MIPS payment years. We believe this will be less burdensome and confusing for MIPS eligible clinicians. As discussed in the CY 2018 Quality Payment Program final rule (82 FR 53618), statistically, larger sample sizes provide more accurate and actionable information. Additionally, a full calendar year performance period is consistent with how many of the measures used in our program were designed to be reported and performed; some of the measures do not allow for a 90-day performance period. We believe these issues make the quality performance category inherently different for reporting requirements and measures than the Promoting Interoperability and improvement activities performance categories. We do not believe reducing the performance period for the quality and cost performance categories will alleviate any issues with clinicians switching practices. Regarding reducing the 2-year lag between performance and payment, as noted in the CY 2017 Quality Payment Final Rule (81 FR 77077), the data submission activities and claims for services furnished during the 1 year performance period (which could be used for claims- or administrative claims-based quality or cost measures) may not be fully processed until the following year. These circumstances require adequate lead time to collect performance data, assess performance, and compute the MIPS adjustment so the applicable MIPS adjustment can be made available to each MIPS eligible clinician at least 30 days prior to when the MIPS payment adjustment is applied each year. Finally, in regard to the challenges we outlined in the proposed rule (83 FR 35893), these were specifically referring to the Promoting Interoperability performance category. We do not believe that these challenges affect the quality performance category, as well.

Comment: A few commenters noted that establishing a 90-day performance period would give CMS an opportunity to set benchmarks based on more current data, rather than from 4 years prior to the applicable MIPS payment year.

Response: We believe that benchmarks based on data from a 90-day performance period would be less reliable than those based on a full calendar year because fewer reported instances would meet the case minimum needed to be included in the benchmarks. This would also cause some measures to not have an available benchmark that could be used for scoring. In addition, using a 90-day performance period would not allow the creation of benchmarks from more current data. This is because we would still need to wait until the end of the data submission period before we could create the benchmarks based on data submitted by all MIPS eligible clinicians, and to publish historical benchmarks prior to the beginning of the performance period, we would still need to use data from 2 years prior to the performance period (4 years prior to the MIPS payment year).

Comment: Several commenters supported the proposal to keep the minimum performance period for the improvement activities performance category at 90 days, noting the proposal maintains stability and simplifies the program. One commenter stated that practices should be able to complete improvement activities lasting 90 days even if the performance spans over two performance periods. The commenter stated that CMS should require practices to complete at least 45 consecutive days during each of two consecutive performance periods to equal a total of at least 90 days, noting that this lowers the burden on clinicians and further encourages participation in this performance category.

Response: We appreciate the support for our proposal. However, we do not agree that an improvement activity should be split into two, 45-day periods. As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77186), after researching several organizations, we believe a minimum of 90 days is a reasonable amount of time required for performing an activity. We do not believe that performance periods as short as 45 days are sufficient for many of the available improvement activities to ensure that the activities being performed result in actual practice improvements.

Comment: One commenter opposed our proposal to keep the minimum performance period for the improvement activities performance category at 90-days and urged CMS to adopt a 12-month performance period. The commenter noted that a 12-month performance period may be in the best interest of patients and may evolve clinicians' approach to delivering care.

Response: We appreciate the commenters' recommendation. However, we believe that a minimum of a continuous 90-day performance period is appropriate for MIPS eligible clinicians to perform improvement activities that would improve clinical practice and provides more flexibility as some improvement activities may be ongoing, while others may be appropriately episodic.

Comment: Many commenters supported our proposal to keep the minimum performance period for the Promoting Interoperability performance category at 90 days, noting that this proposal maintains stability, helps reduce administrative burden, provides clinicians with the time needed to manage changes and updates from their CEHRT vendors and developers, allows for effective measurement, and allows clinicians the flexibility to address scheduled or unanticipated events such as switching EHR vendors, system downtime, and cyber-attacks without jeopardizing patient care. Several commenters requested that CMS consider extending this performance period beyond the CY 2020 MIPS performance period.

Response: We appreciate the commenters' support. We believe it is premature to establish policy beyond CY 2020 at this time appreciating the continued work in this area across HHS. We are finalizing the Promoting Interoperability performance period specific to CY 2019. We will take the comment into consideration for future rulemaking.

Comment: One commenter requested that CMS investigate ways to shorten the time between performance periods and for future MIPS payment years in the Quality Payment Program. This commenter noted concern that 2 years is too long to impact practice patterns and lead to meaningful changes in behavior.

Response: We understand the commenter's concern. However, as discussed in the CY 2017 Quality Payment Program final rule (81 FR 77083), there is a ''2-year lag'' at this time, in order to account for the post-submission processes of calculating the MIPS eligible clinician's final score, establishing budget neutrality and issuing the MIPS payment adjustment factors, and allowing for a targeted review period to occur prior to the application of the MIPS payment

adjustment. We will continue working to shorten the ''2-year lag'' that the commenter describes.

Comment: Several commenters urged CMS to consider the timing of previous year MIPS feedback reports, which are released in July after the close of the performance period, noting that this timeline does not allow for clinicians to make necessary changes before the beginning of the next performance period. Several commenters noted that, if the performance period was reduced to a 90-day minimum with the option to submit additional data, individuals and groups would have greater flexibility to incorporate previous MIPS feedback into their performance during the remaining portion of 2019, thereby increasing quality and patient safety, and to focus more of their attention on improving patient care.

Response: Regarding the release of the feedback reports for the 1st year of MIPS, we provided 3 rounds of feedback including: (1) Round 1—at the point of submission feedback; (2) round 2—pre-performance feedback; and (3) round 3—performance feedback. First, in round 1, at the point of submission we provided real time feedback that was available from the opening to the close of the submission period. Second, in round 2, we provided pre-performance feedback, which was available at the beginning of the close of the submission period and updated the round 2 feedback as new data became available such as CAHPS for MIPS survey, all-cause readmission measure, and cost measures data. Third, in round 3, we provided performance feedback that while it looks similar to round 2 is different in that the data is final with no new data being added and the payment adjustment(s) is included. This is the data that can be used to determine if a targeted review is to be filed. Considering there are opportunities for a clinician to gain insight into their possible performance prior to the release of the performance feedback in July, we encourage MIPS eligible clinicians to review the preliminary feedback and make necessary process and performance improvements, as needed. While we agree that there is some benefit to a 90-day performance period, we believe that more continuous feedback is more beneficial. We also note that operationally our goal is to provide as much continuous submission opportunity as we can support in the future, including allowing clinicians to submit data during the performance period, as feasible. The ability to receive more frequent and continuous submissions will further our ability to provide more frequent feedback to MIPS eligible clinicians.

Comment: A few commenters did not support the 90-day performance period for the Promoting Interoperability performance category and urged CMS to move to full calendar year reporting as soon as possible to achieve value-based care, stating that patients and families should be able to experience the benefits of health IT any day of the year, rather than a particular 3-month period. One commenter noted that a 12-month performance period would more effectively achieve the objectives of MACRA. One commenter also noted that requiring full-year reporting would be less burdensome because it aligns with performance period for the quality performance category. Finally, one commenter also noted that requiring full-year reporting is more likely to prompt changes to clinician workflows.

Response: Although the performance period for the Promoting Interoperability performance category is a minimum of a continuous 90-day period during the calendar year, clinicians may report for a period up to and including the full calendar year. In addition, we do not believe that the duration of the performance period is indicative of the availability of the EHR to patients. We believe it is likely that a clinician who uses an EHR for a period of 90 days will continue to use it year round.

Comment: One commenter urged us to consider the practical implications of a 90-day performance period for Promoting Interoperability measure reporting, emphasizing the need to ensure MIPS eligible clinicians and groups maintain interoperability capabilities in months that are not in the Promoting Interoperability performance period. This commenter noted the reporting periods may vary across eligible clinicians and groups and that a 90-day performance period could reduce the MIPS program's incentives for interoperability and may delay roll-out of enhanced interoperability functionality.

Response: While MIPS eligible clinicians are required to report for a minimum of 90 days, they have the flexibility to report for a longer performance if they choose. Further we believe that once CEHRT is being utilized by the MIPS eligible clinician, it will be used on an ongoing basis and not just during a 90-day performance period.

After consideration of the public comments received, we are finalizing our proposal at § 414.1320(d)(1) that for purposes of the 2022 MIPS payment year and future years, the performance period for the quality and cost performance categories would be the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year. In addition, we are finalizing our proposal at § 414.1320(d)(2) that for purposes of the 2022 MIPS payment year and future years, the performance period for the improvement activities performance category would be a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. We are also finalizing our proposal to add at § 414.1320(e)(1) that for purposes of the 2022 MIPS payment year, the performance period for the Promoting Interoperability performance category would be a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. Finally, we are finalizing revisions to § 414.1320(b)(2) and (c)(2) to refer to the new name of the Promoting Interoperability performance category.

h. MIPS Performance Category Measures and Activities

(1) Data Submission Requirements

(a) Background

We refer readers to § 414.1325 and the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77087 through 77095, and 82 FR 53619 through 53626, respectively) for our previously established policies regarding data submission requirements.

(b) Collection Types, Submission Types and Submitter Types

It has come to our attention that the way we have previously described data submission by MIPS eligible clinicians, groups and third party intermediaries does not precisely reflect the experience users have when submitting data to us. To clarify, we have previously used the term ''submission mechanisms'' to refer not only to the mechanism by which data is submitted, but also to certain types of measures and activities on which data are submitted (for example, electronic clinical quality measures (eCQMs) reported via EHR) and to the entities submitting such data (for example, third party intermediaries on behalf of MIPS eligible clinicians and groups). To ensure clarity and precision for all users, we are proposing to revise existing and define additional terminology to more precisely reflect the experience users have when submitting data to the Quality Payment Program.

In the CY 2019 PFS proposed rule (83 FR 35894), we requested comments on our proposal to define the following terms at § 414.1305:

- Collection type as a set of quality measures with comparable specifications and data completeness criteria, including, as applicable: eCQMs; MIPS Clinical Quality Measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; CMS Web Interface measures; the CAHPS for MIPS survey; and administrative claims measures. The term MIPS CQMs would replace what was formerly referred to as registry measures since entities other than registries may submit data on these measures. These new terms are referenced in the collection type field for the following measure tables of the appendices in the CY 2019 PFS proposed rule (83 FR 36092 through 36358): Table Group A: Proposed New Quality Measures for Inclusion in MIPS for the 2021 MIPS Payment Year and Future Years; Table Group B: Proposed New and Modified MIPS Specialty Measure Sets for the 2021 MIPS Payment Year and Future Years; Table C: Quality Measures Proposed for Removal from the Merit-Based Incentive Payment System Program for the 2019 Performance Period and Future Years; and Table Group D: Measures with Substantive Changes Proposed for the 2021 MIPS Payment Year and Future Years.
- Submitter type as the MIPS eligible clinician, group, or third party intermediary acting on behalf of a MIPS eligible clinician or group, as applicable, that submits data on measures and activities under MIPS.
- Submission type as the mechanism by which a submitter type submits data to CMS, including, as applicable: Direct, log in and upload, log in and attest, Medicare Part B claims and the CMS Web Interface. The direct submission type allows users to transmit data through a computer-to-computer interaction, such as an API. The log in and upload submission type allows users to upload and submit data in the form and manner specified by CMS with a set of authenticated credentials. The log in and attest submission type allows users to manually attest that certain measures and activities were performed in the form and manner specified by CMS with a set of authenticated credentials. We note that there is no submission type for the administrative claims collection type because we calculate measures for this collection type based on administrative claims data available to us.

In the CY 2019 PFS proposed rule (83 FR 35894), we solicited additional feedback and alternative suggestions on terminology that appropriately reflects the concepts described in the proposed definitions of collection type, submitter type and submission type, as well as the term MIPS CQMs to replace the formerly used term of registry measures.

The following is a summary of the comments we received on ''Collection Types, Submission Types and Submitter Types''.

Comment: A few commenters supported the clarification of submission terms, stating that the new definitions recognize the complexity of measure types and submission options and reduce the potential for confusion. Commenters asked whether, if we finalize these terminology updates, educational information will be made available on the Quality Payment Program website so that clinicians will understand and appropriately apply these terms. One commenter also emphasized the importance of ensuring that submitting and attesting to measures is flexible and easy for clinicians to do.

Response: We intend to update the Quality Payment Program website appropriately and provide any relevant educational materials.

Comment: One commenter recommended that, if the ''collection type'' definition only refers to quality measures, CMS change ''collection type'' to ''quality measure type'' and requested that CMS provide a definition for data collection recognizing that all performance categories collect data. Another commenter also recommended that we recommend that we change ''collection type'' to ''measure type'' or ''measure category'' to more intuitively and accurately reflect the meaning of the term.

Response: The proposed definition of collection type states that it is specific to a set of quality measures. Therefore, we do not agree the suggested term of ''quality measure type'' would be the most beneficial in clarifying the actual submission experience for the user, in comparison to how submission mechanisms were discussed in our previous policies. We also note that the usage of the term ''quality measure type'' is commonly used to refer to mean a specific type of measure such as process or outcome measure. While we agree that all performance categories do in fact collect data, for purposes of clarifying the user experience for data submission, it is most beneficial to only refer to data collection in regards to the quality performance category. The suggested terms ''measure type'' or ''measure category'' could create further misunderstanding of the intent of the definition. As far as ''measure type'', there are other measures available in the program than just those available for reporting on in the quality performance category. For the term ''measure category'', we disagree as this could give the implication that this is another performance category within the Quality Payment Program.

Comment: One commenter recommended that we change the term ''submission type'' to ''submission method'' and to define the mechanisms by which CMS means by ''direct,'' ''log in,'' ''upload,'' and ''attest.''

Response: We agree that the term ''submission method'' is an appropriate term for the proposed definition. However, the term did not gain support during user testing that surpassed the proposed terms. According to feedback from user testing, the proposed terms of collection, submitter and submission type, were found to be intuitive and to match the user experience when submitting data to the Quality Payment Program. The direct, log in and upload, log in and attest modes of data submission will be discussed in further detail in forthcoming educational resources. We also encourage review of the terms and wireframes for the submission types on *qpp.cms.gov/design-examples*.

Comment: One commenter recommended that we change ''submitter type'' to ''submitting entity'' and define this as the entity who will be submitting the eligible clinician's data.

Response: We believe that consistent terminology would be most beneficial in providing clarity for users submitting data to the Quality Payment Program. We also note that the term submitter type includes both entities that would submit on a clinician's behalf, as well as actions made directly by clinicians or their practice.

After consideration of the public comments received, we are finalizing our proposal at § 414.1305 to define the following terms:

- Collection type as a set of quality measures with comparable specifications and data completeness criteria, including, as applicable: eCQMs; MIPS Clinical Quality Measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; CMS Web Interface measures; the CAHPS for MIPS survey; and administrative claims measures. The term MIPS CQMs would replace what was formerly referred to as registry measures since entities other than registries may submit data on these measures. These new terms are referenced in the collection type field for the following measure tables of ''Appendix 1: Finalized MIPS Quality

Measures'' in this final rule: Table Group A: Finalized New Quality Measures for Inclusion in MIPS for the 2021 MIPS Payment Year and Future Years; Table Group B: Finalized New and Modified MIPS Specialty Measure Sets for the 2021 MIPS Payment Year and Future Years; Table Group C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years; and Table Group D: Measures with Substantive Changes Finalized for the 2021 MIPS Payment Year and Future Years.

- Submitter type as the MIPS eligible clinician, group, or third party intermediary acting on behalf of a MIPS eligible clinician or group, as applicable, that submits data on measures and activities under MIPS.
- Submission type as the mechanism by which a submitter type submits data to CMS, including, as applicable: Direct, log in and upload, log in and attest, Medicare Part B claims and the CMS Web Interface. The direct submission type allows users to transmit data through a computer-to-computer interaction, such as an API. The log in and upload submission type allows users to upload and submit data in the form and manner specified by CMS with a set of authenticated credentials. The log in and attest submission type allows users to manually attest that certain measures and activities were performed in the form and manner specified by CMS with a set of authenticated credentials. We note that there is no submission type for the administrative claims collection type because we calculate measures for this collection type based on administrative claims data available to us.

(c) Performance Category Measures and Reporting

We previously finalized at § 414.1325(a) and (e), respectively, that MIPS eligible clinicians and groups must submit measures, objectives, and activities for the quality, improvement activities, and advancing care information performance categories and that there are no data submission requirements for the cost performance category and for certain quality measures used to assess performance in the quality performance category; CMS will calculate performance on these measures using administrative claims data. In the CY 2019 PFS proposed rule (83 FR 35894), we proposed to amend § 414.1325(a) to incorporate § 414.1325(e), as they both address which performance categories require data submission; § 414.1325(f) would be redesignated as § 414.1325(e). We also proposed in the CY 2019 PFS proposed rule (83 FR 35894) at § 414.1325(a)(2)(ii) that there is no data submission requirement for the quality or cost performance category, as applicable, for MIPS eligible clinicians and groups that are scored under the facility-based measurement scoring methodology described in § 414.1380(e). We also recognized the need to clarify to users how they submit data to us. In the CY 2019 PFS proposed rule (83 FR 35894), there are five basic submission types that we proposed to define in MIPS: Direct; log in and upload; login and attest; Medicare Part B claims; and the CMS Web Interface. We proposed to reorganize § 414.1325(b) and (c) by performance category in the CY 2019 PFS proposed rule (83 FR 35894). We proposed in the CY 2019 PFS proposed rule (83 FR 35894) to also clarify at § 414.1325(b)(1) that an individual MIPS eligible clinician may submit their MIPS data for the quality performance category using the direct, login and upload, and Medicare Part B claims submission types. In the CY 2019 PFS proposed rule (83 FR 35894), similarly, we proposed to clarify at § 414.1325(b)(2) that an individual MIPS eligible clinician may submit their MIPS data for the improvement activities or Promoting Interoperability performance categories using the direct, login and upload, or login and attest submission types. As for groups, we proposed in the CY 2019 PFS proposed rule (83 FR 35894) to clarify at § 414.1325(c)(1) that groups may submit their MIPS data for the quality performance category using the direct, login and upload, and CMS Web Interface (for groups consisting of 25 or more eligible clinicians) submission types. Lastly, we proposed to clarify at § 414.1325(c)(2) that groups may submit their MIPS data for the improvement activities or Promoting Interoperability performance categories using the direct, login and upload, or login and attest submission types in the CY 2019 PFS proposed rule (83 FR 35894). We believe that these clarifications will enhance the submission experience for clinicians and other stakeholders. As technology continues to evolve, we will continue to look for new ways that we can offer further technical flexibilities on submitting data to the Quality Payment Program. In the CY 2019 PFS proposed rule (83 FR 35894), we requested comment on these proposals. To assist commenters in providing pertinent comments, we developed a website that uses wireframe (schematic) drawings to illustrate a subset of the different submission types available for MIPS participation. Specifically, the wireframe drawings describe the direct, login and attest, and login and upload submission types. We refer readers to the Quality Payment Program at *qpp.cms.gov/design-examples* to review these wireframe drawings. The website will provide specific matrices illustrating potential stakeholder experiences when choosing to submit data under MIPS.

As previously expressed in the 2017 Quality Payment Program final rule (81 FR 77090), we want to move away from claims reporting, since approximately 69 percent of the Medicare Part B claims measures are topped out. Although we would like to move towards the utilization of electronic reporting by all clinicians and groups, we realize that small practices face additional challenges, and this requirement may limit their ability to participate. For this reason, we believe that Medicare Part B claims measures should be available to small practices, regardless of whether they are reporting as individual MIPS eligible clinicians or as groups. Therefore, we proposed amending § 414.1325(c)(1) to make the Medicare Part B claims collection type available to MIPS eligible clinicians in small practices beginning with the 2021 MIPS payment year in the CY 2019 PFS proposed rule (83 FR 35894). Although this will limit the current availability of Medicare Part B claims measures for individual MIPS eligible clinicians that do not meet the definition of a small practice, it will expand the availability of such measures for small practices who choose to participate in MIPS as a group, which currently does not have a claims-based reporting option as a group.

Under § 414.1325(c)(4), we previously finalized that groups may submit their MIPS data using the CMS Web Interface (for groups consisting of 25 or more eligible clinicians) for the quality, improvement activities, and promoting interoperability performance categories. In the CY 2019 PFS proposed rule (83 FR 35894 through 35895), we proposed that the CMS Web Interface submission type would no longer be available for groups to use to submit data for the improvement activities and Promoting Interoperability performance categories at § 414.1325(c)(2). The CMS Web Interface has been designed based on user feedback as a method for quality submissions only; however, groups that elect to utilize the CMS Web Interface can still submit improvement activities or promoting interoperability data via direct, log in and attest or log in and upload submission types. We also recognized that certain groups that have elected to use the CMS Web Interface

may prefer to have their data submitted on their behalf by a third party intermediary described at § 414.1400(a). We recognized the benefit and burden reduction in such a flexibility and therefore proposed to allow third party intermediaries to submit data to the CMS Web Interface in addition to groups in the CY 2019 PFS proposed rule (83 FR 35895). Specifically, we proposed in the CY 2019 PFS proposed rule (83 FR 35895) to redesignate § 414.1325(c)(4) as § 414.1325(c)(1) and amend § 414.1325(c)(1) to allow third party intermediaries to submit data using the CMS Web Interface on behalf of groups. To further our efforts to provide flexibility in reporting to the Quality Payment Program, we solicited comment in the CY 2019 PFS proposed rule (83 FR 35895) on expanding the CMS Web Interface submission type to groups consisting of 16 or more eligible clinicians to inform our future rulemaking.

We previously finalized at § 414.1325(e) that there are no data submission requirements for the cost performance category and for certain quality measures used to assess performance in the quality performance category and that CMS will calculate performance on these measures using administrative claims data. We also finalized at § 414.1325(f)(2), (which, as noted, we proposed to redesignate as § 414.1325(e)(2)) that for Medicare Part B claims, data must be submitted on claims with dates of service during the performance period that must be processed no later than 60 days following the close of the performance period. We neglected to codify this requirement at § 414.1325(e) (which, as noted, we proposed to consolidate with § 414.1325(a)) for administrative claims data used to assess performance in the cost performance category and for administrative claims-based quality measures. Therefore, in the CY 2019 PFS proposed rule (83 FR 35895), we proposed to amend § 414.1325(a)(2)(i) to reflect that claims included in the measures are those submitted with dates of service during the performance period that are processed no later than 60 days following the close of the performance period.

In the CY 2019 PFS proposed rule (83 FR 35895), a summary of these proposed changes is included in Tables 32 and 33. For reference, Table 32 summarizes the data submission types for individual MIPS eligible clinicians that we proposed at § 414.1325(b) and (e) in the CY 2019 PFS proposed rule (83 FR 35895). Table 33 summarizes the data submission types for groups that we proposed at § 414.1325(c) and (e) in the CY 2019 PFS proposed rule (83 FR 35895 through 35896). We requested comment on these proposals.

The following is a summary of the comments we received on ''Performance Category Measures and Reporting''.

Comment: Many commenters supported our proposal to allow small practices to use the Medicare Part B claims-based reporting option for group reporting, with some noting that this option specifically relieves the burden on rural providers. However, several of these commenters opposed limiting the Medicare Part B claims reporting to only clinicians in small practices, stating that many clinicians are excluded from the special small practice policies despite operating as small practices in all other respects, and there may be circumstances where reporting via Medicare Part B claims as individuals is the best option for clinicians in larger multispecialty practices to allow each clinician to focus on quality measures most relevant to his/her specialty and scope of practice. A few commenters stated that this policy would result in a negative impact on clinicians who are part of specialties that do not have relevant eCQMs available to them, but have nonetheless implemented workflows to support reporting data using Medicare Part B claims; requiring them to change these workflows based solely on practice size would cause unnecessary clinician burden without an offsetting benefit to the clinician already participating in the program. Therefore, these commenters recommended that CMS retain the Medicare Part B claims-based reporting option in the quality performance category for all clinicians regardless of practice size. One commenter also requested that we provide a definition for a small practice in the final rule.

Response: We likewise acknowledge that many clinicians that are not in a small practice currently report via Medicare Part B claims. However, as we previously expressed in the CY 2017 Quality Payment Program final rule (81 FR 77090), we want to move away from claims reporting, as more measures are available through health IT mechanisms such as registries, QCDRs, and health IT vendors. We believe it is important to move away from manual methods of reporting and instead utilize more electronic methods such as using EHRs, registries, QCDRs. Also, as we have described above with our revised terms, clinicians that are part of a practice that opts not to work with a third party intermediary can submit data directly to us, which is a flexibility we have under MIPS that was not available under the legacy programs. We note that this change does not require the use of eCQMs by MIPS eligible clinicians that are not considered to be part of a small practice. Rather, MIPS eligible clinicians that do not meet the definition of a small practice will have the ability to select from all other collection types. We refer readers to § 414.1305 for the definition of small practice.

Comment: A few commenters did not support the proposal to make the Medicare Part B claims collection type available to clinicians in small practices, stating that it does not align with the objectives of electronic reporting and Promoting Interoperability. Commenters specifically stated that the small administrative burden to implement CEHRT exceeds the cost of the various benefits of utilizing technology to improve the quality of care and that CEHRT is the only method that is completely accurate based upon the patient record and prevents organizations from ''cherry-picking'' patients to meet the 60 percent reporting threshold. One commenter also noted that registries are available at very affordable costs for clinicians and groups. Another commenter stated concern about how small and rural practices that have made the financial investment into CEHRT would react to this proposed update, stating that the proposal sends an inconsistent message to those small and rural psychiatric practices that made the financial investment to adopt CEHRT.

Response: To clarify, our policy is to make the Medicare Part B claims collection type only available to small practices. We agree that there are many benefits to CEHRT adoption and also agree that many registries are available at low cost. We do not agree that this sends an inconsistent message with the objectives of electronic reporting and Promoting Interoperability as we still encourage all clinicians (small practices and non-small practices) to submit electronically. However, we recognize that small practices have additional challenges and believe that continuing to allow the Medicare Part B claims collection type only to small practices is beneficial. To further highlight alignment in policy regarding small practices across performance categories in MIPS, as discussed in section III.I.3.h.(5) of this final rule for the Promoting Interoperability performance category, small practices can apply for a significant hardship exception if they have issues acquiring an EHR.

Comment: Several commenters opposed the proposed removal of Medicare Part B claims-based reporting

as an option for clinicians. One commenter noted concern because the proposal to expand the definition of a MIPS eligible clinician stated it would also coincide with a decrease in the number of group practices that will be considered a small practice. Commenters requested that CMS finalize a future timeframe for retiring the Medicare Part B claims based submission type for eligible clinicians, stating that: Medicare Part B claims based submission of quality data is still an extremely popular submission method in certain specialties; eliminating this reporting option may reduce the number of clinicians who participate in MIPS reporting; clinicians in many specialties, most notably those that are hospital based, will have to transition to use of a qualified registry or QCDR for quality measure reporting once claims based reporting is no longer an option, and this will require new and unplanned costs and further burden. Commenters also noted that clinicians who elect to report via Medicare Part B claims-based reporting, and choose to report topped out measures, are penalized in their quality score under current methods by receiving a maximum of 7 of 10 points for each topped out measure; therefore there is not an inappropriate incentive for continued use of this method. Another commenter stated that the removal of Medicare Part B claims reporting contradicts the provisions in the Bipartisan Budget Act of 2018 that moves the Agency toward accepting more claims data. Another commenter recommended waiting to see if the number of clinicians reporting through Medicare Part B claims increases over the next years and then determine if a future proposal is appropriate.

Response: We acknowledge that many clinicians that are not in a small practice currently report via Medicare Part B claims. However, we disagree that only allowing the reporting of this collection type to small practices forces non-small practices to transition to the use of a qualified registry or QCDR for quality measure reporting, as there are other collection types and submitter types available in which non-small practices can report (that is, eCQMs, MIPS CQMs, CMS Web Interface measures, the CMS approved survey vendor measure and Administrative claims measures). For example, a non-small practice that does not wish to enter into an arrangement with a third party intermediary can use the MIPS CQM collection type and either login and upload their data or use the direct submission type for the quality performance category. These submission types do not require the usage of a third party intermediary, but we note that there are certain technical capabilities that a practice must have to submit data in this manner. Additional details on the form and manner requirements of these submission types is available at *qpp.cms.gov/design-examples*.

We agree that choosing to report topped out measures is not incentivized. As discussed in the CY 2019 PFS proposed rule (83 FR 35894), we want to move away from claims reporting, since approximately 69 percent of the Medicare Part B claims measures are topped out. This is a contributing factor as to why we are looking to decrease the usage of this option over time, as we have been signaling we would do for many years. We will continue to work with stakeholders on providing further transparency of the future of this collection type. It is unclear to what reference the commenter is discussing where the removal of claims reporting is a contradiction to provisions made in the Bipartisan Budget Act of 2018. We do not believe that this proposal is inconsistent with the Bipartisan Budget Act of 2018.

We do not believe further delay is warranted but will continue to work with stakeholders to provide further clarity on the future of this collection type. Lastly, we disagree that the expansion of the MIPS eligible clinician type as discussed in section III.I.3.c. will decrease the number of small practices. As defined at § 414.1305, a small practice is a TIN consisting of 15 or fewer eligible clinicians during the MIPS determination period. We note that this definition currently includes both eligible clinicians and MIPS eligible clinicians, and therefore, the expansion of the MIPS eligible clinician definition should not negatively impact a practice's ability to be considered a small practice.

Comment: One commenter asked us to acknowledge that, from their experiences participating in MIPS for the CY 2017 transition period, when a group attests for promoting interoperability but uses Medicare Part B claims to submit for the quality performance category as individuals, every clinician must have quality data and this data does not roll-up to the group.

Response: In the CY 2017 Quality Payment Program final rule (81 FR 77087 through 77088), Tables 1 and 2 summarized allowable individual and group submission types. In the 2017 MIPS performance period, Medicare Part B claims submissions for the quality performance category could only be used by individuals, and no group score was calculated for this collection type. In this final rule, we are finalizing our proposal to allow small practices the option to report as individuals or a group using Medicare Part B claims data so that a group performance score can be calculated for quality and combined with other group scores from other performance categories.

Comment: One commenter urged CMS to provide greater detail about whether there is value in the data submitted through the Medicare Part B claims measure collection type, given the reduced number of clinically appropriate and applicable claims measures under Medicare Part B, particularly considering data that is collected from claims forms contains minimal clinical information.

Response: Medicare Part B Claims Measure Specifications do provide value in the data submitted. Denominator eligibility can be determined by billing already included within a Medicare Part B Claim. The eligible clinician can submit a quality data code to attest to the quality action defined by the measure specification. The Medicare Part B Measure Specifications address a number of clinical outcomes on prevalent health conditions (for example, diabetes, hypertension). In addition to the outcomes, the Medicare Part B Claims Measure Specifications provide eligible clinicians who provide services in a small practice to participate within MIPS without incurring additional costs in data abstraction by third party intermediaries.

Comment: One commenter urged CMS to provide greater detail about whether small and rural practices who report their performance solely through Medicare Part B claims measures would be afforded the opportunity to submit fewer than 6 measures (including one outcome or high priority measure) as currently required. This commenter also urged CMS to provide greater detail about whether new Medicare Part B claims quality measures would be accepted for inclusion in the rulemaking process, or if only the current Medicare Part B claims quality measures would be continued for use by small and rural practices.

Response: We did not propose any changes to the quality performance submission criteria for the Medicare Part B claims collection type. We validate the availability and applicability of quality measures for clinicians who collect data via claims with fewer than six measures. Clinicians would only need to report the measures that are applicable. We refer readers to

section III.I.3.i.(1)(b)(vii) of this final rule for more discussion on our data validation process. Any updates to the measures list would go through future rulemaking. We want to clarify, that while reference was made to both small and rural practices by the commenter, this policy is limited to those that are small practices. We note that a practice that is small and rural would be eligible to use the Medicare Part B claims collection type, but only with meeting the special status designation of being a small practice.

Comment: One commenter requested clarification on how CMS would determine that a claims submission is intended for group reporting if the group is only submitting data for the quality performance category of MIPS.

Response: In the scenarios where we only receive Medicare Part B claims submissions for a practice for the quality performance category of MIPS, we intend on calculating the quality performance category for the practice as both a group and as individuals and will apply the quality performance category score that is the greater of the two. We considered requiring an election for assessment as a group but believe this would be unduly burdensome on small practices.

Comment: One commenter disagreed with our proposal to eliminate Web Interface reporting for the improvement activities and Promoting Interoperability performance categories, stating this reduces flexibility for groups and adds unnecessary complexity.

Response: We clarify that the CMS Web Interface has been designed as a method for quality submissions only, based on user feedback. As we developed the CMS Web Interface for usage under the Quality Payment Program, we engaged in user testing with stakeholders and the inclusion of the improvement activities and promoting interoperability performance categories within the CMS Web Interface tool negatively impacted the design. Instead, what users experienced for submissions in the first year of the program was a seamless interaction between the CMS Web Interface and the ability to attest for these two performance categories. With the finalization of this policy, users will have the exact same experiences of reporting data for the promoting interoperability and improvement activities performance categories while still using the CMS Web Interface for the quality performance category. We reiterate that we are simply updating our policy to reflect the existing user experience that stakeholders encounter. We would also like to highlight that groups that elect to utilize the CMS Web Interface can still submit improvement activities or promoting interoperability data via direct and log in and upload, if they choose not to utilize the login and attest submission type.

Comment: One commenter supported our proposal to eliminate Web Interface reporting for the improvement activities and Promoting Interoperability performance categories.

Response: We appreciate the commenter's support.

Comment: One commenter appreciated that we clarified that groups may submit their MIPS data for the improvement activities or Promoting Interoperability performance categories using the direct, login and upload, or login and attest submission types.

Response: Our intent was to provide clarity with the submission experience for clinicians and other stakeholders.

Comment: A few commenters supported our proposal to allow third party intermediaries to submit data using the CMS Web Interface on behalf of groups, which alleviates burden on group practices to report the data themselves.

Response: We appreciate the commenters' support.

After consideration of the public comments received, we are finalizing our proposal to amend § 414.1325(a) to incorporate § 414.1325(e), as they both address which performance categories require data submission; § 414.1325(f) will be redesignated as § 414.1325(e). We are finalizing our proposal at § 414.1325(a)(2)(ii) that there is no data submission requirement for the quality or cost performance category, as applicable, for MIPS eligible clinicians and groups that are scored under the facility-based measurement scoring methodology described in § 414.1380(e). We are finalizing our proposals to reorganize § 414.1325(b) and (c) by performance category and to clarify at § 414.1325(b)(1) that an individual MIPS eligible clinician may submit their MIPS data for the quality performance category using the direct, login and upload, and Medicare Part B claims submission types. We are finalizing our proposal to clarify at § 414.1325(b)(2) that an individual MIPS eligible clinician may submit their MIPS data for the improvement activities or Promoting Interoperability performance categories using the direct, login and upload, or login and attest submission types. We are finalizing our proposal to clarify at § 414.1325(c)(1) that groups may submit their MIPS data for the quality performance category using the direct, login and upload, and CMS Web Interface (for groups consisting of 25 or more eligible clinicians) submission types. We are also finalizing our proposal to clarify at § 414.1325(c)(2) that groups may submit their MIPS data for the improvement activities or Promoting Interoperability performance categories using the direct, login and upload, or login and attest submission types. We are finalizing our proposal to amend § 414.1325(c)(1) to make the Medicare Part B claims collection type available to MIPS eligible clinicians in small practices beginning with the 2021 MIPS payment year. We are finalizing our proposal at § 414.1325(c)(2) to state that the CMS Web Interface submission type will no longer be available for groups to use to submit data for the improvement activities and Promoting Interoperability performance categories. We are finalizing our proposal to redesignate § 414.1325(c)(4) as § 414.1325(c)(1) and amend § 414.1325(c)(1) to allow third party intermediaries to submit data using the CMS Web Interface on behalf of groups. We are finalizing our proposal to redesignate § 414.1325(f)(2) as § 414.1325(e)(2) that for Medicare Part B claims, data must be submitted on claims with dates of service during the performance period that must be processed no later than 60 days following the close of the performance period. Lastly, we are also finalizing our proposal to amend § 414.1325(a)(2)(i) to reflect that claims included in the measures are those submitted with dates of service during the performance period that are processed no later than 60 days following the close of the performance period. We received many comments on our comment solicitation to expand the scope of practices that can utilize the Web Interface and will take them into consideration for future rulemaking.

TABLE 32—DATA SUBMISSION TYPES FOR MIPS ELIGIBLE CLINICIANS REPORTING AS INDIVIDUALS

Performance category/submission combinations accepted	Submission type	Submitter type	Collection type
Quality	Direct Log in and upload. Medicare Part B claims (small practices) [1].	Individual or Third Party Intermediary [2]. Individual	eCQMs. MIPS CQMs. QCDR measures. Medicare Part B claims measures (small practices).
Cost	No data submission required [2]	Individual	
Promoting Interoperability	Direct Log in and upload. Log in and attest.	Individual or Third Party Intermediary.	
Improvement Activities	Direct Log in and upload. Log in and attest.	Individual or Third Party Intermediary.	

[1] Third party intermediary does not apply to Medicare Part B claims submission type.
[2] Requires no separate data submission to CMS: Measures are calculated based on data available from MIPS eligible clinicians' billings on Medicare claims. *Note:* As used in this rule, the term ''Medicare Part B claims'' differs from ''administrative claims'' in that ''Medicare Part B claims'' require MIPS eligible clinicians to append certain billing codes to denominator-eligible claims to indicate the required quality action or exclusion occurred.

TABLE 33—DATA SUBMISSION TYPES FOR MIPS ELIGIBLE CLINICIANS REPORTING AS GROUPS

Performance category/submission combinations accepted	Submission types	Submitter type	Collection type
Quality	Direct Log in and upload. CMS Web Interface (groups of 25 or more eligible clinicians). Medicare Part B claims (small practices) [1].	Group or Third Party Intermediary	eCQMs. MIPS CQMs. QCDR measures. CMS Web Interface measures. Medicare Part B claims measures (small practices). CMS approved survey vendor measure. Administrative claims measures.
Cost	No data submission required [1 2]	Group	
Promoting Interoperability	Direct Log in and upload. Log in and attest.	Group or Third Party Intermediary	
Improvement Activities	Direct Log in and upload. Log in and attest.	Group or Third Party Intermediary	

[1] Third party intermediary does not apply to Medicare Part B claims submission type.
[2] Requires no separate data submission to CMS: Measures are calculated based on data available from MIPS eligible clinicians' billings on Medicare claims. *Note:* As used in this rule, the term ''Medicare Part B claims'' differs from ''administrative claims'' in that ''Medicare Part B claims'' require MIPS eligible clinicians to append certain billing codes to denominator-eligible claims to indicate the required quality action or exclusion occurred.

(d) Submission Deadlines

We previously finalized data submission deadlines in the CY 2017 Quality Payment Program final rule (81 FR 77095 through 77097) at § 414.1325(f), which outlined data submission deadlines for all submission mechanisms for individual eligible clinicians and groups for all performance categories. As discussed in section III.I.3.h.(1) of this final rule, the term submission mechanism, that includes submission via the qualified registry, QCDR, EHR, Medicare Part B claims, the CMS Web Interface and attestation, does not align with the existing process of data submission to the Quality Payment Program. In the CY 2019 PFS proposed rule (83 FR 35896), we proposed to revise regulatory text language at § 414.1325(f), which, as noted, we proposed to redesignate as § 414.1325(e), to outline data submission deadlines for all submission types for individual eligible clinicians and groups for all performance categories. In the CY 2019 PFS proposed rule (83 FR 35896), we also proposed to revise § 414.1325(e)(1) to allow flexibility for CMS to alter submission deadlines for the direct, login and upload, the CMS Web Interface, and login and attest submission types. We anticipate that in scenarios where the March 31st deadline falls on a weekend or holiday, we will extend the submission period to the next business day (that is, Monday). There also may be instances where due to unforeseen technical issues, the submission system may be inaccessible for a period of time. If this scenario were to occur, we anticipate that we will extend the submission period to account for this lost time, to the extent feasible. We note that this revision would also revise the previously finalized policy at § 414.1325(e)(3) stating that data must be submitted during an 8-week period following the close of the performance period, and that the period must begin no earlier than January 2 and end no later than March 31 for the CMS Web Interface. In the CY 2019 PFS proposed rule (83 FR 35896), we proposed to align the deadline for the CMS Web Interface submission type with all other submission type deadlines at § 414.1325(e)(1), while we also proposed to remove the previously finalized policy at § 414.1325(e)(3) because it is no longer needed to mandate a different submission

deadline for the CMS Web Interface submission type. In the CY 2019 PFS proposed rule (83 FR 35896), we also proposed a number of other technical revisions to § 414.1325 to more clearly and concisely reflect previously established policies.

The following is a summary of the comments we received on ''Submission Deadlines''.

Comment: Several commenters supported our proposal to align the deadline for the CMS Web Interface submission type with all other submission type deadlines and appreciated further aligning deadlines within the program, stating that predictable and achievable deadlines are preferred for planning and education purposes. Another commenter urged us to make this new deadline clear to physicians by emphasizing the different deadlines at the start of the performance year.

Response: We will take all feedback into consideration for future educational materials.

Comment: One commenter opposed our proposal to align the deadline for the CMS Web Interface submission type with all other submission type deadlines, stating that this flexibility is being used to shorten the deadline, and that the earliest deadline should be set at March 31.

Response: We disagree that this flexibility is being used to shorten the deadline. We clarify that it is no longer necessary to mandate a different submission deadline for the CMS Web Interface submission type and this proposal will bring further alignment amongst submission types. Furthermore, this policy extends the CMS Web Interface submission deadline by approximately 4 additional weeks.

After consideration of the public comments received, we are finalizing our proposal to redesignate § 414.1325(f) as § 414.1325(e), to outline data submission deadlines for all submission types for individual eligible clinicians and groups for all performance categories. We are finalizing our proposal to revise § 414.1325(e)(1) to allow flexibility for CMS to alter submission deadlines for the direct, login and upload, the CMS Web Interface, and login and attest submission types. We are also finalizing our proposals to align the deadline for the CMS Web Interface submission type with all other submission type deadlines at § 414.1325(e)(1), and to remove the previously finalized policy at § 414.1325(e)(3) because it is no longer needed to mandate a different submission deadline for the CMS Web Interface submission type.

(2) Quality Performance Category

(a) Background

We refer readers to §§ 414.1330 through 414.1340 and the CY 2018 Quality Payment Program final rule (82 FR 53626 through 53641) for our previously established policies regarding the quality performance category.

(i) Assessing Performance on the Quality Performance Category

As discussed in the CY 2019 PFS proposed rule (83 FR 35896), under § 414.1330(a), for purposes of assessing performance of MIPS eligible clinicians on the quality performance category, we will use: Quality measures included in the MIPS final list of quality measures; and quality measures used by QCDRs. We proposed to amend § 414.1330(a) to account for facility-based measurement and the APM scoring standard. For that reason, we proposed at § 414.1330(a) to specify, for a MIPS payment year, that we use the following quality measures, as applicable to assess performance in the quality performance category: Measures included in the MIPS final list of quality measures established by CMS through rulemaking; QCDR measures approved by CMS under § 414.1440; facility-based measures as described under § 414.1380; and MIPS APM measures as described at § 414.1370.

We did not receive any comments on the proposal of how we will assess performance in the quality performance category. Therefore, we are finalizing our proposal to amend § 414.1330(a) to state that for a MIPS payment year, we use the following quality measures, as applicable, to assess performance in the quality performance category: Measures included in the MIPS final list of quality measures established by CMS through rulemaking; QCDR measures approved by CMS under § 414.1440; facility-based measures as described in § 414.1380; and MIPS APM measures as described in § 414.1370.

(ii) Contribution to Final Score

In the CY 2019 PFS proposed rule (83 FR 35896) under § 414.1330(b)(2) and (3), we state that performance in the quality performance category will comprise 50 percent of a MIPS eligible clinician's final score for the 2020 MIPS payment year and 30 percent of a MIPS eligible clinician's final score for each MIPS payment year thereafter. Section 1848(q)(5)(E)(i)(I) of the Act, as amended by section 51003(a)(1)(C)(i) of the Bipartisan Budget Act of 2018, provides that 30 percent of the final score shall be based on performance with respect to the quality performance category, but that for each of the 1st through 5th years for which MIPS applies to payments, the quality performance category performance percentage shall be increased so that the total percentage points of the increase equals the total number of percentage points that is based on the cost performance category performance is less than 30 percent for the respective year. As discussed in section III.I.3.i.(c) of this final rule, we proposed to weight the cost performance category at 15 percent for the 2021 MIPS payment year. Accordingly, we proposed to amend § 414.1330(b)(2) to provide that performance in the quality performance category will comprise 50 percent of a MIPS eligible clinician's final score for the 2020 MIPS payment year, and proposed at § 414.1330(b)(3) that the quality performance category comprises 45 percent of a MIPS eligible clinician's final score for the 2021 MIPS payment year.

We received the following comments on our proposals regarding the quality performance category's contribution to the final score proposal:

Comment: A few commenters supported our proposals.

Response: We thank the commenters for their support.

Comment: Several commenters did not support the proposed reduction of the quality performance category weight to 45 percent from 50 percent for the 2021 MIPS payment year, suggesting that CMS maintain the weight at 50 percent. The commenters indicated that adjusting the weight downward sends the wrong message to physicians regarding quality of care and that de-emphasizing quality runs contrary to the aim of reforming toward a value-based system. Further, commenters stated that altering the weight prematurely leads to less stability with the program and adds complexity. A few commenters recommended that we transfer the weight from the improvement activity category as needed to preserve the weight of the quality category.

Response: As discussed in section III.I.3.h.(3) of this final rule, we are finalizing the proposal to weight the cost performance category at 15 percent for the 2021 MIPS payment year. Accordingly, section 1848(q)(5)(E)(i)(1) of the Act requires that the quality performance category weight to be 45 percent. While we understand that the quality performance category requires additional resources to report, we believe that we are measuring value by rewarding performance in quality while keeping down costs and that clinicians can influence the cost of services that they do not personally perform by

improving care management with other clinicians and avoiding unnecessary services. Regarding the commenters' recommendation that we reduce the weight of the improvement activities performance category to preserve the weight of the quality performance category, we note that we do not have discretion to reduce the weight of the improvement activities performance category except for scenarios where reweighting can occur due to measures and activities and not being available and applicable. Please refer to section III.I.3.i.(1)(e) for information on our reweighting policies.

As discussed in section III.I.3.h.(3) of this final rule, we are finalizing our proposal to weight the cost performance category at 15 percent for the 2021 MIPS payment year. After consideration of the public comments received, we are finalizing our proposal to amend § 414.1330(b)(2) to provide that performance in the quality performance category comprises 50 percent of a MIPS eligible clinician's final score for the 2020 MIPS payment year, and our proposal to amend § 414.1330(b)(3) to provide that the quality performance category comprises 45 percent of a MIPS eligible clinician's final score for the 2021 MIPS payment year.

(iii) Quality Data Submission Criteria

(A) Submission Criteria

(aa) Submission Criteria for Groups Reporting Quality Measures, Excluding CMS Web Interface Measures and the CAHPS for MIPS Survey Measure

In the CY 2019 Quality Payment Program proposed rule (83 FR 35896 through 35897), we referred readers to § 414.1335(a)(1) for our previously established submission criteria for quality measures submitted via claims, registry, QCDR, or EHR. As discussed in section III.I.3.h. of this final rule, we proposed revisions to existing and additional terminology to clarify the data submission processes available for MIPS eligible clinicians, groups and third party intermediaries, to align with the way users actually submit data to the Quality Payment Program. For that reason, we proposed to revise § 414.1335(a)(1) to state that data would be collected for the following collection types: Medicare Part B claims measures; MIPS CQMs; eCQMs; or QCDR measures. Codified at § 414.1335(a)(1)(i), MIPS eligible clinicians and groups must submit data on at least six measures including at least one outcome measure. If an applicable outcome measure is not available, eligible clinicians and groups must report one other high priority measure. If fewer than six measures apply to the MIPS eligible clinician or group, they must report on each measure that is applicable. Furthermore, we proposed beginning with the 2021 MIPS payment year to revise § 414.1335(a)(1)(ii) to indicate that MIPS eligible clinicians and groups that report on a specialty or subspecialty measure set, must submit data on at least six measures within that set, provided the set contain at least six measures. If the set contains fewer than six measures or if fewer than six measures apply to the MIPS eligible clinician or group, they must report on each measure that is applicable.

As previously expressed in the 2017 Quality Payment Program final rule (81 FR 77090), we want to move away from claims reporting, since approximately 69 percent of the Medicare Part B claims measures are topped out. As discussed in section III.I.3.h. of this final rule, we proposed to limit the Medicare Part B claims submission type, and therefore, the Medicare Part B claims measures, to MIPS eligible clinicians in small practices. We refer readers to section III.I.3.h of this final rule for discussion of this proposal.

The following is a summary of the public comments on these proposals and our responses:

Comment: A few commenters did not support the proposed specialty or subspecialty measure set submission criteria, citing the potential difficulty in reporting measures within the set that are not applicable. One commenter requested that, if the proposal is finalized, CMS should clarify how the requirement applies when clinicians submit both MIPS CQMs and QCDR measures to meet the quality performance category requirements, recognizing that some eligible clinicians may not be able to meet the requirement to report on all measures within a specialty or subspecialty set. Another commenter recommended that CMS revise its data submission criteria pertaining to specialty and subspecialty measure sets and require clinicians to report at least one outcome or high priority measure.

Response: To clarify, should a MIPS eligible clinician choose to report on a specialty or a subspecialty measure set, they are only required to submit data on six measures within that set, provided the set contain at least six measures. If the set contains fewer than six measures or if fewer than six measures apply to the MIPS eligible clinician or group, they are required to report on each measure that is applicable. If a MIPS eligible clinician chooses to report only on a specialty or subspecialty measure set and reports on less than 6 quality measures through either the MIPS CQM or Medicare Part B claims collection types, they will be subjected to the measure validation process that will validate whether the clinician actually had less than 6 measures available or applicable to their scope of practice. If a MIPS eligible clinician chooses to report via the QCDR measure collection type, they will be required to meet the reporting requirement of 6 quality measures. If a MIPS eligible clinician reports fewer than 6 quality measures through a QCDR, they will receive zero points for each unreported quality measure. As stated at revised § 414.1335(a)(1)(ii), MIPS eligible clinicians are required to report at least one outcome measure, or if no outcome measures are available or applicable, report another high priority measure in lieu of an outcome measure.

Comment: One commenter sought clarification on the proposed specialty or subspecialty measure set submission criteria. Specifically, the commenter questioned what a MIPS eligible clinician or group is required to do if fewer than 6 measures apply to the MIPS eligible clinician within their specialty or sub-specialty domain. Additionally, the commenter requested clarification on whether outcome measures or high-priority measures for specialty sets were required.

Response: The clinician is required to report at least one outcome measure or, if an applicable outcome measure is not available, one other high priority measure. If a MIPS eligible clinician chooses to report on a specialty or subspecialty measure set, the set contains at least 6 quality measures, and the clinician reports on fewer than 6 measures through the MIPS CQM or Medicare Part B claims collection type, the clinician will be subjected to the measure validation process, which will validate whether fewer than 6 measures were actually available and applicable to their scope of practice. If the measure validation process determines that at least 6 measures were available and applicable to the clinician's scope of practice, they will receive zero points for each unreported measure. We refer readers to Appendix 1: Finalized MIPS Quality Measures in this final rule, where the specialty sets are finalized in Table Group B. There are high priority measures available in all the specialty sets, and therefore a MIPS eligible clinician should be able to select a specialty set that reflects their scope of practice, and be able to report on the measures within that set, including the high-priority measures.

After consideration of the public comments received, we are finalizing our proposal to amend § 414.1335(a)(1) to state that data would be collected for the following collection types: Medicare Part B claims measures; MIPS CQMs; eCQMs; or QCDR measures. Codified at § 414.1335(a)(1)(i), MIPS eligible clinicians and groups must submit data on at least six measures including at least one outcome measure. If an applicable outcome measure is not available, they must report one other high priority measure. If fewer than six measures apply to the MIPS eligible clinician or group, report on each measure that is applicable. We are also finalizing our proposal to amend § 414.1335(a)(1)(ii) to state that MIPS eligible clinicians and groups that report on a specialty or subspecialty measure set, must submit data on at least six measures within that set, provided the set contains at least six measures. If the set contains fewer than six measures or if fewer than six measures apply to the MIPS eligible clinician or group, they must report on each measure that is applicable.

(bb) Submission Criteria for Groups Reporting CMS Web Interface Measures

As noted in the CY 2019 PFS proposed rule (83 FR 35897), we did not propose any changes to the established submission criteria for CMS Web Interface measures. For purposes of clarity and organization, we are finalizing a technical change by moving the regulation text on the sampling requirements for reporting CMS Web Interface measures from § 414.1335(a)(2) to § 414.1340(c)(1). However, beginning with the 2021 MIPS payment year, we proposed to revise the terminology with which CMS Web Interface measures are referenced-to align with the updated submission terminology as discussed in section III.I.3.h. of this final rule. Therefore, we proposed to revise § 414.1335(a)(2) from ''via the CMS Web Interface-for groups consisting of 25 or more eligible clinicians only'', to ''for CMS Web Interface measures''.

In order to ensure that the collection of information is valuable to clinicians and worth the cost and burden of collecting information, and address the challenge of fragmented reporting for multiple measures and submission options, we solicited comment on expanding the CMS Web Interface option to groups with 16 or more eligible clinicians. Preliminary analysis has indicated that expanding the CMS Web Interface option to groups of 16 or more eligible clinicians would likely result in many of these new groups not being able to fully satisfy measure case minimums on multiple CMS Web Interface measures. However, we could possibly mitigate this issue if we require smaller groups (with 16–24 eligible clinicians) to report on only a subset of the CMS Web Interface measures, such as the preventive care measures. We solicited stakeholder feedback on the issue of expanding the CMS Web interface to groups of 16 or more, as well as other factors we should consider with such expansion. We received comments from stakeholders regarding expanding the CMS Web Interface option to groups with 16 or more eligible clinicians. We thank commenters for their input and may take this input into consideration in future years.

As discussed in section III.F.1.c. of this final rule, changes proposed and finalized through rulemaking to the CMS Web Interface measures for MIPS would be applicable to ACO quality reporting under the Shared Savings Program. As discussed in Table Group D: Measures with Substantive Changes Proposed for the 2021 MIPS Payment Year and Future Years of the measures appendix of this final rule, we proposed to remove 6 measures from the CMS Web Interface in MIPS. If finalized, groups reporting CMS Web Interface measures for MIPS would not be responsible for reporting those removed measures. We refer readers to the quality measure appendix for additional details on the proposals related to changes in CMS Web Interface measures.

As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77116), the CMS Web Interface has a two-step attribution process that associates beneficiaries with TINs during the period in which performance is assessed (adopted from the Physician Value-based Payment Modifier (VM) program). The CAHPS for MIPS survey utilizes the same two-step attribution process as the CMS Web Interface. The CY 2017 Quality Payment Program final rule (81 FR 77116) noted that attribution would be conducted using the different identifiers in MIPS. For purposes of the CMS Web Interface and the CAHPS for MIPS survey, we clarified that attribution would be conducted at the TIN level (83 FR 35897).

We did not receive comments on the proposal to revise § 414.1335(a)(2) from ''via the CMS Web Interface-for groups consisting of 25 or more eligible clinicians only'', to ''for CMS Web Interface measures''.

We are finalizing revisions to § 414.1335(a)(2) to state that via the CMS Web Interface measures- for groups consisting of 25 or more eligible clinicians only, groups must report on all measure included in the CMS Web Interface. The group must report on the first 248 consecutively ranked beneficiaries in the sample for each module.

(cc) Submission Criteria for Groups Electing to Report Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey

As noted in the CY 2019 PFS proposed rule (83 FR 35897), we did not propose any changes to the established submission criteria for the CAHPS for MIPS Survey at § 414.1335(a)(3). However, beginning with the 2021 MIPS payment year, we proposed to revise § 414.1335(a)(3) to clarify for the CAHPS for MIPS survey, for the 12-month performance period, a group that wishes to voluntarily elect to participate in the CAHPS for MIPS survey measure must use a survey vendor that is approved by CMS for the applicable performance period to transmit survey measure data to us.

We did not receive comments on the proposal to clarify the requirement to use a CMS approved CAHPS for MIPS survey vendor.

We are finalizing our proposal to amend § 414.1335(a)(3) to clarify for the CAHPS for MIPS survey that beginning with the 2021 MIPS payment year, for the 12-month performance period, a group that wishes to voluntarily elect to participate in the CAHPS for MIPS survey measure must use a survey vendor that is approved by CMS for the applicable performance period to transmit survey measure data to us.

(B) Summary of Data Submission Criteria

In the CY 2019 PFS proposed rule (83 FR 35897), we did not propose any changes to the quality data submission criteria for the 2021 MIPS payment year; however, as discussed in section III.I.3.h. of this final rule, we proposed changes to existing and additional submission related terminology. Similarly, although we did not propose changes to the data completeness criteria at § 414.1340, we proposed changes to existing and additional submission related terminology. For that reason, we proposed to revise § 414.1340 to specify that MIPS eligible clinicians and groups submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs must submit data on at least 60 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment year 2021; MIPS eligible clinicians and groups submitting quality measure data

on the Medicare Part B claims measures must submit data on at least 60 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for the 2021 MIPS payment year; and groups submitting quality measures data on CMS Web Interface measures or the CAHPS for MIPS survey measure, must meet the data submission requirement on the sample of the Medicare Part B patients CMS provides. Tables 34 and 35 clearly capture the data completeness requirements and submission criteria by collection type for individual clinicians and groups.

TABLE 34—SUMMARY OF DATA COMPLETENESS REQUIREMENTS AND PERFORMANCE PERIOD BY COLLECTION TYPE FOR THE 2020 AND 2021 MIPS PAYMENT YEARS

Collection type	Performance period	Data completeness
Medicare Part B claims measures ..	Jan 1–Dec 31	60 percent of individual MIPS eligible clinician's, or group's Medicare Part B patients for the performance period.
Administrative claims measures	Jan 1–Dec 31	100 percent of individual MIPS eligible clinician's Medicare Part B patients for the performance period.
QCDR measures, MIPS CQMs, and eCQMs.	Jan 1–Dec 31	60 percent of individual MIPS eligible clinician's, or group's patients across all payers for the performance period.
CMS Web Interface measures	Jan 1–Dec 31	Sampling requirements for the group's Medicare Part B patients: Populate data fields for the first 248 consecutively ranked and assigned Medicare beneficiaries in the order in which they appear in the group's sample for each module/measure. If the pool of eligible assigned beneficiaries is less than 248, then the group would report on 100 percent of assigned beneficiaries.
CAHPS for MIPS survey measure ..	Jan 1–Dec 31	Sampling requirements for the group's Medicare Part B patients.

TABLE 35—SUMMARY OF QUALITY DATA SUBMISSION CRITERIA FOR MIPS PAYMENT YEAR 2020 AND 2021 FOR INDIVIDUAL CLINICIANS AND GROUPS

Clinician type	Submission criteria	Measure collection types (or measure sets) available
Individual Clinicians	Report at least six measures including one outcome measure, or if an outcome measure is not available report another high priority measure; if less than six measures apply then report on each measure that is applicable. Clinicians would need to meet the applicable data completeness standard for the applicable performance period for each collection type.	Individual MIPS eligible clinicians select their measures from the following collection types: Medicare Part B claims measures (individual clinicians in small practices only), MIPS CQMs, QCDR measures, eCQMs, or reports on one of the specialty measure sets if applicable.
Groups (non-CMS Web Interface).	Report at least six measures including one outcome measure, or if an outcome measure is not available report another high priority measure; if less than six measures apply then report on each measure that is applicable. Clinicians would need to meet the applicable data completeness standard for the applicable performance period for each collection type.	Groups select their measures from the following collection types: Medicare Part B claims measures (small practices only), MIPS CQMs, QCDR measures, eCQMs, or the CAHPS for MIPS survey—or reports on one of the specialty measure sets if applicable. Groups of 16 or more clinicians who meet the case minimum of 200 will also be automatically scored on the administrative claims based all-cause hospital readmission measure.
Groups (CMS Web Interface for group of at least 25 clinicians).	Report on all measures includes in the CMS Web Interface collection type and optionally the CAHPS for MIPS survey. Clinicians would need to meet the applicable data completeness standard for the applicable performance period for each collection type.	Groups report on all measures included in the CMS Web Interface measures collection type and optionally the CAHPS for MIPS survey. Groups of 16 or more clinicians who meet the case minimum of 200 will also be automatically scored on the administrative claims based all-cause hospital readmission measure.

We received comments on the proposal to revise § 414.1340 to specify that MIPS eligible clinicians and groups submitting quality measures data must submit data on at least 60 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment year 2021:

Comment: One commenter requested that CMS clarify the 90-day performance period mentioned in Table 31 of the proposed rule. This commenter requested more information concerning to which measures the performance period would apply and expressed concerns about the differing performance period for measures.

Response: We clarify that in the CY 2019 PFS proposed rule (83 FR 35898), the reference in Table 31 to a 90-day performance period for certain measures was an inadvertent error. To clarify, there is no 90-day performance period for any MIPS quality measure. For the 2020 and 2021 MIPS payment years, the performance period is 12 months. Table 34 Summary of Data Completeness Requirements and Performance Period by Collection Type for the 2020 and 2021 MIPS Payment Years has been updated to reflect this correction.

Comment: One commenter opposed a full calendar-year performance period given the proposed 60 percent data completion requirement for the quality performance category and the potential burden in developing and implementing new applicable measures.

Response: While the data completeness requirement will remain at 60 percent for the 2019 performance

period, we have previously noted our interest in incorporating higher data completeness thresholds in future years to ensure a more accurate assessment of a MIPS eligible clinician's performance on quality measures and to avoid measure selection bias as much as possible, but believe it should be done so in a gradual manner. In the CY 2019 PFS proposed rule (83 FR 35893), we noted our belief that a full calendar year performance period for the quality and cost performance categories will be less confusing for MIPS eligible clinicians. A longer performance period for quality will likely include more patient encounters, which will increase the denominator of the quality measures reported. Statistically, a larger sample size provides more accurate and actionable information. Furthermore, a full calendar year performance period is consistent with how many of the measures used in our program were designed to be performed and reported.

Comment: A few commenters supported the fact that our proposal to maintain the 60 percent data completeness threshold and encouraged CMS to retain this policy for future program years.

Response: We thank the commenters for their support.

Comment: One commenter recommended that CMS increase the data completeness threshold to 100 percent. Other commenters noted that because calculating and submitting an accurate reporting rate requires an analysis of a full set of data and is often a manual and error-prone process, they do not believe it significantly reduces provider burden to have a 60 percent data completeness threshold as compared to 100 percent.

Response: As discussed in the CY 2018 Quality Payment Program final rule (82 FR 53632), we noted concerns about the unintended consequences of accelerating the data completeness threshold so dramatically, which may jeopardize a MIPS eligible clinician's ability to participate and perform well in MIPS, particularly with those clinicians who are not as experienced with MIPS quality measure submission. While we do continue to monitor the data completeness threshold with future intentions of raising the threshold for data completeness, we want to ensure that the data completeness requirement is achievable by all MIPS eligible clinicians. We do agree that it is important to incorporate higher data completeness thresholds in future years to ensure a more accurate assessment of a MIPS eligible clinician's performance on quality measures and to avoid measure selection bias as much as possible, but believe it should be done so in a gradual manner.

Comment: One commenter requested clarification on whether the data completeness criteria is 60 percent of the performance year, regardless of time, or if MIPS eligible clinicians are mandated to include 60 percent of their patient data from the calendar year.

Response: As stated at § 414.1340(b)(2), MIPS eligible clinicians are required to submit data on at least 60 percent of the applicable Medicare Part B patients seen during the performance period, as illustrated in Table 34.

Comment: One commenter expressed support for updating the terminology of the data completeness criteria, stating that it does not change the data completeness criteria from the previous years.

Response: We thank the commenter for their support. We clarify that we did not make any proposals or changes to the data completeness criteria, and only made changes to existing and additional submission related terminology, as explained in the CY 2019 PFS proposed rule (83 FR 35897).

After consideration of the public comments received, we are finalizing revisions to § 414.1340 to specify that MIPS eligible clinicians and groups submitting quality measures data on QCDR measures, MIPS CQMs, or the eCQMs must submit data on at least 60 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment year 2021; MIPS eligible clinicians and groups submitting quality measure data on the Medicare Part B claims measures must submit data on at least 60 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for the 2021 MIPS payment year; and groups submitting quality measures data on CMS Web Interface measures or the CAHPS for MIPS survey measure, must meet the data submission requirement on the sample of the Medicare Part B patients CMS provides, as applicable.

(iv) Application of Facility-Based Measures

Under section 1848(q)(2)(C)(ii) of the Act, the Secretary may use measures for payment systems other than for physicians, such as measures used for inpatient hospitals, for purposes of the quality and cost performance categories. However, the Secretary may not use measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists. We refer readers to section III.I.3.i.(1)(d) of this final rule for a full discussion of facility-based measures and scoring for the 2021 MIPS payment year.

(b) Selection of MIPS Quality Measures for Individual MIPS Eligible Clinicians and Groups Under the Annual List of Quality Measures Available for MIPS Assessment

(i) Background and Policies for the Call for Measures and Measure Selection Process

In the CY 2019 PFS proposed rule (83 FR 35898 through 35899), we noted that developed and announced our Meaningful Measures Initiative.[18] By identifying the highest priority areas for quality measurement and quality improvement, the Meaning Measures Initiative identifies the core quality of care issues that advances our work to improve patient outcomes. Through subregulatory guidance, we will categorize quality measures by the 19 Meaningful Measure areas as identified on the Meaningful Measures Initiative website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.* The categorization of quality measures by Meaningful Measure area would provide MIPS eligible clinicians and groups with guidance as to how each measure fits into the framework of the Meaningful Measure Initiative.

Furthermore, under § 414.1305, a high priority measure is defined as an outcome, appropriate use, patient safety, efficiency, patient experience or care coordination quality measure. Due to the immense impact of the opioid epidemic across the United States, we believe it is imperative to promote the measurement of opioid use and overuse, risks, monitoring, and education through quality reporting. For that reason, beginning with the 2019 performance period, we proposed at § 414.1305 to amend the definition of a high priority measure to include quality measures that relate to opioids and to further clarify the types of outcome measures that are considered high priority. Beginning with the 2021 MIPS payment year, we proposed to define at § 414.1305 a high priority measure to mean an outcome, appropriate use, patient safety, efficiency, patient experience, care coordination, or

[18] Link to Meaningful Measures web page on CMS site to be provided at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

opioid-related quality measure. Outcome measures would include intermediate-outcome and patient-reported outcome measures. We requested comment on this proposal, specifically if stakeholders have suggestions on what aspects of opioids should be measured—for example, whether we should focus solely on opioid overuse. We summarize and respond to the comments received on this proposal below.

Previously finalized MIPS quality measures can be found in the CY 2018 Quality Payment Program final rule (82 FR 53966 through 54174) and in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). The new MIPS quality measures finalized for inclusion in MIPS for the 2019 performance period and future years are found in Table Group A of the ''Appendix 1: Finalized MIPS Quality Measures'' of this final rule. The current specialty measure sets can be found in the CY 2018 Quality Payment Program final rule (82 FR 53976 through 54146). The finalized new and modified quality measure specialty sets can be found in Table Group B of the ''Appendix 1: Finalized MIPS Quality Measures'' of this final rule and include new measures, previously finalized measures with modifications, and previously finalized measures with no modifications.

We note that modifications made to the specialty sets may include the removal of certain previously finalized quality measures. Certain MIPS specialty sets have further defined subspecialty sets, each of which constitutes a separate specialty set. In instances where an individual MIPS eligible clinician or group reports on a specialty or subspecialty set, if the set has less than six measures, that is all the clinician is required to report. MIPS eligible clinicians are not required to report on the specialty measure sets, but they are suggested measures for specific specialties. Please note that the finalized specialty and subspecialty sets are not inclusive of every specialty or subspecialty.

On January 9, 2018,[19] we announced that we would be accepting recommendations for potential new specialty measure sets for Year 3 of MIPS under the Quality Payment Program. These recommendations were based on the MIPS quality measures finalized in the CY 2018 Quality Payment Program final rule, and includes recommendations to add or remove the current MIPS quality measures from the specialty measure sets. All specialty measure set recommendations submitted for consideration were assessed to ensure that they meet the needs of the Quality Payment Program.

In the CY 2017 Quality Payment Program final rule (81 FR 77137), we finalized that substantive changes to MIPS quality measures, to include but are not limited to, measures that have had measure specification changes, measure title changes, or domain changes. MIPS quality measures with finalized substantive changes can be found in Table Group D of the ''Appendix 1: Finalized MIPS Quality Measures'' of this final rule.

As referenced in the CY 2017 Quality Payment Program final rule (81 FR 77291), with regards to eCQMs, in the 2015 EHR Incentive Program final rule, CMS required eligible clinicians, eligible hospitals, and critical access hospitals (CAHs) to use the most recent version of an eCQM for electronic reporting beginning in 2017 (80 FR 62893). We proposed this policy for the end-to-end electronic reporting bonus under MIPS and encourage MIPS eligible clinicians to work with their EHR vendors to ensure they have the most recent version of the eCQM. We will not accept an older version of an eCQM as a submission for the MIPS program for the quality performance category or the end-to-end electronic reporting bonus within that category. MIPS eligible clinicians and groups reporting on the quality performance category are required to use the most recent version of the eCQM specifications. The annual updates to the eCQM specifications and any applicable addenda are available on the electronic quality improvement (eCQI) Resource Center website at *https://ecqi.healthit.gov* for the applicable performance period. Furthermore, as discussed in section III.E. of this final rule, the Medicaid Promoting Interoperability Program generally intends to utilize eCQM measures as they are available in MIPS. We refer readers to section III.E. of this final rule for additional details and criteria on the Medicaid Promoting Interoperability Program.

In MIPS, there are a limited number of CMS Web Interface measures. We solicited comment on building upon the CMS Web Interface submission type by expanding the core set of measures available for that submission type to include other specialty specific measures (such as surgery). We thank stakeholders for their comments, and will consider it for future rulemaking.

To provide clinicians with a more cohesive reporting experience, where they may focus on activities and measures that are meaningful to their scope of practice, we discuss the development of public health priority measurement sets that would include measures and activities across the quality, Promoting Interoperability, and improvement activities performance categories, focused on public health priorities such as fighting the opioid epidemic, in section III.I.3.h.(5), of this final rule. We refer readers to section III.I.3.h.(5) of this final rule for additional details on this concept.

We received comments on the proposal to revise the definition of a high priority measure, to include quality measures that relate to opioids and to further clarify the types of outcome measures that are considered high priority; and the policy that MIPS eligible clinicians must use the most recent specification of MIPS eCQMs while reporting for MIPS:

Comment: A few commenters expressed concern with the proposals to revise the definition of high-priority measures to include opioid related quality measures and to add several new measures to the MIPS program specifically focused on opioid use. The commenters urged CMS to consider the unintended consequences that could result if seriously ill patients experience barriers to receiving appropriate pain management. Specifically, commenters stated that, if the proposed policies are finalized, they could create incentives to reduce opioid prescriptions, even for patients with debilitating pain resulting from advanced disease progression who would respond to opioid treatment with more potential benefit than risk. The commenters also asked CMS to consider protections that could be incorporated into opioid-focused measures, such as exceptions for patients receiving hospice and palliative care and other patients with advanced stage serious illness. Further, commenters suggested that CMS rely on clinical evidence regarding the reliability and validity of measures or activities to address public health and safety concerns with opioids. One commenter also expressed concerns that measures may not take into account numerous factors that play a role in the opioid crisis, including habits outside of clinicians' control such as combining opioids with other medicines, using opioid for something other than pain, and failure to adhere to medicines as prescribed. One commenter

[19] Listserv messaging was distributed through the Quality Payment Program listserv on January 9th, 2018, titled: ''CMS is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure Sets and/or Revisions to the Existing Specialty Measure Sets for the 2019 Program Year of Merit-based Incentive Payment System (MIPS).''

recommended including quality measures that address the application of non-addictive alternatives to pain management, whether in the form of pharmacotherapeutics, medication-assisted treatment, or non-pharmacological options.

Response: To clarify, our intention is not to create barriers for seriously ill patients receiving appropriate pain management, we encourage appropriate treatment, but also encourage proper monitoring, management, follow-up, and education of patients. We believe it is important to consider patients such as those receiving hospice and palliative care, and will discuss with measure stewards of opioid-related measures whether exceptions for such patients may be appropriate. Furthermore, we have considered the reliability and validity of measures, as we require that measures have completed reliability and validity testing prior to them being considered as quality measures in MIPS. We agree with commenters that the application of non-addictive alternatives to pain management is an important area to include in quality measurement, and encourage stakeholders to reach out to the measure stewards for the consideration of their suggestions. Based on the comments and concerns expressed by commenters, we are clarifying that the finalized definition of a high priority measure is broad enough to include all aspects of opioid-related measurement rather than focus on a specific aspect of opioid measurement. We believe there are multiple areas within opioid measurement that are important; for example (but not limited to): Medication management, patient education, patient outcomes, monitoring, pain management, and follow-up.

Comment: Several commenters agreed that opioid-related measures should be categorized as high-priority measures due to national interest. The commenters encouraged CMS to evaluate the inclusion of any opioid-related measures, especially eCQMs that measure developers bring to the table. Commenters stated that any opioid-related quality measures, especially if designated as high-priority measures, need to recognize that numerous factors play a role in opioid use, including factors such as pain control, patient use of other medicines combined with opioids, patient use of opioids for something other than pain, and patient failure to adhere to medicines as prescribed. One commenter cautioned against focusing solely on overuse, but rather focus on a combination of how well patient's pain is controlled, if functional improvement goals have been met, and opioid use. A few commenters indicated that identifying patients by daily use and daily dosage may not, on its own, be a good indication of quality patient care. Commenters also encouraged CMS to include patient-reported outcomes measures that look at symptom management and pain interference.

Response: We will consider opioid-related quality measures as they are submitted through the call for measures process or as QCDR measures, and also encourage the development of fully tested eCQMs. We agree with the commenters that factors such as pain control, use of other medications, and adherence are all important factors and that overuse should not be the only focus of measurement. We encourage stakeholders to submit patient-reported outcomes measures that also relate to opioids during the call for measures process or as QCDR measures during the self-nomination process.

Comment: A few commenters expressed support of the policy to require the reporting of the most current version of the eCQM. One commenter recommended that to improve electronic capture, calculation, and reporting of quality measures, CMS should incent the use of standardized semantic content from recognized developers. Further, the commenter encouraged CMS to incorporate this work into its implementation guides to ensure eCQM calculations and benchmarks are accurate and that EHRs are accurately capturing eCQMs. In addition, a commenter noted that to continue to encourage eCQM reporting, CMS should not remove the 8 eCQMs from the measure list in 2019 as proposed.

Response: We will take these recommendations into consideration for future years of MIPS. We note that eCQM calculation standards are also included as a part of ONC's Health IT Certification Program to ensure accuracy and consistency. We refer readers to the 2015 Edition Health IT Certification Criterion at 45 CFR 170.315(c)(1) (Clinical quality measures) for additional information on the criteria. Furthermore, we have identified those 8 eCQMs for removal for reasons including the measure having high, unvarying performance rates, or the measure is being replaced by a more robust measure that has a more meaningful quality action. Quality actions include steps taken to advance the patient care provided, moving beyond documenting in the medical record or conducting a standard of care process. For example, was a follow-up examination conducted on the patient monitor changes in medical condition or did the specialist follow-up with the primary care physician to close the referral loop. We believe that it is important to have measures in the program that provide meaningful quality measurement, by demonstrating a performance gap and having a robust quality action.

Comment: A few commenters did not support the timeline for removing eCQMs from the measure set because of the time required for EHR vendors to modify systems. One commenter recommended supporting the last two versions of eCQMs to allow sufficient time for vendors and health care organizations to develop and deploy the latest eCQM versions.

Response: As described in the CY 2017 Quality Payment Program final rule (81 FR 77291), in the 2015 EHR Incentive Programs final rule, CMS required EPs, eligible hospitals, and CAHs to use the most recent version of an eCQM for electronic reporting beginning in 2017 (80 FR 62893). Furthermore, we update specifications annually in order to stay relevant with the clinical guidelines, updates to terminology, and to correct any identified issues. We will take this recommendation into further consideration, as we plan for our annual update process improvements.

Comment: A few commenters requested clarification on whether or not practices will be required to use 2015 Edition CEHRT for the entire performance year for quality and the latest version of eCQM to earn the end-to-end bonus.

Response: As described at § 414.1305, the definition of CEHRT for 2019 and subsequent years is EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102), and has been certified to the 2015 Edition health IT certification criteria. In the CY 2017 Quality Payment Program final rule (81 FR 77297), we finalized that the CEHRT bonus would be available to MIPS eligible clinicians who report via qualified registries, QCDRs, EHRs, or the CMS Web Interface for the Quality Payment Program, in a manner that meets the end-to-end reporting requirements. Thus, in order for practices to earn the end-to-end bonus for reporting eCQMs for the 2019 performance period, they will need to be reporting using the latest version of the eCQM and will need to use CEHRT that has been certified to the 2015 Edition.

Comment: A few commenters noted concern with the timeline for the approval and communication of updated quality measures with the 12-month performance period, noting that clinicians and groups relying on this information for measure selection are unable to easily access a measure list until months after the performance period begins. Commenters also noted that QCDR measures have traditionally not been approved until the end of December preceding the performance year, leaving registries with limited time to update their dashboards in time for the January 1 start of the new performance year. Commenters stated that clinicians need additional time to work with their EHRs to ensure that they are capturing the elements necessary to report on a measure. Therefore, commenters urged CMS to approve and communicate updates earlier.

Response: With regard to MIPS quality measures, the final specifications of the measures can only be posted once the final rule is published. For Year 2 of the program there was a delay in posting the measures within the Quality Payment Program Explore Measures Tool due to technical difficulties. However, the measure specifications were made available on the Quality Payment Program resource library (*http://qpp.cms.gov*) prior to the beginning of the performance period. We will continue to post the year 3 measure specifications on the Quality Payment Program resource library prior to the beginning of the performance period and will make every effort to update the Quality Payment Program Explore Measures Tool with the year 3 measures prior to the performance period, or as close to the beginning of the performance period as technically feasible. We also note that we do not incorporate the QCDR measures into the Quality Payment Program Explore Measures Tool, rather these will be available on the Quality Payment Program resource library. During the limited timeframe available between November 1st and January 1st, we have reviewed over a thousand QCDR measure submissions for consideration in the upcoming MIPS performance period, communicated those decisions to the QCDRs, and posted the qualified postings by January 1 of the performance period. QCDRs and registries are notified prior to January 1 regarding which measures will be approved for the upcoming performance period. In section III.I.3.k.(3) of this final rule, we describe the finalized policy to move the self-nomination period up to begin in July 1 and end on September 1, thereby giving us an earlier start to evaluate and make decisions on QCDR measures.

Comment: Many commenters stated that the current timeline for release of measure specifications in December is overly burdensome and hinders the consistency of measure data in terms of comparability of results over time as it does not allow adequate time to build and test systems prior to QCDRs reporting measures on January 1.

Response: We understand the commenters' concerns, and interpret their reference to measures to mean the MIPS quality measure specifications not the QCDR measure specifications. We clarify that it is not technically feasible to release the MIPS quality measure specifications until the final rule is published. We will take the commenters suggestion in to consideration as we consider the operational feasibility of releasing the MIPS quality measure specifications earlier than December. As stated in the CY 2017 Quality Payment Program final rule (81 FR 77368), in order for a QCDR to be approved for a given performance period, they must support the minimum of 6 quality measures to be approved. Similar to previous performance periods, we plan to provide QCDRs and qualified registries with time to select additional MIPS quality measures to support for the upcoming performance period based upon their review of the measure specifications. Furthermore, we note that we expect that QCDRs and qualified registries would be up and running by January 1 of the performance period to accept and retain data, to allow clinicians to begin their data collection on January 1 of the performance period. However, the data will not be submitted to us until the start of data submission for the 2019 performance period.

After consideration of the public comments received, we are finalizing our proposal, beginning with the 2021 MIPS payment year, to define a high priority measure at § 414.1305 as an outcome, appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. Outcome measures include intermediate-outcome and patient-reported outcome measures.

In the CY 2017 Quality Payment Program final rule (81 FR 77090), we indicated that we intend to reduce the number of claims-based measures in future program years as more measures become available through electronic collection types such as eCQMs or MIPS CQMs. In section III.I.3.h of this final rule, we are finalizing our proposal to limit the Medicare Part B claims collection type to small practices, which furthers our goal of moving away from Medicare Part B claims measures. We strongly encourage measure stewards to keep this in mind as they develop and submit measures for consideration, during the call for measures process (specifically for the MIPS quality performance category).

(ii) Topped Out Measures

In the CY 2018 Quality Payment Program final rule (82 FR 53637 through 53640), we finalized the 4-year timeline to identify topped out measures, after which we may propose to remove the measures through future rulemaking. After a measure has been identified as topped out for 3 consecutive years through the benchmarks, we may propose to remove the measure through notice and comment rulemaking. Therefore, in the 4th year, if finalized through rulemaking, the measure would be removed and would no longer be available for reporting during the performance period. We refer readers to the 2018 MIPS Quality Benchmarks' file, that is located on the Quality Payment Program resource library (*https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Resource-library.html*) to determine which measure benchmarks are topped out for 2018 and would be subject to the cap if they are also topped out in the 2019 MIPS Quality Benchmarks' file. It should be noted that the final determination of which measure benchmarks are subject to the topped out cap would not be available until the 2019 MIPS Quality Benchmarks' file is released in late 2018.

In the CY 2019 PFS proposed rule (83 FR 35899 through 35900), we proposed that once a measure has reached an extremely topped out status (for example, a measure with an average mean performance within the 98th to 100th percentile range), we may propose the measure for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped out measure lifecycle, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, after taking into account any other relevant factors. We are concerned that topped out non-high priority process measures require data collection burden without added value for eligible clinicians and groups participating in MIPS. It is important to remove these types of measures, so that available measures provide meaningful value to

clinicians collecting data, beneficiaries, and the program. However, we would also consider retaining the measure if there are compelling reasons as to why it should not be removed (for example, if the removal would impact the number of measures available to a specialist type or if the measure addressed an area of importance to the Agency).

Since QCDR measures are not approved or removed from MIPS through the rulemaking timeline or cycle, we proposed to exclude QCDR measures from the topped out timeline that was finalized in the CY 2018 Quality Payment Program final rule (82 FR 53640). When a QCDR measure reaches topped out status, as determined during the QCDR measure approval process, it may not be approved as a QCDR measure for the applicable performance period. Because QCDRs have more flexibility to develop innovative measures, we believe there is limited value in maintaining topped out QCDR measures in MIPS.

We received comments on the following proposals: (1) Once a measure has reached an extremely topped out status (for example, a measure with an average mean performance within the 98th to 100th percentile range), we may propose the measure for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped out measure lifecycle; and (2) to exclude QCDR measures from the topped out timeline that was finalized in the CY 2018 Quality Payment Program final rule:

Comment: Several commenters supported the topped out proposal, stating that it would reduce clinician burden, discontinue measures that have limited value to the Quality Payment Program, and continue to focus on measures that are clinically meaningful to patients. One commenter noted that this proposal will allow CMS to differentiate between exceptional, high performing, and other clinicians. Several commenters recommended that topped out measures be removed regardless of the collection type.

Response: We disagree that topped out measures should be removed regardless of the collection type. There have been instances where measures have been specified through multiple collection types, but have only become topped out in one or two of the collection types. If there is an opportunity to collect more robust data on a measure, while the measure is not topped out for that particular collection type, we believe we should continue to do so.

Comment: Several commenters did not support the proposal to exclude QCDR measures from the topped out timeline, indicating that review processes for QCDR and MIPS measures should be standardized and provide clinicians, groups, and measure stewards sufficient notice to review and potentially replace topped out measures. One commenter indicated that applying the topped out policy to QCDR measures will also ensure consistency across the program and minimize complexity. A few commenters indicated that maintaining QCDR measures in the program for a minimum number of years will also limit measures with sufficient historical data to set a benchmark that permits the evaluation of performance. Several commenters noted that removal of topped out QCDR measures would limit the number of specialty-specific measures available and stated that and the proposal does not allow sufficient time and volume of cases to determine if QCDR measures have a valid benchmark. One commenter recommended a two-year retention policy for extremely topped out QCDR measures to reduce burden and confusion for clinicians.

Response: We note that the process and timeline in which MIPS quality measures and QCDR measures are approved for a given MIPS performance period is different, as is the criteria for consideration. QCDRs are expected to be nimble and innovative enough to develop QCDR measures that are robust in their quality action and demonstrate a performance gap. We believe topped out measures do not add value in the realm of quality measurement, and believe they should be removed from the program as appropriate. We do not agree that removing topped out QCDR measures would create complexity, since it is a well-established process that QCDR measures are reviewed for approval on an annual basis, and is something that stakeholders should be aware of. We also do not believe that topped out QCDR measures should be retained in the program for 2 years; this may inadvertently impact a high performing clinician who may not receive a high score when compared to other clinicians reporting on the same measure. For example, a clinician whose performance rate is at 96 percent on a topped out measure may receive fewer points than another clinician whose reporting rate is at 98 percent on the same measure, when both performance rates would be considered high performing. We do not agree that the removal of topped out QCDR measures would impact the number of available specialty-specific measures available, since QCDR measures are reviewed and approved on a more accelerated timeline in comparison to the MIPS quality measures. Furthermore, MIPS eligible clinicians who wish to use QCDRs, are not limited to reporting on QCDR measures.

Comment: Many commenters did not support the proposal to allow the identification and removal of extremely topped out measures. Several commenters noted that removal of measures will have a large impact on small practices and specialists who have limited options regarding relevant quality measures. Several commenters stated that more time is needed to determine if measures are truly topped out because benchmarks may reflect the performance of only top-performing clinicians rather than performance across all clinicians. They stated that additional time would allow for the collection of more robust data. Many commenters stated that topped out measures should all have the same 4-year timeline because the process to develop a measure that could replace a topped out measure is lengthy and recommended close communication with measure stewards. A few commenters recommended a 2-year timeline for the removal of extremely topped out measures. A few commenters encouraged CMS to defer to measure developers and national endorsement organizations to define which measures are topped out. One commenter noted that additional factors should be taken into consideration prior to removing an extremely topped out measure, including the type of measure, the length of time the measure is reported, measure steward and specialist input, performance results, reporting options, data sources, small sample size, public health issues covered, and whether measures are used in other programs. One commenter recommended that prior to removing a topped out measure, CMS be transparent about the data used to determine topped out status, so the public has an understanding of how many clinicians reported the measure and the performance rate.

Response: We note that in addition to the quality measures available in the MIPS quality measure set, QCDR measures are also available. We review measure benchmarks as a part of our process for identifying topped out and extremely topped out measures and believe that extremely topped out measures, such as those with an average mean performance within the 98th to 100th percentile, leave no room for further quality improvement, thereby providing clinicians little value. We

utilized the 2018 quality measure benchmarks as a part of the criteria used to identify those measures for removal. The benchmarks are reflective of the performance of those clinicians who have reported on the measure and will continue to do so should the measure be available in the program which is why we do not believe there will be variances in the high performing data submitted if the measure is retained. We do not believe that we should retain the extremely topped out measures within a 4 year timeline because the measures take a lengthy time to replace. While the timeline to add MIPS quality measures does typically take about 2 years, we note there are additional measures (QCDR measures) available for reporting through QCDRs. We appreciate the commenters' feedback suggesting we defer to measure developers and national endorsement organizations to define which measures are topped out; we can take this suggestion in to future consideration. In the CY 2019 PFS proposed rule (83 FR 35900), we stated we would also consider retaining the measure if there are compelling reasons as to why it should not be removed (for example, if the removal would impact the number of measures available to a specialist type or if the measure addressed an area of importance to the Agency). We encourage stakeholders to continue to submit quality measures that address measurement gaps as we incrementally remove quality measures that are extremely topped out, merely reflect the standard of care without a quality action, or are duplicative of other more robust quality measures, as we believe they no longer provide meaningful measurement to clinicians.

After consideration of the public comments received, we are finalizing our proposal that once the measure has reached an extremely topped out status (for example, a measure with an average mean performance within the 98th to 100th percentile range), we may propose the measure for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped out measure lifecycle, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, after taking into account any other relevant factors. However, we will also consider retaining the measure if there are compelling reasons as to why it should not be removed (for example, if the removal would impact the number of measures available to a specialist type or if the measure addressed an area of importance to CMS).

We are also finalizing our proposal to exclude QCDR measures from the topped out timeline that was finalized in the CY 2018 Quality Payment Program final rule (82 FR 53640). When a QCDR measure reaches topped out status, as determined during the QCDR measure approval process, it may not be approved as a QCDR measure for the applicable performance period.

(iii) Removal of Quality Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77136 through 77137), we discussed removal criteria for quality measures, including that a quality measure may be considered for removal if the Secretary determines that the measure is no longer meaningful, such as measures that are topped out. Furthermore, if a measure steward is no longer able to maintain the quality measure, it would also be considered for removal.

We have previously communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set. In the CY 2017 Quality Payment Program final rule (81 FR 77101), we explained that we believe that outcome measures are more valuable than clinical process measures and are instrumental to improving the quality of care patients receive. In the CY 2018 Quality Payment Program quality measure set, 102 of the 275 quality measures are process measures that are not considered high priority. As discussed above, beginning with the 2021 MIPS payment year, we proposed to define at § 414.1305 a high priority measure to mean an outcome, appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. Because the removal of all non-high priority process measures would impact most specialty sets, nearly 94 percent, we believe incrementally removing non-high priority process measures through notice and comment rulemaking is appropriate.

As described in the CY 2019 PFS proposed rule (83 FR 35900), beginning with the 2019 performance period, we proposed to implement an approach to incrementally remove process measures where prior to removal, consideration will be given to, but is not limited to:

- Whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the measure addresses a priority area highlighted in the Measure Development Plan at *https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measure-development.html*.
- Whether the measure promotes positive outcomes in patients.
- Considerations and evaluation of the measure's performance data.
- Whether the measure is designated as high priority or not.
- Whether the measure has reached an extremely topped out status within the 98th to 100th percentile range, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, as described in section III.I.3.(b)(ii) of this final rule.

We received the following comments on the proposal to implement a process to incrementally remove process measures:

Comment: While some commenters supported the inclusion of population measures, several commenters recommended the removal of population health measures, which it believed are often incorrectly attributed, especially for specialty clinicians and rural clinicians, and often have a very low statistical reliability at the individual clinician and group practice levels.

Response: We believe that population measures may reduce burden on clinicians and allow for assessment of public health issues on a larger scale. Reliability is one of the many important and scientific issues that CMS addresses and tests during our measure development process regardless of measure type (that is, whether the measures are population-based or provider-specific measures). We recognize that specialty clinicians and rural clinicians may be more likely to have a smaller sample size, and that this may result in lower reliability. At the same time, we also recognize that many clinicians or groups may have sufficient volume depending on the measures under development, and because measure reliability also depends on the particular cohort and outcome of the specific measures under development. As part of the CMS standardized measure development process, we will address the reliability issue in several ways. We will consult national experts and stakeholders including health care providers and patients in conceptualizing and selecting measures for development and conduct rigorous testing of the measure reliability and volume threshold for use.

Comment: Many commenters supported the removal of 34 MIPS measures to align with CMS's Meaningful Measures framework and allow eligible clinicians to reduce and

prioritize other measures, providing a focus on improving patient care and outcomes. A few commenters encouraged CMS to continue to review its quality measure sets to identify the most meaningful measures and further align hospital and clinician reporting requirements.

Response: We agree that alignment across quality programs is important in an effort to reduce clinician burden, and will seek to continue to look for ways to align with other programs while maintaining the objective and goals of MIPS through future rulemaking.

Comment: Many commenters did not support the proposal to remove measures, stating that many specialists will not have enough relevant measures to meet reporting requirements, clinicians may still be required to report removed measures to other payers, and process measures are under the control of the clinician and often important when coupled with other measures including cost measures. A few commenters indicated that important quality of care aspects may only be captured by a process measure, even those that are topped out. One commenter disagreed with the removal of topped out measures generally until the vast majority of peer reviewed literature demonstrates a significant change in practice patterns. One commenter recommended delaying the removal of measures, to allow time for clinicians to comply with program requirements.

Response: We note that prior to proposing to remove quality measures from the program, we take into consideration the impacts the removal would have on the number of measures available to clinicians in the program. We do not agree that we should delay the removal of measures. We continue to believe that non-high priority process measures impose data collection burden without adding value for eligible clinicians and groups participating in MIPS. Typically, process measures merely reflect the standard of care and do not have a robust quality action. In many instances, process measures have high, unvarying performance leaving no room for improvement. We understand that there are some process measures that are valuable, but believe that it is important that they address one of the high priority areas and demonstrate a performance gap in order to be meaningful. Furthermore, we do understand that important quality of care aspects may only be captured by some topped out process measures, and encourage clinicians to continue to measure and monitor their progress in these areas; however, we do not believe that these measures provide value or should be tied to a pay for performance program such as MIPS. If a MIPS quality measure is removed from the program, it is because the measure no longer has value in the performance payment program; however, we believe that clinicians can still collect and evaluate data on these metrics for their own internal quality improvement goals or areas of improvement as outlined in peer reviewed literature. We are aware that there are certain process measures that may be required to be reported to other payers; however, note that this difference may reflect different underlying goals of their program. Another consideration is that these process measures with high, unvarying performance, may also impact a MIPS eligible clinician's ability to receive a high score in the quality performance category. While we agree that process measures are under the control of the clinician and often important when coupled with other measures including cost measures, we do not believe that this justifies retaining extremely topped out measures in MIPS.

Comment: Several commenters expressed concern about the timeline for removing measures. A few commenters requested that CMS maintain the 4-year measure removal policy since it would give clinicians, professional societies, and third party vendors (for example, registries) some time to prepare and develop an alternative reporting strategy. One commenter recommended an incremental phased approach according to a specified timeline, similar to the 4-year timeline currently in place for removing topped out measures from the program in order to ensure that the removal of the measures is truly warranted and to allow clinicians time to begin implementing other measures for reporting purposes. One commenter recommend that CMS only propose removal of measures during the official measure process to assist with predictability.

Response: To clarify, similar to how MIPS quality measures are proposed and finalized into the MIPS program through notice-and-comment rulemaking, we utilize a similar approach for removing measures from the program. We do not believe that a 4-year timeline to remove all measures is appropriate. A topped out measure timeline that is 4 years long is appropriate for measures with high performance where special scoring caps are applied as a response to the high unvarying performance; however, we are still finalizing the policy to remove extremely topped out measures (within the 98–100 percent range) through the following rulemaking cycle after the measure is identified as extremely topped out. This is to note that there are exceptions to the 4 year timeline, and in instances where there are more robust measures being proposed and finalized, we believe it is appropriate to remove duplicative measures through notice-and-comment rulemaking without consideration to a longer timeline. In addition, measures that are not maintained or updated to reflect current clinical guidelines are not reflective of a clinician's scope of practice, should also be proposed for removal in the next rulemaking cycle. Furthermore, the removal of low-bar, standard of care process measures aligns with our goals to have more outcomes based measures in the program. Furthermore, a 4-year timeline does not take into consideration that we may propose new quality measures that are more robust in their quality action that would deem the existing process measure to be duplicative. Also, as process measures top out, they will inadvertently impact a clinician's ability to achieve a high score for that specific measure. As stated earlier above, we will only propose the removal of MIPS quality measures through formal notice-and-comment rulemaking, and we believe that this annual process will provide stakeholders with sufficient notice and opportunity to voice their concerns on specific measure removals through the public comment process.

Comment: One commenter also requested that CMS evaluate measures for removal based on the collection type. They stated that the differences in collection types can be enough of a workflow and cost consideration in alterations that it should be a factor in the consideration of measures removal. For example, there are several eCQMs proposed for removal due to a duplicative measure being available; however, in most instances, that duplicative measure is not available as an eCQM. This would potentially force practices to maintain relationships and pay for reporting through multiple vendors to maintain their list of measures.

Response: Initially, we proposed to remove specific MIPS quality measures that were duplicative of new, robust measures. We have taken the comments into consideration and in instances where the new measure does not have eCQM available as a collection type, we have decided not to remove the existing (duplicative) measure for the eCQM collection type only. We refer readers to Appendix 1: Finalized Quality Measures of this final rule for additional detail on

these eCQMs. We clarify that we do look at the availability of measures through the different collection types as we review measures for possible inclusion or removal, and will continue to monitor and consider the availability through the collection types as criteria when removing quality measures from MIPS.

After consideration of the public comments received, we are finalizing our proposal, beginning with the 2021 MIPS payment year, to implement an approach to incrementally remove process measures where prior to removal, consideration will be given to, but will not be limited to:

- Whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the measure addresses a priority area highlighted in the Measure Development Plan: *https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measure-development.html*.
- Whether the measure promotes positive outcomes in patients.
- Considerations and evaluation of the measure's performance data.
- Whether the measure is designated as high priority or not.
- Whether the measure has reached an extremely topped out status within the 98th to 100th percentile range, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made.

(iv) Categorizing Measures by Value

In the CY 2019 PFS proposed rule (83 FR 35900), we outlined the various types of MIPS quality and QCDR measures available for reporting in the quality performance category, such as outcome, high-priority, composite, and process measures, we acknowledge that not all measures are created equal. For example, the value or information gained by reporting on certain process measures does not equate that which is collected on outcome measures. We seek to ensure that the collection and submission of data is valuable to clinicians and worth the cost and burden of collecting the information.

Based on this, we solicited comment on implementing a system where measures are classified as a particular value (gold, silver or bronze) and points are awarded based on the value of the measure. For example, higher value measures that are considered ''gold'' standard, which could include outcome measures, composite measures, or measures that address agency priorities (such as opioids). The CAHPS for MIPS survey, which collects patient experience data, may also be considered a high value measure. Measures that are considered second tier, or at a ''silver'' standard would be measures that are considered process measures that are directly related to outcomes and have a good gap in performance (there is no high, unwavering performance) and demonstrate room for improvement; or topped out outcome measures. Lower value measures, such as standard of care process measures or topped out process measures would be considered ''bronze'' measures. We refer readers to section III.I.3.i.(1)(b)(xi) of this final rule for discussion on the assignment of value and scoring based on measure value.

We have received comments from stakeholders regarding categorizing measure by value. We thank commenters for their input and may take this input into consideration in future years.

(3) Cost Performance Category

For a description of the statutory basis and our existing policies for the cost performance category, we refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77162 through 77177, and 82 FR 53641 through 53648, respectively).

(a) Weight in the Final Score

In the CY 2018 Quality Payment Program final rule, we established that the weight of the cost performance category would be 10 percent of the final score for the 2020 MIPS payment year (82 FR 53643). We had previously finalized in the CY 2017 Quality Payment Program final rule at § 414.1350(b)(3) that beginning with the 2021 MIPS payment year, the cost performance category would be 30 percent of the final score, as required by section 1848(q)(5)(E)(i)(II)(aa) of the Act (81 FR 77166). Section 51003(a)(1)(C) of the Bipartisan Budget Act of 2018, enacted on February 9, 2018, amended section 1848(q)(5)(E)(i)(II)(bb) of the Act such that for each of the second, third, fourth, and fifth years for which the MIPS applies to payments, not less than 10 percent and not more than 30 percent of the MIPS final score shall be based on the cost performance category score. Additionally, this provision shall not be construed as preventing the Secretary from adopting a 30 percent weight if the Secretary determines, based on information posted under section 1848(r)(2)(I) of the Act, that sufficient cost measures are ready for adoption for use under the cost performance category for the relevant performance period. Section 51003(a)(2) of the Bipartisan Budget Act of 2018 amended section 1848(r)(2) of the Act to add a new paragraph (I), which we discuss in section III.I.3.h.(3)(b)(i) of this final rule.

In light of these amendments, in the proposed rule (83 FR 35900 through 35901), we proposed at § 414.1350(d)(3) that the cost performance category would make up 15 percent of a MIPS eligible clinician's final score for the 2021 MIPS payment year. As discussed in section III.I.3.h.(3)(b)(iv) of this final rule, § 414.1350(b) will be redesignated as § 414.1350(d). We proposed to delete the existing text under § 414.1350(b)(3) and address the weight of the cost performance category for the MIPS payment years following 2021 in future rulemaking. We also proposed a technical change to the text at § 414.1350(b) (redesignated as § 414.1350(d)) to state that the cost performance category weight will be as specified under redesignated § 414.1350(d), unless a different scoring weight is assigned by CMS under section 1848(q)(5)(F) of the Act (83 FR 35901).

We believe that measuring cost is an integral part of measuring value, and we believe that clinicians have a significant impact on the costs of patient care. However, we proposed to only modestly increase the weight of the cost performance category for the 2021 MIPS payment year from the 2020 MIPS payment year because we recognize that cost measures are still relatively early in the process of development and that clinicians do not have the level of familiarity or understanding of cost measures that they do of comparable quality measures (83 FR 35900 through 35901). As described in section III.I.3.h.(3)(b)(ii) of this final rule, we are finalizing the addition of 8 episode-based measures to the cost performance category beginning with the 2019 MIPS performance period. This is a first step in developing a more robust and clinician-focused measurement of cost performance. We will continue to work on developing additional episode-based measures that we may consider proposing for the cost performance category in future years. Introducing more measures over time would allow for more clinicians to be measured in this performance category. It would also allow time for more outreach to clinicians to better educate them on the cost measures. We considered maintaining the weight of the cost performance category at 10 percent for the 2021 MIPS payment year as we recognize that clinicians are still learning about the cost performance category and being introduced to new measures. We invited comment on

whether we should consider an alternative weight for the 2021 MIPS payment year.

The following is a summary of the public comments received on these proposals and our responses:

Comment: Several commenters supported our proposal to increase the weight of the cost performance category to 15 percent for the 2021 MIPS payment year, noting the importance of managing cost in measuring the value of a clinician as well as the opportunity to gradually increase the weight of the performance category.

Response: We thank the commenters for their support for this proposal.

Comment: Several commenters opposed our proposal to increase the weight of the cost performance category to 15 percent for MIPS payment year 2021. They believed that the increased flexibility provided by the Bipartisan Budget Act of 2018 should be used to maintain the weight at 10 percent for MIPS payment year 2021 and in future years. Some commenters requested that the weight of the cost performance category not be increased until CMS can address issues of social and complexity risk factors and of clinical risk adjustment for measures in areas such as oncology. Some commenters suggested maintaining the weight of the cost performance category at 10 percent until CMS is able to provide more detailed and actionable performance data and develop more reliable and valid measures.

Additionally, several commenters opposed our proposal to increase the weight of the cost performance category because we proposed to add new episode-based measures (as detailed in section III.I.3.h.(3)(b)(ii) of this rule) and clinicians should have time to learn about these measures before the category weight is increased. Additionally, several commenters suggested CMS wait to increase the cost performance category weight until sufficient episode groups exist for additional specialties.

Response: We continue to investigate ways to best accommodate the issue of clinical and social risk adjustment in measures contained in the cost performance category. All measures included in the cost performance category are adjusted for clinical risk. We have adopted a complex patient bonus at the final score level that adjusts again for patient clinical complexity as well as some elements of social complexity. We also continue to consider ways to offer actionable feedback on cost measures to clinicians in the future.

In regards to the episode-based measures, we do not believe the introduction of these new measures should mean that the weight of the performance category should be maintained, especially since stakeholders had the opportunity to gain experience with the new measures through field testing in the fall of 2017. The performance category also still includes two measures that were used in the first 2 years of MIPS. The Bipartisan Budget Act of 2018 gave CMS increased flexibility to establish the weight of the cost performance category for the first 5 years of MIPS, but the weight is still required to be 30 percent beginning with the 2024 MIPS payment year. Therefore, we believe it is necessary to begin adjusting the weight gradually, including increasing the weight to 15 percent for the 2021 MIPS payment year. We will concurrently look to increase the number of clinicians who are measured in the cost performance category by developing and considering for inclusion in the Quality Payment Program more episode-based measures that cover additional types of clinicians and specialties.

After consideration of the public comments, we are finalizing our proposal at § 414.1350(d)(3) to weight the cost performance category at 15 percent for the 2021 MIPS payment year as proposed. Additionally, we are also finalizing our proposal to delete the existing text under § 414.1350(b)(3) and address the weight of the cost performance category for the MIPS payment years following 2021 in future rulemaking as proposed. Finally, we are finalizing our proposed technical change to the text at § 414.1350(b) (redesignated as § 414.1350(d)) to state that the cost performance category weight will be as specified under redesignated § 414.1350(d), unless a different scoring weight is assigned by CMS under section 1848(q)(5)(F) of the Act, as proposed.

In accordance with section 1848(q)(5)(E)(i)(II)(bb) of the Act, we will continue to evaluate whether sufficient cost measures are ready for adoption under the cost performance category and move towards the goal of increasing the weight to 30 percent of the final score. To provide for a smooth transition, we anticipate that we would increase the weight of the cost performance category by 5 percentage points each year until we reach the required 30 percent weight for the 2024 MIPS payment year. We invited comments on this approach to weighting the cost performance category for the 2022 and 2023 MIPS payment years, considering our flexibility in setting the weight between 10 percent and 30 percent of the final score, the availability of cost measures, and our desire to ensure a smooth transition to a 30 percent weight for the cost performance category. We appreciate the comments we received and will consider them as we develop proposals for future rulemaking.

(b) Cost Criteria

(i) Background

Under § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. In the CY 2018 Quality Payment Program final rule, we established two cost measures (total per capita cost measure and Medicare spending per beneficiary (MSPB) measure) for the 2018 MIPS performance period and future performance periods (82 FR 53644). These measures were previously established for the 2017 MIPS performance period (81 FR 77168). We will continue to evaluate cost measures that are included in MIPS on a regular basis and anticipate that measures could be added or removed through rulemaking as measure development continues. In general, we expect to evaluate cost measures according to the measure reevaluation and maintenance processes outlined in the ''Blueprint for the CMS Measures Management System'' (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/BlueprintVer14.pdf*). As described in section 2 of the Blueprint for the CMS Measures Management System Version 14.0, we will conduct annual evaluations to review the continued accuracy of the measure specifications. Annual updates ensure that the procedure, diagnostic, and other codes used in the measure account for updates to coding systems over time. To the extent that these updates would constitute a substantive change to a measure, we would ensure the changes are proposed for adoption through rulemaking. We will also comprehensively reevaluate the measures every 3 years to ensure that they continue to meet measure priorities. As a part of this comprehensive reevaluation, we will gather information through environmental scans and literature reviews of recent studies and new clinical guidelines that may inform potential refinements. We will also analyze measure performance rates and re-assess the reliability and validity of the measures. Throughout these

reevaluation efforts, we will summarize and consider all stakeholder feedback received on the measure specifications during the implementation process, and may seek input through public comment periods. In addition, the measure development contractor may acquire individual input on measures by convening Technical Expert Panels (TEPs) and clinical subcommittees. Aside from these regular measure reevaluations, there may be ad-hoc reviews of the measures if new evidence comes to light which indicates that significant revisions may be required.

We will also continue to update the specifications to address changes in coding, risk adjustment, and other factors. The process for updating measure specifications will take place through ongoing maintenance and evaluation, during which we expect to continue seeking stakeholder input. As we noted above, any substantive changes to a measure would be proposed for adoption in future years through notice and comment rulemaking. We appreciate the feedback that we have received so far throughout the measure development process and believe that stakeholders will continue to provide feedback to the measure development contractor on episode-based cost measures by submitting written comments during public comment opportunities, by participating in the clinical subcommittees convened by the measure development contractor, or by attending education and outreach events. We will take all comments and feedback into consideration as part of the ongoing measure evaluation process.

As we noted in the CY 2017 Quality Payment Program final rule (81 FR 77137) regarding quality measures, which we believe would also apply for cost measures, some updates may incorporate changes that would not substantively change the intent of the measure. Examples of such changes may include updated diagnosis or procedure codes or changes to exclusions to the patient population or definitions. While we address such changes on a case-by-case basis, we generally believe these types of maintenance changes are distinct from substantive changes to measures that result in what are considered new or different measures. As described in section 3 of the Blueprint for the CMS Measures Management System Version 14.0, if substantive changes to these measures become necessary, we expect to follow the pre-rulemaking process for new measures, including resubmission to the Measures Under Consideration (MUC) list and consideration by the Measure Applications Partnership (MAP). The MAP provides an additional opportunity for an interdisciplinary group of stakeholders to provide feedback on whether they believe the measures under consideration are attributable and applicable to clinicians. The MAP also reviews measures for clinician level feasibility, reliability, and validity. They also consider whether the measures are scientifically acceptable and reflect current clinical guidelines.

Section 51003(a)(2) of the Bipartisan Budget Act of 2018 amended section 1848(r)(2) of the Act to add a new paragraph (I) requiring the Secretary to post on the CMS website information on cost measures in use under MIPS, cost measures under development and the time-frame for such development, potential future cost measure topics, a description of stakeholder engagement, and the percent of expenditures under Medicare Part A and Part B that are covered by cost measures. This information shall be posted no later than December 31 of each year beginning with 2018. We expect this posting will provide a list of the cost measures established for the cost performance category for the current performance period (for example, the posting in 2018 would include a list of the measures for the 2018 MIPS performance period), as well as a list of any cost measures that may be proposed for a future performance period through rulemaking. We will provide hyperlinks to the measure specifications documents and include the percent of Medicare Part A and Part B expenditures that are covered by these cost measures. The posting will also include a list and description of the measures under development at that time. We intend to summarize the timeline for measure development, including the stakeholder engagement activities undertaken, which may include a TEP, clinical subcommittees, field testing, and education and outreach activities, such as national provider calls and listening sessions. Finally, the posting will provide an overview of potential future topics in cost measure development, such as any clinical areas in which measures may be developed in the future (83 FR 35901 through 35902).

(ii) Episode-Based Measures for the 2019 and Future Performance Periods

Episode-based measures differ from the total per capita cost measure and MSPB measure because episode-based measure specifications only include items and services that are related to the episode of care for a clinical condition or procedure (as defined by procedure and diagnosis codes), as opposed to including all services that are provided to a patient over a given timeframe.

We discussed our progress in the development of episode-based measures in the CY 2018 Quality Payment Program proposed rule (82 FR 30049 through 30050) and received significant positive feedback on the process used to develop the measures as well as the measures' clinical focus that was informed by expert opinion (82 FR 53644 through 53646). The specific measures selected for the initial round of field testing were included based on the volume of beneficiaries impacted by the condition or procedure, the share of cost to Medicare impacted by the condition or procedure, the number of clinicians/clinician groups attributed, and the potential for alignment with existing quality measures.

We have developed episode-based measures to represent the cost to Medicare for the items and services furnished to a patient during an episode of care (''episode''). Episode-based measures are developed to let attributed clinicians know the cost of the care clinically related to their initial treatment of a patient and provided during the episode's timeframe. Specifically, we define cost based on the allowed amounts on Medicare claims, which include both Medicare payments and beneficiary deductible and coinsurance amounts. Episode-based measures are calculated using Medicare Parts A and B fee-for-service claims data and are based on episode groups. Episode groups:

- Represent a clinically cohesive set of medical services rendered to treat a given medical condition.
- Aggregate all items and services provided for a defined patient cohort to assess the total cost of care.
- Are defined around treatment for a condition (acute or chronic) or performance of a procedure.

Items and services in the episode group could be treatment services, diagnostic services, and ancillary items and services directly related to treatment (such as anesthesia for a surgical procedure). They could also be items and services that occur after the initial treatment period that may be furnished to patients as follow-up care or to treat complications resulting from the treatment. An episode is a specific instance of an episode group for a specific patient and clinician. For example, in a given year, a clinician might be attributed 20 episodes (instances of the episode group) from the episode group for heart failure. In section III.I.3.h.(3)(b)(iv) of this final rule, we discuss the attribution rules for cost measures.

After episodes are attributed to one or more clinicians, items and services may be included in the episode costs if they are furnished within a patient's episode window. Items and services will be included if they are the trigger event for the episode or if a service assignment rule identifies them as a clinically related item or service during the episode. The detailed specifications for these measures, which include information about the service assignment rules, can be reviewed at *qpp.cms.gov*.

To ensure a more accurate comparison of cost across clinicians, episode costs are payment standardized and risk adjusted. Payment standardization adjusts the allowed amount for an item or service to facilitate cost comparisons and limit observed differences in costs to those that may result from health care delivery choices. Payment standardized costs remove any Medicare payment differences due to adjustments for geographic differences in wage levels or policy-driven payment adjustments such as those for teaching hospitals. Risk adjustment accounts for patient characteristics that can influence spending and are outside of clinician control. For example, for the elective outpatient PCI episode-based measure, the risk adjustment model may account for a patient's history of heart failure.

The measure development contractor has continued to seek extensive stakeholder feedback on the development of episode-based measures, building on the processes outlined in the CY 2018 Quality Payment Program final rule (82 FR 53644). These processes included convening a TEP and clinical subcommittees to solicit expert and clinical input for measure development, conducting national field testing on the episode-based cost measures developed, and seeking input from clinicians and stakeholders through engagement activities. Seven clinical subcommittees were convened through an open call for nominations between March 17, 2017 and April 24, 2017, composed of nearly 150 clinicians affiliated with almost 100 specialty societies. These subcommittees met at an in-person meeting and through webinars from May 2017 to January 2018 to select an episode group or groups to develop and provide detailed clinical input on each component of episode-based cost measures. These components included episode triggers and windows, item and service assignment, exclusions, attribution methodology, and risk adjustment variables.

As described in the CY 2018 Quality Payment Program final rule (82 FR 53645), we provided an initial opportunity for clinicians to review their performance based on the new episode-based measures developed by the clinical subcommittees in the fall of 2017 through national field testing.

During field testing, we sought feedback from stakeholders on the draft measure specifications, feedback report format, and supplemental documentation through an online form. We received over 200 responses, including 53 comment letters, during the field test feedback period. We shared the feedback on the draft measure specifications with the clinical subcommittees who considered it in providing input on measure refinements after the end of field testing. A field testing feedback summary report is publicly available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2018-field-testing-feedback-summary-report.pdf.*

To engage clinicians and stakeholders, we conducted extensive outreach activities including hosting National Provider Calls (NPCs) to provide information about the measure development process and field test reports, and to give stakeholders the opportunity to ask questions.

The new episode-based measures developed by the clinical subcommittees were considered by the NQF-convened MAP, and were all conditionally supported by the MAP, with the recommendation of obtaining NQF endorsement. We intend to submit these episode-based measures to NQF for endorsement in the future. The MAP provides an opportunity for an interdisciplinary group of stakeholders to provide input on whether the measures under consideration are attributable and applicable to clinicians. The MAP also reviews measures for clinician level feasibility, reliability, and validity. Following the successful field testing and review through the MAP process, we proposed to add 8 episode-based measures listed in Table 36 as cost measures for the 2019 MIPS performance period and future performance periods (83 FR 35902).

The attribution methodology for these measures is discussed in section III.I.3.h.(3)(b)(iv)(B) of this final rule. The detailed specifications for these measures can be reviewed at *qpp.cms.gov*. These specifications documents consist of (i) a methods document that outlines the methodology for constructing the measures, and (ii) a measure codes list file that contains the medical codes used in that methodology. First, the methods document provides a high-level overview of the measure development process, including discussion of the detailed clinical input obtained at each step, and details about the components of episode-based cost measures: Defining an episode group; assigning costs to the episode group; attributing the episode group; risk adjusting episode group costs; and aligning cost with quality. The methods document also contains the detailed measure methodology that describes each logic step involved in constructing the episode groups and calculating the cost measure. Second, the measure codes list file contains the codes used in the specifications, including the episode triggers, exclusions, episode sub-groups, assigned items and services, and risk adjustors.

TABLE 36—EPISODE-BASED MEASURES PROPOSED FOR THE 2019 MIPS PERFORMANCE PERIOD AND FUTURE PERFORMANCE PERIODS

Measure topic	Measure type
Elective Outpatient Percutaneous Coronary Intervention (PCI)	Procedural.
Knee Arthroplasty	Procedural.
Revascularization for Lower Extremity Chronic Critical Limb Ischemia	Procedural.
Routine Cataract Removal with Intraocular Lens (IOL) Implantation	Procedural.
Screening/Surveillance Colonoscopy	Procedural.
Intracranial Hemorrhage or Cerebral Infarction	Acute inpatient medical condition.
Simple Pneumonia with Hospitalization	Acute inpatient medical condition.
ST-Elevation Myocardial Infarction (STEMI) with Percutaneous Coronary Intervention (PCI)	Acute inpatient medical condition.

The following is a summary of the public comments received on these proposals and our responses:

Comment: Several commenters supported our proposed adoption of the 8 episode-based measures under the cost performance category for the 2021 MIPS payment year. These commenters noted their support for the significant clinician input into the measures.

Response: We thank the commenters for their support.

Comment: Several commenters supported the development of episode-based measures but expressed concern about including them in the MIPS cost performance category for the 2019 MIPS performance period. They recommended that there be additional time for clinicians to understand and address their performance on the measures. One commenter indicated that although the measures had been made available as part of field testing in the fall of 2017, the feedback that was made available did not facilitate action to improve on the part of the clinician. Another commenter suggested that CMS use 2019 as a pilot year to better test these new episode-based measures.

Response: We will continue to work to make clinicians more familiar with the measures through education and outreach activities. For example, we have held cost performance category webinars to help clinicians understand the cost measures in use for the MIPS 2018 performance period, and expect to hold similar webinars in the future. We believe that the extensive field testing activities conducted in the fall of 2017 in combination with future education and outreach will help to ensure clinicians will understand these episode-based measures and what actions they could take to improve their performance in the measures. We do not believe that an additional year of pilot testing is necessary at this time given the field testing and extensive involvement of clinicians in the development of these measures.

Comment: Many commenters requested more detailed feedback on cost measures in order to improve their performance, stating that it is difficult to manage costs without receiving data on the patients attributed to them for purposes of the cost measures. Some commenters requested that CMS provide information on attributed patients on a regular basis, such as quarterly. Some commenters expressed concern that in contrast with the Value Modifier program, CMS has not provided detailed feedback on cost measures, such as identifying beneficiaries and the services they received for the 2017 MIPS performance period. One commenter also suggested the use of an alternative metric, such as the average ratio of the observed cost compared to the expected cost, as a final comparison for the episode-based measures, as they believe this to be more informative and actionable for clinicians.

Response: We have conducted user research on the feedback provided for the first year of MIPS. In addition to that feedback, we are also reviewing the QRURs from the legacy VM program and conducting user research about what is valuable within the information provided historically. We are committed to maturing the feedback experience for year 2 and may consider providing beneficiary-level data on cost measures in the future. Additionally, while we are unsure whether or not the average ratio of the observed cost to expected cost would be more informative than our current feedback reports, we will continue to monitor the information provided, and explore ways to provide actionable information to clinicians as we develop the measures for the cost performance category.

Comment: A few commenters supported the development and inclusion of episode-based measures but expressed concern that measures for their particular specialty or focus area, such as urology, chiropractic medicine, and medical oncology, were not yet included. A few commenters suggested that CMS continue to engage with stakeholders and provide a transparent process as CMS continues to develop additional episode-based measures. One commenter recommended that CMS develop or include quality measures in tandem with cost measures to prevent unintended consequences of attempts to reduce cost which could adversely affect quality of care.

Response: We continue to work to develop new episode-based measures that could be considered for inclusion in the cost performance category in future years. We expect that future measures may apply to a greater range of specialties and clinical areas, such as urology and the other focus areas suggested by commenters. Section 1848(r)(2)(D)(i)(I) of the Act requires us to establish care episode groups and patient condition groups, which account for a target of an estimated one half of expenditures under parts A and B with such target increasing over time as appropriate. While we have developed some episode-based measures to target that goal as required, we shall continue our work to develop additional measures focusing on both additional specialty types as well as consider the important issue of measuring both cost and quality. By continuing to gather detailed clinician and expert input on episode-based measures, such as through clinical subcommittees and technical expert panels, we hope to identify and mitigate potential unintended consequences at each stage of measure development and testing.

Comment: A few commenters expressed concern with the overall process for adding episode-based measures to the MIPS program on an annual basis. They indicated that while clinician input is valuable in defining the measures, it is also of particular importance to have an underlying structure for episode-based measures that defines responsibility for patients as they cross between multiple episodes. They opposed inclusion of episode-based measures until these issues are addressed. Additionally, several commenters offered alternative frameworks to consider in the future development of episode-based measures, including moving towards a tool that offers a multi-payer perspective. One commenter urged CMS to develop episode-based measures that are specific to discrete episodes of care. A few commenters encouraged CMS to consider other factors when developing episode-based measures including Activities of Daily Living (ADLs), counter quality measures, patient specific pricing, and medical innovations.

Response: We rely on a comprehensive framework and systematic process for creating episode-based measures that account for the roles and responsibilities of individual clinicians in the care of individual patients experiencing specific health conditions. This framework has been applied in constructing all of the new cost measures for use in MIPS, and in revising episode groups that had been developed under section 1848(n)(9)(A) of the Act. Our current process includes: (1) A transparent conceptual framework for creating episodes of care that assigns costs for patients to those clinicians with the ability to influence those costs; (2) a mechanism for incentivizing high quality treatment that lowers preventable high cost future adverse health events; and (3) a data-driven stakeholder input process for acquiring and implementing clinical input that ensures clinical face validity and actionability of constructed episode-based cost measures. This framework was developed in part based on stakeholder comments on measures in the Value Modifier program and overcomes the fundamental shortcomings of earlier episode grouping approaches previously studied

by CMS. Shortcomings of previously studied episode grouping approaches included lack of actionability arising from the unpredictable and clinically inappropriate assignment of costs, limited relevance as episode constructions did not focus on the role of attributed clinicians in providing patient care, and limited transparency arising from the use of complicated software algorithms.

Our conceptual framework provides a comprehensive foundation for episode-based measures that can be used to incentivize high-value care by attributed clinicians at each stage of the patient care continuum, and allows for progressively adding new episode-based measures in a logically cohesive and consistent manner. The framework involves three distinct types of episode groups: Procedural, acute inpatient medical condition, and chronic. Procedural episode groups are triggered by performance of a major procedure, acute inpatient medical condition episode groups are triggered by evaluation and management claims during hospitalizations with specific DRGs, and chronic condition episode groups are triggered by evaluation and management claims with particular diagnoses. Attribution is determined by the clinician(s) involved in the triggering claims, with consistent rules within each type of episode group. Services, and their associated costs, are assigned to an episode based on a clinical determination of whether a service is under the influence of the attributed clinician (for example, routine follow-up care or adverse health outcomes such as a readmission). Clinical determinations of service assignment are made using common criteria and methods across episode groups, to encourage distinctions in service assignment and reflect differences in clinical influence across episode groups. Risk adjustment employs a common starting point of the CMS–HCC model across episode groups, but risk adjustment models can be enhanced by the use of risk factors specifically adapted for each episode group. This allows, for instance, for adjustments to be made for an acute condition episode group based on whether the condition is a stand-alone presentation of the condition versus the exacerbation of an ongoing chronic condition. The framework also allows for complete stratification in risk adjustment through the use of episode sub-groups, with the definition of sub-groups (such as unilateral vs. bilateral) being based on common principles across episode groups. Episodes from distinct episode groups can overlap with one another to ensure that each clinician treating a patient with multiple health issues has incentives for providing high value care. When a given service is clinically related to only one overlapping episode, it is assigned only to that one. When a service is clinically related to two overlapping episodes, it is assigned to both to ensure joint accountability. Since each episode's cost is compared to a risk-adjusted expected cost only for other episodes from the same episode group, there is no issue of double counting. This approach allows for development of distinct episode groups that cover a patient's care continuum, including an underlying chronic condition as well as a procedure or treatment for an exacerbation. As an example, a patient receiving chronic care for coronary artery disease (CAD) (a chronic episode) could have an acute incidence of STEMI requiring PCI for stabilization (an acute inpatient medical condition episode), and due to having severe CAD could later receive a coronary artery bypass graft (CABG) procedure (a procedural episode). This logically, cohesive framework for episode group development avoids a series of challenges raised by previously studied episode grouping approaches that assign services to only a single episode, including lack of transparency and predictability in what an attributed clinician will be held accountable for at the beginning of an episode. For information on how this framework has been operationalized, refer to the measure specifications available at *https://qpp.cms.gov*.

Using this conceptual framework, we have created a concrete process for developing new measures over time. To prioritize the areas for development of the new cost measures, our measure development contractor convened a clinical committee, comprised of over 70 clinicians affiliated with over 50 specialty societies that provided input necessary to develop a public posting of 117 episode groups for development in December 2016. We then used criteria vetted by a standing technical expert panel—comprised of 19 clinicians, health researchers, and representatives of patient advocacy organizations—to divide these 117 episode groups into 18 clinical areas. The prioritization criteria focused on identifying areas where potential episode-based measures could affect the highest number of beneficiaries and clinicians, address particularly high cost procedures and conditions, provide an opportunity for improvement, and best align with quality measures.

Our measure development contractor has and is continuing to convene clinical subcommittees for each of the priority clinical areas. The composition of a subcommittee for an area principally consists of practicing clinicians who are candidates for attribution of episode-based measures developed for that area. Each clinical subcommittee prioritizes specific episode measures for development within its area based on the criteria above. The structure for developing specific cost measures relies on a systematic data-based conceptual framework for triggering logic, cohort definition, attribution, and cost assignment. For the 8 episode-based measures discussed in this rule, nearly 150 clinicians affiliated with 98 specialty societies participated in the clinical subcommittees in the creation of these measures. After positive reception of the initial development process, 267 clinicians affiliated with more than 120 specialty societies are now participating in the clinical subcommittees and workgroups developing 11 additional episode-based cost measures. The structure of episode-based cost measure development provides a vehicle for continued stakeholder engagement as additional measures are developed in the future.

Comment: A few commenters recommended that episode-based measures not be included in the MIPS cost performance category if the measures have not been endorsed by the NQF or supported by the MAP. They stated that the NQF process gives important insights into the reliability, validity, and usability of measures.

Response: The episode-based measures were reviewed by the MAP and received the recommendation of ''conditional support for rulemaking,'' with the MAP recommending that the measures be submitted for NQF endorsement. This review provided stakeholders with additional public comment opportunities, which the MAP considered along with submission materials regarding the scientific acceptability, reliability, validity, and usability of the measures. We intend to submit the episode-based measures for NQF endorsement in an upcoming review cycle.

Comment: One commenter expressed concern that particular episode-based measures did not properly account for risk because of the nature of their construction and lack of clinical data. Specifically, this commenter stated that a combined measure of intracranial hemorrhage and cerebral infraction

would produce distortions in results. This commenter also stated that risk adjustment for this measure did not include a measure of stroke severity. Another commenter expressed uncertainty about the risk adjustment methodology and also suggested the use of both inpatient and outpatient claims data to obtain a complete understanding of the patient's risk factors. One commenter suggested excluding Implantable Cardioverter Defibrillator (ICD) implantation MS–DRGs (222–227) from the Elective Outpatient PCI and STEMI with PCI measures to ensure there are no adverse incentives to providing a service that is both covered and clinically indicated. One commenter expressed concern that the episode-based measure for Revascularization for Lower Extremity Chronic Critical Limb Ischemia should have a longer measurement period. One commenter requested that post-discharge events unrelated to the initial pneumonia hospitalization and any hospice costs be excluded for the Simple Pneumonia episode-based measure. The same commenter also stated that new episodes for the same measure should not be started for a patient if they already have an ongoing episode.

Response: We understand the interest in risk adjustment and other aspects of measure construction. To summarize, the risk adjustment for the eight episode-based measures includes risk adjustors from the CMS–HCC model and additional measure-specific risk adjustors recommended by the Clinical Subcommittee for the measure. Risk adjustors are defined using the beneficiary's Medicare claims history (including inpatient, outpatient, and Part B Physician/Supplier claims) during the period prior to the start of the episode. Claims from the triggering hospitalization or on the triggering Part B Physician/Supplier claim are typically not included, as we understand it may be difficult to discern which claims are due to complications and which were already present at the initiation of the episode. We believe that utilizing the claims from the look back window adequately identifies patient comorbidities. To address the specific comments, we believe that the Intracranial Hemorrhage and Cerebral Infarction measure accurately assesses clinician cost performance as there are separate sub-groups for Intracerebral Hemorrhage and Cerebral Infarction such that patients within each sub-group are compared only with each other (that is, a patient being treated for Cerebral Infarction would only be compared to other patients being treated for Cerebral Infarction). The risk adjustors for this measure were developed with significant input from a Neuropsychiatric Disease Management Clinical Subcommittee, which recommended specific risk adjustors that include MS–DRG severity for Intracranial Hemorrhage or Cerebral Infarction and Nonspecific Cerebrovascular Disorders. Additional risk adjustors were included to account for comorbidities that could lead to worse outcomes such as aphasia and dysphagia. However, measures of stroke severity such as the NIH stroke scale were not included in the risk adjustment model to avoid possible unintended consequences (for example, coding of higher severity for improvement of individual episode risk adjustment) and to avoid penalizing clinicians who do not code for severity, especially since ICD–10–CM codes for NIH Stroke Scale have only been operational since October 2017. The Revascularization for Lower Extremity Chronic Critical Limb Ischemia measure has a 30-day pre-trigger period and a 90-day post-trigger period. This episode window was determined through extensive input from a Peripheral Vascular Disease Management Clinical Subcommittee, which we believe to be an appropriate length of time for which the attributed clinician can reasonably influence services. The measure specifications, including the post-discharge assigned services, for the Simple Pneumonia with Hospitalization measure were developed with significant clinical input from the Pulmonary Disease Management Clinical Subcommittee, which only assigned services they believed the attributed clinician could reasonably influence. For this reason, the costs associated with the hospice setting are not assigned to Simple Pneumonia with Hospitalization episodes. We will conduct annual evaluations to review the continued accuracy of the measure specifications. Finally, we do not exclude episodes if a patient already qualifies for another episode since we believe that allowing for overlapping episodes incentivizes communication and care coordination as a patient progresses through the care continuum. For example, if a patient is re-hospitalized for pneumonia after an initial pneumonia episode, this triggers two separate episodes of care for pneumonia. The risk adjustment model adjusts for differences in clinical complexity at the time each episode begins. This ensures that the attributed clinicians managing each hospitalization face analogous incentives to provide the patient high value care. The assigned services for the STEMI with PCI and Elective Outpatient PCI measures were developed with input from the Cardiovascular Disease Management Clinical Subcommittee, with the goal of capturing complications of Myocardial Infarction (MI) or Heart Failure (HF) admissions. Given this clinical intent of the measure, we believe that MS–DRGs with MI or HF in the measure (MS–DRGs 222–223: Defib with Cath with MI/HF) are appropriate to include as assigned services. We agree, however, with the comment about removing assignments of the MS–DRGs without MI or HF (MS–DRGs 224–225: Defib with Cath without MI/HF and MS–DRGs 226–227: Defib without Cath without MI/HF), as these are more likely to be elective ICD placements. Given the scope of the measure, we believe it is appropriate to assign services that are part of an admission for MI or HF, while excluding services that are elective. To maintain a consistent framework across all measures, we are implementing this revision where relevant in STEMI with PCI, Elective Outpatient PCI, and Revascularization for Lower Extremity Chronic Critical Limb Ischemia.

Comment: One commenter expressed concern with the possibility of high cost variation for some episode-based measures depending on the codes that trigger the episodes or the place of service in which an episode is triggered. To account for this variation, the commenter suggested incorporating a sub-group based on the triggering DRG code for the Intracranial Hemorrhage or Cerebral Infarction measure and the STEMI with PCI measure, a sub-group based on triggering procedure code for the Elective Outpatient PCI measure, and a place of service sub-group for the Revascularization for Lower Extremity Chronic Critical Limb Ischemia measure and Screening/Surveillance Colonoscopy measure.

Response: The measure specifications, including the episode triggers and the sub-groups for each measure, were determined with significant clinical input from the Clinical Subcommittees that developed each episode-based measure. To adjust for patient differences outside attributed clinicians' influence, the Clinical Subcommittees could choose to risk adjust for a specific patient factor or sub-group by that factor. Risk adjustment ensures that a measure accounts for average cost differences associated with the specific factor, while sub-grouping involves estimating an entirely separate risk adjustment model for patients with that factor. Sub-grouping is only appropriate

in cases where a sufficient number of episodes are present in the sub-population to ensure a statistically meaningful model and where a separate model for the sub-population is necessary. Balancing these considerations, the Clinical Subcommittees addressed concerns raised by the commenter by: Including indicators for MS–DRG in risk adjustment models for the Intracranial Hemorrhage or Cerebral Infarction measure and the STEMI with PCI measure to reflect the presence of Complication or Comorbidity (CC) or Major Complication or Comorbidity (MCC); and including place of service factors in risk adjustment models for the Revascularization for Lower Extremity Chronic Critical Limb Ischemia measure and the Screening/Surveillance Colonoscopy measure. For the Elective Outpatient PCI measure, the current inclusion of other risk adjustment factors is designed to control for factors outside of the clinician's influence that may dictate the particular triggering procedure used.

Comment: Several commenters expressed support for the episode-based measure development process implemented by CMS that incorporates significant stakeholder input as well as support for the measures. One commenter commended CMS for convening the Clinical Subcommittees, specifically noting that they believed members of the subcommittee that developed the Screening/Surveillance Colonoscopy measure were part of a successful and deliberative process. Two commenters also supported the Routine Cataract with IOL Implantation measure, stating the measure accurately reflected the costs of the procedure and will provide actionable data to clinicians. Another commenter expressed appreciation for the pace of the development process and urged CMS to continue this level of engagement with stakeholders in other areas of the Quality Payment Program.

Response: We recognize the importance of clinician input in developing episode-based measures that provide actionable data and aim to continue this level of engagement in the development of future episode-based measures for MIPS.

Comment: One commenter supported the total per capita cost measure and stated it is the best initial metric for assessing the cost-effectiveness of primary care providers while fulfilling MACRA's mandate to evaluate a primary care provider's cost performance.

Response: We agree that this measure is important as a measure of the overall cost of care, even as we develop episode-based measures which are also important measures of the cost of care.

Comment: Several commenters opposed the continued inclusion of the total per capita cost measure and the MSPB measure in the cost performance category. They stated that the measures included all services provided to a patient, even those for which the attributed clinician could not control. One commenter requested that these measures only be applied to primary care clinicians and not to specialists. Finally, one commenter expressed concerns with how total per capita cost measure has not yet been endorsed by NQF, and MSPB measure has only been endorsed at the facility-level.

Response: While we appreciate the interest in the total per capita cost and MSPB measures' NQF endorsement status, we continue to believe that these measures are tested and reliable for Medicare populations and provide an important measurement of clinician cost performance (82 FR 53644) while we continue to develop episode-based measures that precisely identify services that are part of an episode that could be considered directly under the control of a clinician. Versions of the total per capita cost and MSPB measures were included in the QRURs and used in the VM for many years before the implementation in MIPS. These measures have an important place in cost measurement given that the episode-based measures will only apply to a subset of clinicians at this time.

The total per capita cost measure uses a primary care attribution method in which a specialist would not be attributed a patient unless that patient did not see a primary care clinician (based on the Medicare specialty) during the year. For some patients who do not see a primary care clinician in a year, a specialist may serve as a primary care clinician due to an underlying disease or condition which the specialist focuses on. For the MSPB measure, we do not believe it is appropriate to limit attribution to primary care clinicians as specialists may perform procedures or manage patients in the hospital and can have a significant influence on the overall spending during the hospitalization.

Both the total per capita cost and MSPB measures are being refined as part of the measure maintenance and re-evaluation process, incorporating substantial stakeholder input. We are completing an extensive outreach initiative in the fall of 2018 to share performance information with clinicians as part of field testing, a part of measure re-evaluation. After considering the stakeholder feedback on these refinements, we may propose the re-evaluated measures for use in MIPS to replace the current versions of the measures in the program.

Comment: Several commenters expressed concern about the risk and specialty adjustment methods used in the measures that are part of the cost performance category. In particular, several commenters stated that measures do not appropriately account for sociodemographic status, which can drive differences in average episode costs. Additionally, commenters noted that measures did not take into account the risks associated with complex or dual-eligible patients or patients seen by certain specialists. Another noted the lack of risk-adjustment for cancer treatment. One commenter also expressed concern about the differences in case-mix across specialties for a given measure, specifically STEMI with PCI. The commenter stated that under this measure, hospitalists may be attributed episodes that include more medically complex patients who require post-ICU care on a general medicine floor, making these hospitalists appear to be costlier than other clinicians.

Response: We understand stakeholders' concerns regarding risk adjustment for social risk factors and dual eligible status. As we have previously stated, we are concerned about holding clinicians to different standards for the outcomes of their patients with social risk factors, because we do not want to mask potential disparities. We believe that the path forward should incentivize improvements in health outcomes for disadvantaged populations while ensuring that beneficiaries have adequate access to excellent care. We thank commenters for this important feedback and will continue to consider options to account for social risk factors that would allow us to view disparities and potentially incentivize improvement in care for patients and beneficiaries. We recognize the concern regarding risk adjusting for complex patients, including those with cancer treatment, and regarding the variation in case-mix across specialties for a given episode. Our risk adjustment methodology, which employs a common starting point of the CMS–HCC model across episode groups and can include the use of risk factors specifically adapted for each episode group is designed to account for patient comorbidities that predict a complex hospitalization and lead to higher costs that are outside the influence of attributed clinicians, regardless of

which specialty designations those clinicians choose to identify.

Comment: Several commenters requested that certain clinicians be excluded or included in the cost performance category on the basis of their type of practice, particularly non-patient facing clinicians.

Response: We have established a policy to assign a zero percent weight to the cost performance category if there are not sufficient measures applicable and available to a MIPS eligible clinician (see, for example, 81 FR 77322 through 77325). We believe it is possible that a clinician may not have sufficient cost measures applicable or available to them based on their specialty or type of practice, including clinicians who are non-patient facing. We continue to work to expand the reach of the cost performance category to as many clinicians as possible, including non-patient facing clinicians in accordance with section 1848(q)(2)(C)(iv) of the Act.

After consideration of the public comments, we are finalizing our proposal to include the 8 episode-based measures listed in Table 36 in the cost performance category beginning with the 2019 MIPS performance period with a modification to the STEMI with PCI, Elective Outpatient PCI, and Revascularization for Lower Extremity Chronic Critical Limb Ischemia episode-based measures to remove assignments of the MS–DRGs without MI or HF (MS–DRGs 224–225: Defib with Cath without MI/HF and MS–DRGs 226–227: Defib without Cath without MI/HF).

(iii) Reliability

In the CY 2017 Quality Payment Program final rule (81 FR 77169 through 77170), we finalized a reliability threshold of 0.4 for measures in the cost performance category. We seek to ensure that MIPS eligible clinicians are measured reliably. In the CY 2017 Quality Payment Program final rule, we finalized a case minimum of 20 for the episode-based measures specified for the 2017 MIPS performance period (81 FR 77175). We examined the reliability of the proposed 8 episode-based measures listed in Table 36 at various case minimums and found that all of these measures meet the reliability threshold of 0.4 for the majority of clinicians and groups at a case minimum of 10 episodes for procedural episode-based measures and 20 episodes for acute inpatient medical condition episode-based measures. Furthermore, these case minimums would balance the goal of increased reliability with the goal of adopting cost measures that are applicable to a larger set of clinicians and clinician groups. Our analysis indicated that the case minimum for procedural episode-based measures could be lower than that of acute inpatient medical condition episode-based measures while still ensuring reliable measures.

Table 37 presents the percentage of TINs and TIN/NPIs with 0.4 or higher reliability, as well as the mean reliability for the subset of TINs and TIN/NPIs who met the proposed case minimums of 10 episodes for procedural episode-based measures and 20 episodes for acute inpatient medical condition episode-based measures for each of the proposed episode-based measures. Each row in Table 37 provides the percentage of TINs and TIN/NPIs who had reliability of 0.4 or higher among all the TINs and TIN/NPIs who met the case minimum for that measure during the study period (6/1/2016 to 5/31/2017).

TABLE 37—PERCENTAGE OF TINS AND TIN/NPIS WITH 0.4 OR HIGHER RELIABILITY FROM JUNE 1, 2016 TO MAY 31, 2017 AT PROPOSED CASE MINIMUMS

Measure name	Percentage TINs with 0.4 or higher reliability (%)	Mean reliability for TINs	Percentage TIN/NPIs with 0.4 or higher reliability (%)	Mean reliability for TIN/NPIs
Elective Outpatient Percutaneous Coronary Intervention (PCI)	100.0	0.73	84.1	0.53
Knee Arthroplasty	100.0	0.87	100.0	0.81
Revascularization for Lower Extremity Chronic Critical Limb Ischemia	100.0	0.74	100.0	0.64
Routine Cataract Removal with Intraocular Lens (IOL) Implantation	100.0	0.95	100.0	0.94
Screening/Surveillance Colonoscopy	100.0	0.96	100.0	0.93
Intracranial Hemorrhage or Cerebral Infarction	100.0	0.70	74.9	0.48
Simple Pneumonia with Hospitalization	100.0	0.64	31.8	0.40
ST-Elevation Myocardial Infarction (STEMI) with PCI	100.0	0.59	100.0	0.59

Based on this analysis, we proposed at § 414.1350(c)(4) and (5) a case minimum of 10 episodes for the procedural episode-based measures and 20 episodes for the acute inpatient medical condition episode-based measures beginning with the 2019 MIPS performance period (83 FR 35904). We stated that these case minimums would ensure that the measures meet the reliability threshold for groups and individual clinicians. We stated that we believe that the proposed case minimums for these procedural and acute inpatient medical condition episode-based measures would achieve a balance between several important considerations. In order to help clinicians become familiar with the episode-based measures as a robust and clinician-focused form of cost measurement, we want to provide as many clinicians as possible the opportunity to receive information about their performance on reliable measures. This is consistent with the stakeholder feedback that we have received throughout the measure development process. We stated that we believe that calculating episode-based measures with these case minimums would accurately and reliably measure the performance of a large number of clinicians and clinician group practices.

We stated that we recognize that the percentage of TIN/NPIs with 0.4 or greater reliability for the Simple Pneumonia with Hospitalization measure, while still meeting our reliability threshold, is somewhat lower than that of the other proposed acute inpatient medical condition episode-based measures, as well as all of the proposed procedural episode-based measures. For this reason, we considered an alternative case minimum of 30 for both TIN/NPIs and TINs for this measure. At this case minimum, 100 percent of TIN/NPIs would have 0.4 or greater reliability and the mean reliability would increase to 0.49 for TIN/NPIs and 0.70 for TINs. However, the number of TINs and TIN/NPIs that would meet the case minimum for this important measure would decrease by 29 percent for TINs and by 84 percent for TIN/NPIs. We invited comments on

this alternative case minimum for TIN/NPIs and TINs for the Simple Pneumonia with Hospitalization episode-based measure.

We previously finalized a case minimum of 35 for the MSPB measure (81 FR 77171), 20 for the total per capita cost measure (81 FR 77170), and 20 for the episode-based measures specified for the 2017 MIPS performance period (81 FR 77175). We proposed to codify these final policies under § 414.1350(c) (83 FR 35904).

In general, higher case minimums increase reliability, but also decrease the number of clinicians who are measured. We aim to measure as many clinicians as possible in the cost performance category. Some clinicians or smaller groups may never see enough patients in a single year to meet the case minimum for a specific episode-based measure. For this reason, we solicited comment on whether we should consider expanding the performance period for the cost performance category measures from a single year to 2 or more years in future rulemaking. We believe this would allow us to more reliably measure a larger number of clinicians. However, we are also concerned that expanding the performance period would increase the time between the measurement of performance and the application of the MIPS payment adjustment. In addition, it would take a longer period of time for us to introduce new cost measures as we would expect to adopt them through rulemaking prior to the beginning of the performance period.

The following is a summary of the public comments received on these proposals and our responses:

Comment: Many commenters expressed concern with the reliability thresholds that we use to inform the determination of case minimums in the cost performance category. Several of these commenters suggested that measures should have case minimums that would reflect 0.8 reliability for all TINs and TIN/NPI combinations. One commenter stated that using a low reliability threshold would result in measuring the acuity of patients as opposed to the performance of a clinician. Another commenter suggested that we consider whether a standard case minimum for all episode group should continue to be set or case minimums should be set accordingly for each individual measure. One commenter also suggested increasing to a 20 episode case minimum for procedural episode-based measures.

Response: Because we aim to balance the need for consistent program standards with ensuring that measures are reliable, we proposed to set a different case minimum for the procedural and acute inpatient medical condition episode-based measures. We aim to measure cost for as many clinicians as possible, and limiting measures to reliability of 0.7 or 0.8 would result in few individual clinicians with attributed cost measures. In addition, a 0.4 reliability threshold ensures moderate reliability for most MIPS eligible clinicians and group practices that are being measured on cost. Under the proposed case minimum of 10 episodes for the procedural episode-based measures, the reliability of the measures already exceeds the 0.4 reliability threshold we have previously established, with most having higher than 0.7 reliability. Using a 20 episode case minimum, while having a slight increase in reliability, will reduce clinician coverage. Therefore, retaining the proposed case minimum of 10 episodes for the procedural measures allows us to maximize the number of clinicians covered by these measures, while still exceeding the 0.4 moderate reliability threshold. We will continue to evaluate reliability as we develop new measures and propose them for inclusion in MIPS in future rulemaking.

Comment: Several commenters supported our alternative proposal for a case minimum of 30 for the Simple Pneumonia with Hospitalization measure. The commenters stated that using a more reliable measure would be preferred over measuring more clinicians.

Response: We agree that our proposed alternative case minimum of 30 episodes for the Simple Pneumonia with Hospitalization measure would have slightly higher reliability, but we also believe that maintaining a consistent case minimum across all acute inpatient medical condition episode-based measures would accurately and reliably assess cost measure performance for a large number of clinicians and clinician groups. We believe it is in the interests of MIPS participants, particularly specialists who treat patients for this condition, to have this new episode-based measure available to them. A consistent case minimum for acute inpatient medical condition episode-based measures would also make it easier for clinicians to understand because it establishes cohesiveness across the different measures as stakeholders are still becoming familiar with these new measures. The mean reliability of the Simple Pneumonia with Hospitalization measure at 20 episodes exceeds the 0.4 reliability threshold (indicating moderate reliability) for TINs and meets that threshold for TIN/NPIs.

Comment: One commenter stated that small practices are less reliably measured by cost measures and that it will be difficult for small practices to analyze cost data in order to improve.

Response: While we have not examined the issue of practice size in relation to the reliability of the cost measures, we have examined the issue of case size in relation to the reliability of cost measures. The results of the analysis of episode-based cost measures can be found in our National Summary Data Report on Eight Wave 1 Episode-Based Cost Measures at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Updated-2017-National-Summary-Data-Report.pdf*. To some degree, the size of a practice correlates with the case size for cost measures, as an individual clinician can only see so many patients. We believe that establishing case minimums that are based on moderate reliability allow us to measure all clinicians and groups that meet those case minimums. We note that the scores on the measures in the cost performance category are only a component of the MIPS final score, which also includes a small practice bonus available within the quality performance category to accommodate the issues that may be faced by small practices.

After consideration of the public comments, we are finalizing our proposed case minimum of 10 episodes for the procedural episode-based measures and 20 episodes for the acute inpatient medical condition episode-based measures beginning with the 2019 MIPS performance period at § 414.1350(c)(4) and (5) as proposed. We are also finalizing our proposal to codify our previously finalized case minimum of 35 for the MSPB measure, 20 for the total per capita cost measure, and 20 for the episode-based measures specified for the 2017 MIPS performance period at § 414.1350(c) as proposed. We will take the comments we received on expanding the performance period for measures in the cost performance category into account for future rulemaking.

(iv) Attribution

(A) Attribution Methodology for Cost Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77168 through 77169; 77174 through 77176), we adopted final policies concerning the attribution methodologies for the total

per capita cost measure, the MSPB measure, and the episode-based measures specified for the 2017 MIPS performance period in addition to an attribution methodology for individual clinicians and groups. We proposed to codify these final policies under § 414.1350(b).

The following is a summary of the public comments received on these proposals and our responses:

Comment: Several commenters expressed concern with the attribution methods finalized in the 2017 Quality Payment Program final rule (81 FR 77168 through 77169), which we proposed to codify. These commenters stated that it was unclear to clinicians which patients would be attributed to them. They recommended a number of methods to improve this process, such as offering feedback on the patients that may be attributed to a clinician at some time during the performance period or allowing clinicians to define attribution with the use of patient relationship codes.

Response: We will continue to look at ways to facilitate the engagement of clinicians in the measures in the cost performance category and will look into offering as much information as is feasible to clinicians.

Comment: Several commenters expressed concern with the attribution methodology for the total per capita cost measure that we finalized in the CY 2017 Quality Payment Program final rule (81 FR 77168 through 77169), which we proposed to codify. In particular, they expressed concerns with the identification of clinicians such as nurse practitioners and physician assistants as primary care clinicians under this methodology, because many of them work in specialist practices.

Response: We believe that attribution methods that include nurse practitioners (NP) and physician assistants (PA) as primary care clinicians best represents the role they play in clinical care. Under the attribution methodology for the total per capita cost measure, a patient who saw a primary care physician more often than an NP or PA in a specialty practice would be attributed to that primary care physician. As we have observed in rulemaking for the Value Modifier (79 FR 67961), including NPs and PAs in the first step of attribution in the total per capita care cost measure did not significantly affect the attribution of patients.

Comment: Several commenters expressed concern with the attribution methods used for the MSPB measure for which we finalized policy in the CY 2017 Quality Payment Program final rule (81 FR 77168 through 77169) and which we proposed to add to regulatory text. Many of the commenters expressed concern that the method of attribution was assigning patients to non-patient facing specialists such as pathologists and radiologists because they may provide expensive services, but do not provide overall care management for the patient. A few commenters requested that non-patient facing clinicians not be attributed this measure.

Response: We believe that the MSPB measure continues to be an important measure of the overall cost of care for a patient and the clinician who provides the plurality of care. We believe that a clinician who provides the plurality of care in a hospital has opportunities to affect the cost of care for that patient. In some cases that may be a non-patient facing clinician, who in order to provide the plurality of care, would have provided a significant amount of service to a hospitalized patient.

After consideration of the public comments, we are finalizing our proposal to codify the previously adopted final policies at § 414.1350(b) as proposed.

(B) Attribution Rules for the Episode-Based Measures

In section III.I.3.h.(3)(b)(ii) of this final rule, we finalized 8 episode-based measures for the cost performance category for the 2019 MIPS performance period and future performance periods, which can be categorized into two types of episode groups: Acute inpatient medical condition episode groups, and procedural episode groups. These measures only include items and services that are related to the episode of care for a clinical condition or procedure (as defined by procedure and diagnosis codes), as opposed to including all services that are provided to a patient over a given period of time. The attribution methodology will be the same for all of the measures within each type of episode groups—acute inpatient medical condition episode groups and procedural episode groups. Our approach to attribution will ensure that the episode-based measures reflect the roles of the individuals and groups in providing care to patients.

For acute inpatient medical condition episode groups specified beginning in the 2019 performance period, we proposed at § 414.1350(b)(6) to attribute episodes to each MIPS eligible clinician who bills inpatient evaluation and management (E&M) claim lines during a trigger inpatient hospitalization under a TIN that renders at least 30 percent of the inpatient E&M claim lines in that hospitalization (83 FR 35905). We stated that a trigger inpatient hospitalization is a hospitalization with a particular MS–DRG identifying the episode group. These MS–DRGs, and any supplementary trigger rules, are identified in the measure specifications posted at *qpp.cms.gov*. The measure score for an individual clinician (TIN/NPI) is based on all of the episodes attributed to the individual. The measure score for a group (TIN) is based on all of the episodes attributed to a TIN/NPI in the given TIN. If a single episode is attributed to multiple TIN/NPIs in a single TIN, the episode is only counted once in the TIN's measure score. We stated that we believe that establishing a 30 percent threshold for the TIN would ensure that the clinician group is collectively measured across all of its clinicians who are likely responsible for the oversight of care for the patient during the trigger hospitalization.

This proposed attribution approach differs from the attribution approach previously established for episode-based measures for acute inpatient medical conditions specified for the 2017 performance period in the CY 2017 Quality Payment Program final rule (81 FR 77174 through 77175). The previous approach attributed episodes to TIN/NPIs who individually exceed the 30 percent E&M threshold, while excluding all episodes where no TIN/NPI exceeds the 30 percent threshold. Throughout the measure development process, stakeholders have discussed the team-based nature of acute care, in which multiple clinicians share management of a patient during a hospital stay. The previous approach outlined in the CY 2017 Quality Payment Program final rule (81 FR 77174 through 77175) does not capture patients' episodes when a group collaborates to manage a patient but no individual clinician exceeds the 30 percent threshold. Based upon stakeholder feedback, our proposed approach emphasizes team-based care and expands the measures' coverage of clinicians, patients, and cost.

We provided an example to illustrate the proposed attribution rules for acute inpatient medical condition episode groups in the proposed rule (83 FR 35905).

For procedural episode groups specified beginning in the 2019 MIPS performance period, we proposed at § 414.1350(b)(7) to attribute episodes to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes (83 FR 35905). These trigger services are identified in the measure specifications posted at *qpp.cms.gov*. We stated that the measure score for an individual

clinician (TIN/NPI) is based on all of the episodes attributed to the individual. The measure score for a group (TIN) is based on all of the episodes attributed to a TIN/NPI in the given TIN. If a single episode is attributed to multiple TIN/NPIs in a single TIN, the episode is only counted once in the TIN's measure score. We stated that we believe this approach best identifies the clinician(s) responsible for the patient's care. This attribution method is similar to that used for procedural episode-based measures in the 2017 MIPS performance period but more clearly defines that the services must be provided during the episode and how we would address instances in which two NPIs in the same TIN provided a trigger service.

The following is a summary of the public comments received on these proposals and our responses:

Comment: One commenter supported our proposed attribution methods for the procedural and acute inpatient medical condition episode-based measures.

Response: We appreciate the support of the commenter.

Comment: A few commenters agreed with the importance of shared accountability in attribution, with one commenter noting that they believed the proposed methodology represented a novel approach to this shared accountability. However, a few commenters opposed our proposed attribution methodology for acute inpatient medical condition episode-based measures. A few commenters recommended that the required percentage be increased. A few commenters expressed concern that a single patient could be attributed to many clinicians in a practice if they participated in MIPS as individuals under this proposed attribution method. This commenter stated that a clinician billing for a single service during a hospitalization could not be expected to have a significant effect on costs. A few commenters stated that this change in attribution methodology had been made following the episode-based measure field testing and could undercut the viability of measures established with clinical input.

Response: We appreciate the support for the emphasis on team-based care and shared accountability in the attribution methodology. We also appreciate the interest in increasing the E&M threshold percentage as part of the attribution methodology for the acute inpatient medical condition episode-based measures. While there is interest in increasing the E&M threshold and concern about the impact of the proposed attribution methodology on clinicians participating in MIPS as individuals, we believe that the methodology as proposed appropriately balances the interest in team-based care and enabling as many clinicians as possible to be attributed to these new acute inpatient medical condition episode-based measures. Specifically, we believe that an E&M threshold requirement of 30 percent reflects stakeholder input throughout the measure development process to reasonably reflect the nature of care in an inpatient setting, and it is in the interests of a large number of clinicians and clinician groups to be able to access these episode-based measures. We disagree that the proposed methodology undercuts the viability of the episode-based measures. Each component of the measures reflects feedback that the measure development contractor has gathered from clinical subcommittees, a technical expert panel, and public comments, including during field testing in 2017. We believe that the changes made to the attribution methodology after field testing reflect the purpose of such testing—which we believe goes beyond the typical testing associated with many performance measures—to reveal issues and to gather stakeholder feedback to inform potential measure refinements. This included feedback on the importance of incorporating considerations of care coordination into the attribution methodology. We believe that a clinician participating as an individual who bills one E&M claim within a TIN that has 30 percent of the total E&Ms for that trigger inpatient stay does not necessarily have limited influence on episode costs due to the nature of inpatient care involving teams. In addition, we seek to incentivize clinicians to engage in greater care coordination throughout a patient's trajectory. The case minimum of 20 for acute inpatient medical condition episode-based measures as finalized above ensures that clinicians are reliably measured in providing care to beneficiaries with those specific conditions. We note that the mean reliability for the measures meets or exceeds the established 0.4 reliability threshold under this attribution methodology for TINs and TIN/NPIs.

Comment: Some commenters expressed concern with our procedural episode groups proposal to attribute episodes to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes. One commenter suggested that a clinician should be required to bill at least two service codes in order to be attributed a procedural episode in order to increase the reliability of the measure. One commenter recommended that a single clinician should not be solely attributed the costs for a patient based on the provision of a trigger service, but that the responsibility should be shared among all clinicians who treated the patient during the episode. One commenter stated that the same patient would be attributed twice if a two-stage procedure were performed.

Response: We believe that in the case of a procedural episode, the clinician who performs the service has a significant influence on the costs of care that are part of the episode that follows the provision of that service. These clinicians perform significant therapeutic and diagnostic services, and the episode-based measures are intended to limit costs to those which the clinician can affect, such as by avoiding complications or better managing the patient during the episode. In many cases, it would not be practical to require more than a single service, such as in cases of surgical services which may encompass much of the period of the episode.

After consideration of the public comments, we are finalizing as proposed our proposal at § 414.1350(b)(6) for acute inpatient medical condition episode groups specified beginning in the 2019 performance period, to attribute episodes to each MIPS eligible clinician who bills inpatient evaluation and management (E&M) claim lines during a trigger inpatient hospitalization under a TIN that renders at least 30 percent of the inpatient E&M claim lines in that hospitalization. Additionally, we also finalizing as proposed our proposal at § 414.1350(b)(7) for procedural episode groups specified beginning in the 2019 MIPS performance period, to attribute episodes to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes.

(4) Improvement Activities Performance Category

(a) Background

In CY 2017 Quality Payment Program final rule (81 FR 77179 through 77180), we codified at § 414.1355 that the improvement activities performance category would account for 15 percent of the final score. We refer readers to section III.I.3.i.(1)(e) of this final rule where we proposed to modify § 414.1355 to provide further technical clarifications. In addition, in the CY 2018 Quality Payment Program final

rule (82 FR 53649), we codified at § 414.1380(b)(3)(iv) that the term recognized be accepted as equivalent to the term certified when referring to the requirements for a patient-centered medical home to receive full credit for the improvement activities performance category for MIPS. We also finalized at § 414.1380(b)(3)(x) that for the 2020 MIPS payment year and future years, to receive full credit as a certified or recognized patient-centered medical home or comparable specialty practice, at least 50 percent of the practice sites within the TIN must be recognized as a patient-centered medical home or comparable specialty practice (82 FR 53655). We refer readers to section III.I.3.i.(1)(e)(i)(D) of this final rule for details on our proposals regarding patient-centered medical homes.

In the CY 2017 Quality Payment Program final rule (81 FR 77539), we codified the definition of improvement activities at § 414.1305 to mean an activity that relevant MIPS eligible clinicians, organizations, and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes. Further, in that final rule (81 FR 77190), we codified at § 414.1365 that the improvement activities performance category would include the subcategories of activities provided at section 1848(q)(2)(B)(iii) of the Act. We also codified subcategories for improvement activities at § 414.1365 (81 FR 77190).

We also previously codified in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77180 and 82 FR 53651, respectively) data submission criteria for the improvement activities performance category at § 414.1360(a)(1). In addition, we established exceptions for: Small practices; practices located in rural areas; practices located in geographic HPSAs; non-patient facing individual MIPS eligible clinicians or groups; and individual MIPS eligible clinicians and groups that participate in a MIPS APM or a patient-centered medical home submitting in MIPS (81 FR 77185, 77188). Specifically, we codified at § 414.1380(b)(3)(vii) that non-patient facing MIPS eligible clinicians and groups, small practices, and practices located in rural areas and geographic HPSAs receive full credit for the improvement activities performance category by selecting one high-weighted improvement activity or two medium-weighted improvement activities; such practices receive half credit for the improvement activities performance category by selecting one medium-weighted improvement activity (81 FR 77185). We refer readers to section III.I.3.i.(1)(e)(i)(B) of this final rule for our proposals related to that provision. In addition, we specified at § 414.1305 that rural areas refers to ZIP codes designated as rural, using the most recent HRSA Area Health Resource File data set available (81 FR 77188, 82 FR 53582). Lastly, we finalized the meaning of Health Professional Shortage Areas (HPSA) at § 414.1305 to mean areas as designated under section 332(a)(1)(A) of the Public Health Service Act (81 FR 77188). In the CY 2018 Quality Payment Program final rule (82 FR 53581), we modified the definition of small practices at § 414.1305 to mean practices consisting of 15 or fewer eligible clinicians.

In the CY 2019 PFS proposed rule (83 FR 35906 through 35912), we requested comments on our proposals to: (1) Revise § 414.1360(a)(1) to more accurately describe the data submission criteria; (2) delete § 414.1365 and move improvement activities subcategories to § 414.1355(c); (3) update the criteria considered for nominating new improvement activities; (4) modify the Annual Call for Activities timeline for the CY 2019 performance period and future years; (5) add 6 new improvement activities for the CY 2019 performance period and future years; (6) modify 5 existing improvement activities for the CY 2019 performance period and future years; and (7) remove 1 existing improvement activity for the CY 2019 performance period and future years. In addition, we also requested comments on our proposals with respect to the CMS Study on Factors Associated with Reporting Quality Measures for the CY 2019 performance period and future years the following proposals: (1) Change the title of the study to CMS Study on Factors Associated with Reporting Quality Measures; (2) increase the sample size to a minimum of 200 participants; (3) limit the focus group requirement to a subset of the 200 participants; and (4) require that at least one of the minimum of three required measures be a high priority measure. We are also making clarifications to: (1) Considerations for selecting improvement activities for the CY 2019 performance period and future years; and (2) the weighting of improvement activities.

These topics are discussed in more detail below.

(b) Submission Criteria

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77181) for submission mechanism policies we finalized and codified for the transition year of MIPS. In the CY 2018 Quality Payment Program final rule (82 FR 53651), we continued these policies for future years. Specifically, we finalized that for MIPS Year 2 and future years, MIPS eligible clinicians or groups must submit data on MIPS improvement activities in one of the following manners: Qualified registries; EHR submission mechanisms; QCDR; CMS Web Interface; or attestation. Additionally, we finalized that for activities that are performed for at least a continuous 90-days during the performance period, MIPS eligible clinicians must submit a yes response for activities within the improvement activities inventory. In addition, in the case where an individual MIPS eligible clinician or group is using a health IT vendor, QCDR, or qualified registry for their data submission, we finalized that the MIPS eligible clinician or group must certify all improvement activities were performed and the health IT vendor, QCDR, or qualified registry would submit on their behalf (82 FR 53650 through 53651). We also updated § 414.1360 to reflect those changes (82 FR 53651). We refer readers to section III.I.3.h.(1) of this final rule, MIPS Performance Category Measures and Activities, where we discuss our finalized policies to update the data submission process for MIPS eligible clinicians, groups and third party intermediaries, by updating our terminology. We also refer readers to changes to § 414.1325 for data submission requirements. In the CY 2019 PFS proposed rule (83 FR 35906), we proposed those changes to more closely align with the actual submission experience users have.

In alignment with those proposals, we also proposed to revise § 414.1360(a)(1) to more accurately reflect the data submission process for the improvement activities performance category. In particular, in the CY 2019 PFS proposed rule (83 FR 35906), we proposed that instead of ''via qualified registries; EHR submission mechanisms; QCDR, CMS Web Interface; or attestation,'' as currently stated, we revised the first sentence to state that data would be submitted ''via direct, login and upload, and login and attest'' as discussed in section III.I.3.h.(1)(b) of this final rule. In addition, we proposed to add further additions to § 414.1360(a)(1) to specify, submit a yes response for each improvement activity that is performed for at least a continuous 90-day period during the applicable performance period.

We did not receive any comments on these proposals. Therefore, we are

finalizing our proposals, as proposed, to revise the first sentence of § 414.1360(a)(1) to state that data must be submitted via direct, login and upload, and login and attest. In addition, we are finalizing our proposal, as proposed, to update § 414.1360(a)(1) to specify: Submit a yes response for each improvement activity that is performed for at least a continuous 90-day period during the applicable performance period.

(c) Subcategories

In the CY 2017 Quality Payment Program final rule (81 FR 77190), we finalized at § 414.1365 that the improvement activities performance category includes the subcategories of activities provided at section 1848(q)(2)(B)(iii) of the Act. It has since come to our attention that it is unnecessary to have a separate regulation text included under § 414.1365 since the subcategories are not a component of the scoring calculations. Therefore, in the CY 2019 PFS proposed rule (83 FR 35906 through 35907), we proposed to delete § 414.1365 and move the same improvement activities subcategories to § 414.1355(c). We reiterate that we did not propose any changes to the subcategories themselves. These subcategories are:

- Expanded practice access, such as same day appointments for urgent needs and after-hours access to clinician advice.
- Population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a QCDR.
- Care coordination, such as timely communication of test results, timely exchange of clinical information to patients or other clinicians, and use of remote monitoring or telehealth.
- Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision making mechanisms.
- Patient safety and practice assessment, such as through the use of clinical or surgical checklists and practice assessments related to maintaining certification.
- Participation in an APM.
- Achieving health equity, such as for MIPS eligible clinicians that achieve high quality for underserved populations, including persons with behavioral health conditions, racial and ethnic minorities, sexual and gender minorities, people with disabilities, people living in rural areas, and people in geographic HPSAs.
- Emergency preparedness and response, such as measuring MIPS eligible clinician participation in the Medical Reserve Corps, measuring registration in the Emergency System for Advance Registration of Volunteer Health Professionals, measuring relevant reserve and active duty uniformed services MIPS eligible clinician activities, and measuring MIPS eligible clinician volunteer participation in domestic or international humanitarian medical relief work.
- Integrated behavioral and mental health, such as measuring or evaluating such practices as: Co-location of behavioral health and primary care services; shared/integrated behavioral health and primary care records; cross training of MIPS eligible clinicians, and integrating behavioral health with primary care to address substance use disorders or other behavioral health conditions, as well as integrating mental health with primary care.

The following is a summary of the public comments received on our proposals and our responses:

Comment: One commenter supported the definition of achieving health equity and underserved populations. The commenter recommended that we explicitly include people with limited English in those groups.

Response: We will take this suggestion into consideration for the future.

After consideration of the public comments received, we are finalizing our proposal, as proposed, to delete § 414.1365 and move the same improvement activities subcategories to § 414.1355(c).

(d) Improvement Activities Inventory

In the CY 2019 PFS proposed rule (83 FR 35907 through 35910), we proposed to: (1) Adopt one new criterion and remove one existing criterion for nominating new improvement activities beginning with the CY 2019 performance period and future years; (2) modify the timeframe for the Annual Call for Activities; (3) add 6 new improvement activities for the CY 2019 performance period and future years; (4) modify 5 existing improvement activities for the CY 2019 performance period and future years; and (5) remove 1 existing improvement activity for the CY 2019 performance period and future years. We are also making clarifications to: (1) Considerations for selecting improvement activities for the CY 2019 performance period and future years; and (2) the weighting of improvement activities.

(i) Annual Call for Activities

In the CY 2017 Quality Payment Program final rule (81 FR 77190), for the transition year of MIPS, we implemented the initial Improvement Activities Inventory and took several steps to ensure it was inclusive of activities in line with statutory and program requirements. For Year 2, we provided an informal process for submitting new improvement activities or modifications for potential inclusion in the comprehensive Improvement Activities Inventory for the Quality Payment Program Year 2 and future years through subregulatory guidance (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Annual-Call-for-Measures-and-Activities-for-MIPS_Overview-Factsheet.pdf*). In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), for Year 3 and future years, we finalized a formal Annual Call for Activities process for adding possible new activities or providing modifications to the current activities in the Improvement Activities Inventory, including information required to submit a nomination form similar to the one we utilized for Year 2 (82 FR 53656 through 53659). It is important to note that in order to submit a request for a new activity or a modification to an existing improvement activity the stakeholder must submit a nomination form available at *www.qpp.cms.gov* during the Annual Call for Activities.

(A) Criteria for Nominating New Improvement Activities

In the CY 2019 PFS proposed rule (83 FR 35907 through 35908), we proposed to add one new criterion and remove a previously adopted criterion from the improvement activities nomination criteria. We also clarified our considerations in selecting improvement activities.

(aa) Currently Adopted Criteria

In the CY 2017 Quality Payment Program final rule (81 FR 77190 through 77195), we discussed guidelines for the selection of improvement activities. In the CY 2018 Quality Payment Program final rule, we formalized the Annual Call for Activities process for Year 3 and future years and added additional criteria; stakeholders would apply one or more of the below criteria when submitting nominations for improvement activities (82 FR 53660):

- Relevance to an existing improvement activities subcategory (or a proposed new subcategory);

- Importance of an activity toward achieving improved beneficiary health outcome;
- Importance of an activity that could lead to improvement in practice to reduce health care disparities;
- Aligned with patient-centered medical homes;
- Focus on meaningful actions from the person and family's point of view;
- Support the patient's family or personal caregiver;
- Activities that may be considered for an advancing care information bonus;
- Representative of activities that multiple individual MIPS eligible clinicians or groups could perform (for example, primary care, specialty care);
- Feasible to implement, recognizing importance in minimizing burden, especially for small practices, practices in rural areas, or in areas designated as geographic HPSAs by HRSA;
- Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes; or
- CMS is able to validate the activity.

(bb) New Criteria

We believe it is important to place attention on public health emergencies, such as the opioid epidemic, when considering improvement activities for inclusion in the Inventory, because their inclusion raises awareness for clinicians about the urgency of the situation and to promote clinician adoption of best practices to combat those public health emergencies. A list of the public health emergency declarations is available at *https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx*. Therefore, in the CY 2019 PFS proposed rule (83 FR 35907 through 35908), we proposed to adopt an additional criterion entitled ''Include a public health emergency as determined by the Secretary'' to the criteria for nominating new improvement activities beginning with the CY 2019 performance period and future years. We invited public comment on our proposal.

The following is a summary of the public comments received on our proposals and our responses:

Comment: Many commenters supported the additional criterion for nominating improvement activities to include public health emergencies, noting that such activities are important for patient care and will help raise clinician awareness and promote best practices related to the medically appropriate, evidence-based, and safe use of opioids in treating chronic and acute pain and the use of non-opioid pain management treatment alternatives. One commenter stated this criteria could help ensure patients receive the most appropriate pain and substance use disorder treatments. Another commenter stated this criteria could support efforts to mobilize health care resources to assist those in need and aid providers in relief efforts.

Response: We appreciate the commenters' support.

Comment: One commenter requested clarification regarding whether a public health emergency is required to be listed for an improvement activity to be considered and whether the improvement activities will be removed once the public health emergency has been resolved.

Response: A list of federal public health emergency declarations is available at *https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx*. Modifications to existing improvement activities in the Improvement Activities Inventory, including whether an improvement activity should be removed due to a change in a public health emergency status, will be considered through the formal Annual Call for Activities on a case-by-case basis.

Comment: A few commenters did not support the proposed addition of the public health emergency criteria. One commenter stated there is a need for adequate notice and tracking mechanisms and recommended that improvement activities should progress through the formal review process. Another commenter recommended a process outside the Annual Call for Activities that enables clinicians to propose an activity for immediate implementation during a public health emergency declaration and that such activities remain optional and be granted full credit even if the duration does not span at least 90 continuous days.

Response: We agree that there is a need for adequate notice in order to allow clinicians time to prepare. To be clear, Improvement Activities will continue to be proposed and adopted via rulemaking; we are merely adding a new criteria such that public health emergencies are considered when stakeholders nominate improvement activities and while we select improvement activities for proposal and adoption into the Inventory. We do not agree that we should create a separate process outside of the Annual Call for Activities or that such activities should remain optional and be granted full credit even if the duration does not span at least 90 continuous days. In the CY 2017 Quality Payment Program final rule (81 FR 77186), we specified at § 414.1360 that MIPS eligible clinicians or groups must perform improvement activities for at least 90 consecutive days during the performance period for improvement activities performance category credit.

Comment: One commenter suggested that there should be a bonus associated with the submission of an improvement activity regarding a public health emergency.

Response: We disagree as we do not believe the submission of an improvement activity should get bonus points. We are not able to provide bonus points for improvement activities at this time.

After consideration of the public comments received, we are finalizing our proposal, as proposed to adopt an additional criterion entitled ''Include a public health emergency as determined by the Secretary'' to the criteria for nominating new improvement activities beginning with the CY 2019 performance period and future years.

(cc) Removal of One Criteria

In the CY 2017 Quality Payment Program final rule (81 FR 77202 through 77209), we adopted a policy to award a bonus to the Promoting Interoperability performance category score for MIPS eligible clinicians who use CEHRT to complete certain activities in the improvement activities performance category. We included a designation column in the Improvement Activities Inventory at Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77817) that indicated which activities qualified for the Promoting Interoperability (formerly Advancing Care Information) bonus codified at § 414.1380(b)(4)(i)(D).

In the CY 2019 PFS proposed rule (83 FR 35982), under the Promoting Interoperability performance category, we proposed a new approach for scoring that moves away from the base, performance, and bonus score methodology currently established. This new approach removes the availability of a bonus score for attesting to completing one or more specified improvement activities using CEHRT beginning with the CY 2019 performance period and future years. As a result, we do not believe the criterion for selecting improvement activities for inclusion in the program entitled ''Activities that may be considered for an advancing care information bonus'' remains relevant. Therefore, we proposed to remove the criterion for selecting improvement activities for inclusion in the program entitled ''Activities that may be considered for an advancing care information bonus''

beginning with the CY 2019 performance period and future years (83 FR 35908).

If our proposals to add one criterion and remove one criterion are adopted as proposed, the new list of criteria for nominating new improvement activities for the CY 2019 performance period and future years would be as follows:

- Relevance to an existing improvement activities subcategory (or a proposed new subcategory);
- Importance of an activity toward achieving improved beneficiary health outcome;
- Importance of an activity that could lead to improvement in practice to reduce health care disparities;
- Aligned with patient-centered medical homes;
- Focus on meaningful actions from the person and family's point of view;
- Support the patient's family or personal caregiver;
- Representative of activities that multiple individual MIPS eligible clinicians or groups could perform (for example, primary care, specialty care);
- Feasible to implement, recognizing importance in minimizing burden, especially for small practices, practices in rural areas, or in areas designated as geographic HPSAs by HRSA;
- Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes;
- Include a public health emergency as determined by the Secretary; or
- CMS is able to validate the activity.

We did not receive any comments on our proposal. Therefore, we are finalizing our proposal, as proposed, to remove the criterion entitled ''Activities that may be considered for an advancing care information bonus'' beginning with the CY 2019 performance period and future years. We note that this policy is being finalized in alignment with those in section III.I.3.h.(5)(d)(ii) of this final rule.

(B) Considerations in Selecting Improvement Activities

As noted in the CY 2017 Quality Payment Program final rule, we intend to use the criteria for nominating new improvement activities in selecting improvement activities for inclusion in the program (82 FR 53659). However, we clarify here that those criteria are but one factor in determining which improvement activities we ultimately propose. For example, we also generally take into consideration other factors, such as whether the nominated improvement activity uses publically available products or techniques (that is, does not contain proprietary products or information limiting an activity) or whether the nominated improvement activity duplicates any currently adopted activity (83 FR 35908).

(C) Weighting of Improvement Activities

Given stakeholder feedback requesting additional transparency regarding the weighting of improvement activities (82 FR 53657), in the CY 2019 PFS proposed rule (83 FR 35908 through 35909), we summarized considerations we have previously used to assign weights to improvement activities included in the Improvement Activities Inventory (see Appendix 2: Improvement Activities, Tables A and B). We also made a few clarifications and solicited comment for future weighting considerations. These topics are discussed in more detail below.

(aa) Summary of Past Considerations

In the CY 2017 Quality Payment Program final rule (81 FR 77191), we explained that to define the criteria and establish weighting for each activity, we engaged multiple stakeholder groups, including the Centers for Disease Control and Prevention, Health Resources and Services Administration, Office of the National Coordinator for Health Information Technology, SAMHSA, Agency for Healthcare Research and Quality, Food and Drug Administration, the Department of Veterans Affairs, and several clinical specialty groups, small and rural practices and non-patient facing clinicians. Activities were proposed to be weighted as high based on the extent to which they align with activities that support the patient-centered medical home, since that is the standard under section 1848(q)(5)(C)(i) of the Act for achieving the highest potential score for the improvement activities performance category, as well as with our priorities for transforming clinical practice (81 FR 77191). Activities that require performance of multiple actions, such as participation in the Transforming Clinical Practice Initiative (TCPI), participation in a MIPS eligible clinician's state Medicaid program, or an activity identified as a public health priority (such as emphasis on anticoagulation management or utilization of prescription drug monitoring programs) were also proposed to be weighted as high (81 FR 77191). We also stated that we believe that high-weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being (81 FR 77194). In the past, we have given certain improvement activities high-weighting due to the intensity of the activity; for example, one improvement activity was changed to high-weighting because it often involves travel and work under challenging physical and clinical circumstances (81 FR 77194). Also, we note that successful participation in the CMS Study on Factors Associated with Reporting Quality Measures as discussed in section III.I.3.h.(4)(e) of this final rule would result in full credit for the improvement activities performance category of 40 points; if participants do not meet the study guidelines, they will need to follow the current improvement activities guidelines (81 FR 77197).

(bb) Clarifications

In this final rule, we are clarifying: (a) Our consideration of giving high-weighting due to activity intensity; and (b) differences between high- and medium-weighting.

(AA) High-Weighting Due to Activity Intensity

As stated previously, we have given certain improvement activities high-weighting due to the intensity of the activity (81 FR 77194). To elaborate, we believe that an activity that requires significant investment of time and resources should be high-weighted. For example, we finalized the CAHPS for MIPS survey as high-weighted (81 FR 77827), because it requires a significant investment of time and resources. As part of the requirements of this activity, MIPS eligible clinicians: (1) Must register for the CAHPS for MIPS survey; (2) must select and authorize a CMS-approved survey vendor to collect and report survey data using the survey and specifications provided by us; and (3) are responsible for vendor's costs to collect and report the survey (ranges from approximately $4,000 to $7,000 depending on services requested).

In contrast, we believe medium-weighted improvement activities are simpler to complete and require less time and resources as compared to high-weighted improvement activities. For example, we finalized the Cost Display for Laboratory and Radiographic Orders improvement activity as medium-weighted (82 FR 54188), because the information required to be used is readily available (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html*) at no cost through the Medicare clinical laboratory fee schedule and can be distributed in a variety of manners with very little investment (for example, it may be displayed in the clinic, provided to patients through hardcopies, or incorporated in the electronic health record).

(BB) High- Versus Medium-Weighting

We recognize that we did not previously explicitly state separate considerations for medium-weighted activities. This is because an improvement activity is only either high or medium-weighted. In this final rule, we are clarifying that an improvement activity is by default medium-weight unless it meets considerations for high-weighting as discussed previously (83 FR 35909).

(cc) Request for Comments

We intend to more thoroughly revisit our improvement activity weighting policies in next year's rulemaking. We invited public comment on the need for additional transparency and guidance on the weighting of improvement activities as we work to refine the Annual Call for Activities process for future years. Furthermore, in light of the finalized policy to remove bonus points for improvement activities that may be applicable to the Promoting Interoperability performance category as discussed in sections III.I.3.h.(4)(d)(i)(A)(cc) and III.I.3.h.(5)(d)(ii), we recognize the need to continue incentives for CEHRT. Therefore, for future consideration, we solicited comment on potentially applying high-weighting for any improvement activity employing CEHRT. We also invited public comment on any other additional considerations for high- or medium-weighting.

Comment: One commenter supported more transparency regarding the differences between high-weight and medium-weight activities and encouraged continued education related to the improvement activities performance category as new activities are added. Another commenter recommended that improvement activities related to Continuing Medical Education (CME) be weighted in a bifurcated manner with more substantial CME's potentially counting as high-weighted.

Response: We will take these comments into consideration as we develop future policy.

(D) Timeframe for the Annual Call for Activities

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would accept submissions for prospective improvement activities and modifications to existing improvement activities at any time during the performance period to be added to the Improvement Activities Under Review (IAUR) list, for the applicable performance period, which would be displayed on a CMS website following the close of the Annual Call for Activities. In addition, we finalized that for the Annual Call for Activities, only nominations and modifications submitted by March 1st would be considered for inclusion in the IAUR list and Improvement Activities Inventory for the performance period occurring in the following calendar year (82 FR 53660). For example, for the CY 2018 Annual Call for Activities, we received nominations for new and modified improvement activities from February 1st through March 1st. Currently, an improvement activity nomination submitted during the CY 2018 Annual Call for Activities would be vetted in CY 2018, and after review, if accepted by CMS, would be proposed during the CY 2018 rulemaking cycle for possible implementation in the CY 2019 performance period and future years.

However, the previously established timeline, which includes prospective new and modified improvement activities submission period, review, and publication of proposed improvement activities for implementation in the next performance period, has become operationally challenging. Based on our experience over the past 2 years, we have found that processing and reviewing the volume of improvement activities nominations requires more time than originally thought. In addition, preparations and drafting for annual rulemaking begin around the time of the close date for the current Annual Call for Activities (that is, March 1st), leaving incorporation into the proposed rule challenging. Therefore, in the CY 2019 PFS proposed rule, beginning with the CY 2019 performance period, we proposed to: (1) Delay the year for which nominations of prospective new and modified improvement activities would apply; and (2) expand the submission timeframe/due date for nominations (83 FR 35909).

Beginning with the CY 2019 performance period, we proposed to change the performance year for which the nominations of prospective new and modified improvement activities would apply, such that improvement activities nominations received in a particular year will be vetted and considered for the next year's rulemaking cycle for possible implementation in a future year. This timeframe parallels the Promoting Interoperability performance category Annual Call for EHR Measures timeframe available at *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/CallForMeasures.html*. For example, an improvement activity nomination submitted during the CY 2020 Annual Call for Activities would be vetted, and if accepted by CMS, would be proposed during the CY 2021 rulemaking cycle for possible implementation starting in CY 2022. We believe this change would give us adequate time to thoroughly vet improvement activity nominations prior to rulemaking (83 FR 35909).

Second, beginning with the CY 2019 performance period, we proposed to change the submission timeframe for the Annual Call for Activities from February 1st through March 1st to February 1st through June 30th, providing approximately 4 additional months for stakeholders to submit nominations. We believe this change would assist stakeholders by providing additional time to submit improvement activities nominations. Consistent with previous policy, nominations for prospective new and modified improvement activities would be accepted during the Annual Call for Activities time period only and would be included in the IAUR displayed on a CMS website following the close of the Annual Call for Activities (83 FR 35909).

The following is a summary of the public comments received on our proposals and our responses:

Comment: Several commenters supported the proposed change to the Annual Call for Activities timeframe citing that the modified timeline provides a longer window during which to propose new improvement activities, allows for more advance notice to implement new activities that have been finalized, aligns the Annual Call for Activities with the Annual Call for Measures, and reduces overall program complexity. One commenter noted the new timeframe would ensure that the inventory includes an appropriate number of measures that are meaningful to each specialty, including non-physician Medicare clinicians, and that are appropriate for the patient-centered health care team and have a positive impact on patient care.

Response: We appreciate the commenters' support.

Comment: Several commenters did not support the proposed extension of the timeframe for the Annual Call for Activities and recommended that we maintain the current schedule because this would ensure the improvement activities inventory include activities that are timely, important, relevant, and meaningful to the evolving practice of medicine and to public health. One commenter noted extending the timeframe from submission to

implementation is a barrier to previously stated goals in aligning improvement activities with the quality improvement cycle. Another commenter noted the benefit of being able to modify or add measures each year outweighs the need for additional submission time and that improvement activities do not require the same reliability and validity testing necessary for successful quality measures and that improvement activities be considered annually informed by the quality improvement cycle. One commenter stated the proposal would impede the ability of groups to create activities that raise awareness of novel or pressing issues and promote best practices in a timely manner. Another commenter urged us to take a modified approach to its proposal in which the timeframe to modify existing measures would be shorter than that for new measures. One commenter stated that delaying consideration of improvement activities until the following year's rule making does not appropriately reward early adopters of activities and suggested that early adopters of an improvement activity could be given credit.

Response: Although improvement activities do not have the same testing requirements as quality measures, we believe that improvement activities are equally important in facilitating clinical practice improvement. As such, sufficient time is needed to thoroughly review all submissions to ensure we maintain an inventory that is both meaningful and robust. In addition, we cannot increase the submission period without increasing our review period. It would not be operationally feasible to do otherwise. We also do not believe that there is a benefit to providing for a review period that does not allow for an adequate time to thoroughly vet improvement activity nominations prior to rulemaking. However, we will continue to monitor the timeline to assess if there are any future improvements that can be made to more quickly incorporate new improvement activities into the program when feasibly possible. We disagree that the timeframe would impede the promotion of best practices or awareness of improvement-related activities or issues because stakeholders are not precluded from referencing that a particular activity has been submitted for consideration as part of the Annual Call for Activities to raise awareness and promote best practices. We recognize that the proposed extended timeframe does not align with the submission, review, and implementation of quality measures as part of the Annual Call for Measures; however, we note our proposal parallels our timeframe with the Promoting Interoperability performance category Annual Call for EHR Measures timeframe (we refer readers to section III.I.3.h.(5)(f) of this final rule for more information) and achieves alignment between those performance categories.

After consideration of the public comments received on our proposal, we are finalizing our proposal, as proposed, to change the performance year for which the nominations of prospective new and modified improvement activities would apply, such that beginning with the CY 2019 performance period, improvement activities nominations received in a particular year will be vetted and considered for the next year's rulemaking cycle for possible implementation in a future year. In addition, we are finalizing our proposal, as proposed, to change the submission timeframe for the Annual Call for Activities from February 1st through March 1st to February 1st through June 30th, providing approximately 4 additional months for stakeholders to submit nominations beginning with the CY 2019 performance period.

(ii) New Improvement Activities and Modifications to and Removal of Existing Improvement Activities

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would add new improvement activities to the Improvement Activities Inventory through notice-and-comment rulemaking. We referred readers to Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199) and Table F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229) for our previously finalized Improvement Activities Inventory. In the CY 2019 PFS proposed rule (83 FR 36359 through 36368), for CY 2019 performance period and future years, we proposed 6 new improvement activities; we also proposed to: (1) Modify 5 existing activities; and (2) remove 1 existing activity. We also proposed changes to our CMS Study on Factors Associated with Reporting Quality Measures in section III.I.3.h.(4)(e) of this final rule.

Comment: A few commenters supported the overall approach for the improvement activities performance category because of its goal-oriented and technology-neutral approach to compliance, stating that this provides the flexibility needed for clinicians to select the most effective approaches for their patients that could include connected health technology innovations. One commenter supported the stability in the improvement activities performance category and the transparent process for adding improvement activities to the inventory.

Response: We appreciate the commenters' support.

A summary of the public comments received on specific improvement activities proposals and our responses may be found in Tables A and B of Appendix 2: Improvement Activities in this final rule.

(e) CMS Study on Factors Associated With Reporting Quality Measures

(i) Background

In the CY 2017 Quality Payment Program final rule (81 FR 77195), we created the Study on Improvement Activities and Measurement. In CMS' quest to create a culture of improvement using evidence based medicine on a consistent basis, fully understanding the strengths and limitations of the current processes is crucial to better understand and improve these current processes. We proposed to conduct a study on clinical improvement activities and measurement to examine clinical quality workflows and data capture using a simpler approach to quality measures (81 FR 77196). The lessons learned in this study on practice improvement and measurement may influence changes to future MIPS data submission requirements. The goals of the study are to see whether there will be improved outcomes, reduced burden in reporting, and enhancements in clinical care by selected MIPS eligible clinicians (81 FR 77196). This study shall inform us on the root causes of clinicians' performance measure data collection and submission burdens, as well as challenges that hinder accurate and timely quality measurement activities. Our goals are to use high quality, low cost measures that are meaningful, easy to understand, operable, reliable, and valid. As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77195) the CMS Study on Burden Associated with Quality Reporting goals are to see whether there will be improved outcomes, reduced burden in reporting, and enhancements in clinical care by selected MIPS eligible clinicians desiring:

- A more data driven approach to quality measurement.
- Measure selection unconstrained by a CEHRT program or system.
- Improving data quality submitted to CMS.

• Enabling CMS to get data more frequently and provide feedback more often.

This study evolved into ''CMS Study on Burdens Associated with Reporting Quality Measures'' in the CY 2018 Quality Payment Program final rule (82 FR 53662).

This study is ongoing, participants are recruited on a yearly basis for a minimum period of 3 years, and current participants can opt-in or out when the study year ends (81 FR 77195). Successful participation in the study would result in full credit for the improvement activities performance category of 40 points; if participants do not meet the study guidelines, they will need to follow the current improvement activities requirements (81 FR 77197). To meet the study requirements, study participants must partake in two web-based survey questionnaires, submit data for at least three MIPS clinician quality measures to CMS during the CY 2019 performance period, and be available for selection and participation in at least one focus group meeting (82 FR 53662).

Although we did not propose any changes to the study purpose, aim, eligibility, or credit, in the CY 2019 PFS proposed rule (83 FR 35910 through 35911), we proposed, for the CY 2019 performance period and future years, changes to the: (1) Title of the study; (2) sample size to allow enough statistical power for rigorous analysis within some categories, (3) focus group and survey requirements; and (4) measure requirements. These proposals are discussed in more detail below.

(ii) Title

In the CY 2019 PFS proposed rule (83 FR 35910), beginning with the CY 2019 performance period, we proposed to change the title of the study from ''CMS Study on Burdens Associated with Reporting Quality Measures'' to ''CMS Study on Factors Associated with Reporting Quality Measures'' to more accurately reflect the study's intent and purpose. To assess the root causes of clinician burden associated with the collection and submission of clinician quality measures for MIPS, as depicted in CY 2017 Quality Payment Program final rule (81 FR 77195), replacing ''Burden'' with ''Factors'' in the title will eliminate possible response or recall bias that may occur with data collection. Having ''burden'' in the study title may elicit the tendency of survey participants reporting more on their perception of burden and challenges, and/or suppressing other factors that are associated with their quality measure data collection and submission, that may be relevant to examining the root cause of burden.

The following is a summary of the public comments related to our proposal and our response:

Comment: One commenter supported the title change stating that the terminology changes will attract a more diverse group of study participants and encourage clinician participants in the study who will work to simplify measures and ensure that that measures bring maximum value to CMS, clinicians, and beneficiaries.

Response: We appreciate the commenters' support.

After consideration of the comments, we are finalizing our proposal, as proposed, to change the title of the study from ''CMS Study on Burdens Associated with Reporting Quality Measures'' to ''CMS Study on Factors Associated with Reporting Quality Measures'' beginning with the CY 2019 performance period.

(iii) Sample Size

(A) Current Policy

In the CY 2017 Quality Payment Program final rule (81 FR 77196), we initially finalized a sample size of 42 participants (comprising of groups and individual MIPS eligible facilities). In the CY 2018 Quality Payment Program final rule (82 FR 53661), we increased that number and finalized a sample size of a minimum of 102 individual and group participants for performance periods occurring in CY 2018 for the following categories:

• 20 urban individuals or groups of <3 eligible clinicians—(broken down into 10 individuals & 10 groups).

• 20 rural individuals or groups of <3 eligible clinicians—(broken down into 10 individuals & 10 groups).

• 10 groups of 3–8 eligible clinicians.

• 10 groups of 8–20 eligible clinicians.

• 10 groups of 20–100 eligible clinicians.

• 10 groups of 100 or greater eligible clinicians.

• 6 groups of >20 eligible clinicians reporting as individuals—(broken down into 3 urban & 3 rural).

• 6 specialty groups—(broken down into 3 reporting individually & 3 reporting as a group).

• Up to 10 non-MIPS eligible clinicians reporting as a group or individual (any number of individuals and any group size).

(B) New Sample Size

In the CY 2019 PFS proposed rule (83 FR 35910 through 35911), we proposed to again increase the sample size for the CY 2019 performance period and future years from a minimum of 102 to a minimum of 200 MIPS eligible clinicians, which will enable us to more rigorously analyze the statistical difference between the burden and factors associated within the categories listed above. This proposed increase in sample size would provide the minimum sample needed to get a significant result with adequate statistical power to determine whether there are any statistically significant differences in quality measurement data submission associated with: (1) The size of practice or facility; (2) clinician specialty of practice; (3) region of practice; (4) individual or group reporting; and (5) clinician quality measure type. This rigorous statistical analysis is important, because it facilitates tracing the root causes of measurement burdens and data submission errors that may be associated with various sub-groups of clinician practices using quantitative analytical methods. We believe that a larger sample size would also account for any attrition (drop out of study participants before the study ends). Therefore, we proposed that the new sample size distribution would be:

• 40 urban individuals or groups of <3 eligible clinicians—(broken down into 20 individuals & 20 groups).

• 40 rural individuals or groups of <3 eligible clinicians—(broken down into 20 individuals & 20 groups).

• 20 groups of 3–8 eligible clinicians.

• 20 groups of 8–20 eligible clinicians.

• 20 groups of 20–100 eligible clinicians.

• 20 groups of 100 or greater eligible clinicians.

• Up to 6 groups of >20 eligible clinicians reporting as individuals—(broken down into 3 urban & 3 rural).

• Up to 6 specialty groups—(broken down into 3 reporting individually & 3 reporting as a group).

• Up to 10 non-MIPS eligible clinicians reporting as a group or individual (any number of individuals and any group size).

The following is a summary of the public comments related to our proposals and our responses:

Comment: One commenter supported the continuation of the study to gather data on clinical improvement activities and measurement to examine clinical quality workflows and data and the proposal to increase the sample size of the study, stating that this would be a simpler approach and allow more clinicians to participate and increase the ability to conduct rigorous statistical analysis with sufficient power.

Response: We appreciate the commenter's support.

Comment: One commenter recommended that clinicians located in both urban and rural health practitioner shortage areas and clinicians who serve a high proportion of low-income patients and patients of color be included as study participants.

Response: We have been recruiting participants from health practitioner shortage areas, as well as areas with high proportion of patients of color and minority groups.

Comment: One commenter requested that CMS assure the quality reporting burden study includes a sample of clinicians with multiple special status categories, such as Certified Registered Nurse Anesthetists, citing there is likely a sufficient number of clinicians that meet the CMS special status requirements in the six specialty groups. The commenter also requested CMS ascertain the burden placed on special status clinicians in outpatient and ASC facilities.

Response: We appreciate the commenter's recommendation. The study welcomes all MIPS eligible clinicians, including Certified Registered Nurse Anesthetists, and non-MIPS clinicians to apply. We hope to further expand the scope of the study in the future.

After consideration of the comments received, we are finalizing our proposal, as proposed, to increase the sample size for the CY 2019 performance period and future years from a minimum of 102 to a minimum of 200 MIPS eligible clinicians.

(iv) Focus Group

(A) Current Policies

We previously finalized in the CY 2017 Quality Payment Program final rule (81 FR 77195) that for the transition year of MIPS, study participants were required to attend a monthly focus group to share lessons learned in submitting quality data along with providing survey feedback to monitor effectiveness. The focus group includes providing visual displays of data, workflows, and best practices to share amongst the participants to obtain feedback and make further improvements (81 FR 77196). The focus groups are used to learn from the practices about how to be more agile as we test new ways of measure recording and workflow (81 FR 77196). In the CY 2018 Quality Payment Program final rule (82 FR 53662), for Year 2 and future years, we reduced that requirement and finalized that study participants would be required to complete at least two web-based survey questionnaire and attend up to 4 focus group sessions throughout the year, but certain study participants would be able to attend less frequently. Each study participant is required to complete a survey prior to submitting MIPS data and another survey after submitting MIPS data (82 FR 53662). The purpose of reducing focus group attendance and survey participation was to ease requirements for MIPS eligible clinicians or group of clinicians who may have nothing new to contribute, without compromising the minimum sample needed for focus groups. For example, if a MIPS eligible clinician submitted all 6 measures after collecting 90 days of data and attended the first available focus group and/or survey, the clinician may have nothing new or relevant to discuss with the research team on subsequent focus groups and/or surveys.

(B) New Requirements for Focus Group and Survey Participation

Although we proposed in the section previously to increase the sample size of the study to a minimum of 200 MIPS eligible clinicians, we do not believe we need focus groups for the entirety of that population. We believe that requiring focus groups for all proposed minimum of 200 MIPS eligible clinicians would only result in bringing the data to a saturation point, a situation whereby the same themes and information are recurring, and no new insights are given by additional sources of data from focus groups.

Instead, we believe that selecting a subset of clinicians, purposively, to participate in focus groups would be a more appropriate approach because that would allow us to understand the experience of select clinicians without imposing undue burden on all. This study is voluntary as clinicians nominate themselves to participate and we select a cohort from among these volunteers. Therefore, in the CY 2019 PFS proposed rule (83 FR 35911), we proposed to make the focus group participation a requirement only for a selected subset of the study participants, using purposive sampling and random sampling methods, beginning with the CY 2019 performance period and future years. Those selected would be required to participate in at least one focus group meeting and complete survey requirement, in addition to all the other study requirements. As previously established, each study participant is required to complete a survey prior to submitting MIPS data and another survey after submitting MIPS data. This requirement would continue to apply for each selected subset participating in a focus group.

We did not receive any comments on our proposal. Therefore, we are finalizing our proposals, as proposed, to make the focus group participation a requirement only for a selected subset of the study participants, using purposive sampling and random sampling methods, beginning with the CY 2019 performance period and future years. Those selected would be required to participate in at least one focus group meeting and complete the survey requirements, in addition to all the other study requirements (81 FR 77195).

(v) Measure Requirements

(A) Current Requirements

In the CY 2017 Quality Payment Program final rule (81 FR 77196), we finalized that for CY 2017, MIPS eligible clinicians or groups participating in the CMS Study would submit their data and workflows for a minimum of three MIPS clinician quality measures that are relevant and prioritized by their practice. One of the measures must be an outcome measure, and one must be a patient experience measure (81 FR 77196). We also finalized that for future years, participating MIPS eligible clinicians or groups would select three of the measures for which they have baseline data from the 2017 performance period to compare against later performance years. We note that participating MIPS eligible clinicians could elect to report on more measures originally as this would provide more options from which to select in subsequent years for purposes of measuring improvement. In the CY 2018 Quality Payment Program final rule, we finalized for the Quality Payment Program Year 2 and future years, that study participants could submit all their quality measures data at once, as it is done in the MIPS program, (*qpp.cms.gov*) (82 FR 53662).

(B) Measure Requirements

In the CY 2019 PFS proposed rule (83 FR 35911), we proposed to continue the previously required minimum number of measures. That is, for the CY 2019 performance period and future years: participants must submit data and workflows for a minimum of three MIPS quality measures for which they have baseline data. However, instead of requiring one outcome measure and one patient experience measure as previously finalized, we proposed that, for the CY 2019 performance period and future years, at least one of the minimum of three measures must be a high priority measure as defined at

§ 414.1305. As defined there and discussed in section III.I.3.h.(2) of this final rule, a high priority measure means an outcome, appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. Outcome measures includes intermediate-outcome and patient-reported outcome measures. We believe that focusing on high priority measures, rather than patient experience measures, is important at this time, because it better aligns with the MIPS quality measures data submission criteria. We invited public comment on our proposal.

We did not receive any comments on our proposal. Therefore, we are finalizing our proposal, as proposed, that for the CY 2019 performance period and future years, at least one of the minimum of three measures must be a high priority measure as defined at § 414.1305.

We note that although the aforementioned activities (that is, the CMS Study on Factors Associated with Reporting Quality Measures) constitute an information collection request as defined in the implementing regulations of the Paperwork Reduction Act of 1995 (5 CFR part 1320), the associated burden is exempt from application of the Paperwork Reduction Act. Specifically, section 1848(s)(7) of the Act, as added by section 102 of MACRA (Pub. L. 114–10) states that Chapter 35 of title 44, United States Code, shall not apply to the collection of information for the development of quality measures.

(5) Promoting Interoperability (PI) (Previously Known as the Advancing Care Information Performance Category)

(a) Background

Section 1848(q)(2)(A) of the Act includes the meaningful use of CEHRT as a performance category under the MIPS. In prior rulemaking, we referred to this performance category as the advancing care information performance category, and it is reported by MIPS eligible clinicians as part of the overall MIPS program. As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of the MIPS shall be used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians will be evaluated under all four of the MIPS performance categories, including the advancing care information performance category.

(b) Renaming the Advancing Care Information Performance Category

In this final rule, we are adopting several scoring and measurement policies that will bring the performance category to a new phase of EHR measurement with an increased focus on interoperability and improving patient access to health information. To better reflect this focus, we renamed the advancing care information performance category to the Promoting Interoperability (PI) performance category. We believe this change will help highlight the enhanced goals of this performance category. We are finalizing revisions to the regulation text under 42 CFR part 414, subpart O, to reflect the new name.

(c) Certification Requirements Beginning in 2019

Under the definition of CEHRT under § 414.1305, for the performance periods in 2017 and 2018, MIPS eligible clinicians had flexibility to use EHR technology certified to either the 2014 or 2015 Edition certification criteria, or a combination of the two Editions, to meet the objectives and measures specified for the Promoting Interoperability performance category (82 FR 53671 through 53672). As we finalized previously (82 FR 53671–53672) beginning with the performance period in 2019, MIPS eligible clinicians must use EHR technology certified to the 2015 Edition certification criteria as specified at § 414.1305. We believe it is appropriate to require the use of 2015 Edition CEHRT beginning in CY 2019. In reviewing the state of health information technology, it is clear the 2014 Edition certification criterion are out of date and insufficient for clinician needs in the evolving health information technology (IT) industry. It will be beneficial to health IT developers and health care providers to move to more up-to-date standards and functions that better support interoperable exchange of health information and improve clinical workflows.

We received many comments regarding the requirement to use the 2015 Edition of CEHRT beginning in 2019. As we stated in the CY 2019 PFS proposed rule (83 FR 35912 through 35913), we did not propose to change the requirement. Because the requirement was not a subject of this rulemaking, we are not responding to the comments we received, although we may consider them to inform our future policy making in this subject area.

(d) Scoring Methodology

(i) Scoring Methodology for 2017 and 2018 Performance Periods

Section 1848(q)(5)(E)(i)(IV) of the Act states that 25 percent of the MIPS final score shall be based on performance for the Promoting Interoperability performance category. Accordingly, under § 414.1375(a), the Promoting Interoperability performance category comprises 25 percent of a MIPS eligible clinician's final score for the 2019 MIPS payment year and each MIPS payment year thereafter, unless we assign a different scoring weight. We proposed to revise § 414.1375(a) (83 FR 35913) to specify the various sections of the statute (sections 1848(o)(2)(D), 1848(q)(5)(E)(ii), and 1848(q)(5)(F) of the Act) under which a different scoring weight may be assigned for the Promoting Interoperability performance category. We established the reporting criteria to earn a performance category score for the Promoting Interoperability performance category under § 414.1375(b). We proposed to revise § 414.1375(b)(2)(i) to replace the reference to ''each required measure'' with ''each base score measure'' to improve the precision of the text. Under § 414.1380(b)(4), the Promoting Interoperability performance category score is comprised of a score for participation and reporting, known as the ''base score,'' and a score for performance at varying levels above the base score requirements, known as the ''performance score,'' as well as any applicable bonus scores. We proposed several editorial changes to § 414.1380(b)(4) in an effort to more clearly and concisely capture the previously established policies. For further explanation of our scoring policies for performance periods in 2017 and 2018 for the Promoting Interoperability performance category, we refer readers to 81 FR 77216 through 77227 and 82 FR 53663 through 53664.

A general summary overview of the scoring methodology for the performance period in 2018 is provided in the Table 38.

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TABLE 38: 2018 Performance Period Promoting Interoperability Performance Category Scoring Methodology
Promoting Interoperability Objectives and Measures

2018 Promoting Interoperability Objective	2018 Promoting Interoperability Measure	Required/ Not Required for Base Score (50%)	Performance Score (up to 90%)	Reporting Requirement
Protect Patient Health Information	Security Risk Analysis	Required	0	Yes/No Statement
Electronic Prescribing	e-Prescribing **	Required	0	Numerator/ Denominator
Patient Electronic Access	Provide Patient Access	Required	Up to 10%	Numerator/ Denominator
	Patient-Specific Education	Not Required	Up to 10%	Numerator/ Denominator
Coordination of Care Through Patient Engagement	View, Download, or Transmit (VDT)	Not Required	Up to 10%	Numerator/ Denominator
	Secure Messaging	Not Required	Up to 10%	Numerator/ Denominator
	Patient-Generated Health Data	Not Required	Up to 10%	Numerator/ Denominator
Health Information Exchange	Send a Summary of Care **	Required	Up to 10%	Numerator/ Denominator
	Request/Accept Summary of Care **	Required	Up to 10%	Numerator/ Denominator
	Clinical Information Reconciliation	Not Required	Up to 10%	Numerator/ Denominator
Public Health and Clinical Data Registry Reporting	Immunization Registry Reporting	Not Required	0 or 10%*	Yes/No Statement
	Syndromic Surveillance Reporting	Not Required	0 or 10%*	Yes/No Statement
	Electronic Case Reporting	Not Required	0 or 10%*	Yes/No Statement
	Public Health Registry Reporting	Not Required	0 or 10%*	Yes/No Statement
	Clinical Data Registry Reporting	Not Required	0 or 10%*	Yes/No Statement
Bonus (up to 25%)				
Report to one or more additional public health agencies or clinical data registries beyond the one identified for the performance score		5% bonus		Yes/No Statement
Report improvement activities using CEHRT		10% bonus		Yes/No Statement
Report using only 2015 Edition CEHRT		10% bonus		Based on measures submitted

* A MIPS eligible clinician may earn 10 percent for each public health agency or clinical data registry to which the clinician reports, up to a maximum of 10 percent under the performance score.

** Exclusions are available for these measures.

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We did not receive any comments on the proposed revisions to the regulation text at §§ 414.1375(a) and (b)(2)(i), and § 414.1380(b)(4). We are finalizing these revisions as proposed.

We heard from many stakeholders that the current scoring methodology is complicated and difficult to understand. By providing flexibility and offering clinicians multiple measures to choose from within the performance score, it appears some clinicians may have been confused by the options. Other MIPS eligible clinicians have indicated that they dislike the base score because it is a required set of measures and provides no flexibility because the scoring is all or nothing. If a MIPS eligible clinician cannot fulfill the base score, they cannot

earn a performance and/or bonus score. We have also received feedback from clinicians and specialty societies that the current requirements detract from their ability to provide care to their patients. In addition, stakeholders have indicated that the requirements of the Promoting Interoperability performance category for clinicians do not align with the requirements of the Medicare Promoting Interoperability Program for eligible hospitals and critical access hospitals (CAHs) and that this creates a burden for the medical staff who are tasked with overseeing the participation of both clinicians and hospitals in these programs.

Based on the concerns expressed by stakeholders, we proposed a new scoring methodology (83 FR 35913–395918) and moved away from the base, performance and bonus score methodology that we currently use. We stated our belief that this change would provide a simpler, more flexible, less burdensome structure, allowing MIPS eligible clinicians to put their focus back on patients. The introduction of this new scoring methodology would continue to encourage MIPS eligible clinicians to push themselves on measures that are most applicable to how they deliver care to patients, instead of focusing on measures that may not be as applicable to them. Our goal was to provide increased flexibility to MIPS eligible clinicians and enable them to focus more on patient care and health data exchange through interoperability. Additionally, we wanted to align the requirements of the Promoting Interoperability performance category with the requirements of the Medicare Promoting Interoperability Program for eligible hospitals and CAHs as we had proposed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20515 through 20537). As the distinction between ambulatory and inpatient CEHRT has diminished and more clinicians are sharing hospitals' CEHRT, we stated our belief that aligning the requirements between programs would lessen the burden on health care providers and facilitate their participation in both programs.

(ii) Proposed Scoring Methodology Beginning With the MIPS Performance Period in 2019

In the CY 2019 PFS proposed rule (83 FR 35914 through 35918), we proposed a new scoring methodology, beginning with the performance period in 2019, to include a combination of new measures, as well as the existing Promoting Interoperability performance category measures, broken into a smaller set of four objectives and scored based on performance. We stated our belief that this would be an overhaul of the existing program requirements as it would eliminate the concept of base and performance scores. We proposed a smaller set of objectives that consisted of e-Prescribing, Health Information Exchange, Provider to Patient Exchange, and Public Health and Clinical Data Exchange. We proposed these objectives to promote specific HHS priorities and satisfy the requirements of section 1848(o)(2) of the Act. We included the e-Prescribing and Health Information Exchange objectives in part to capture what we believe are core goals for the 2015 Edition of CEHRT and also to satisfy the statutory requirements. These core goals promote interoperability between health care providers and health IT systems to support safer, more coordinated care. The Provider to Patient Exchange objective promotes patient awareness and involvement in their health care through the use of APIs, and ensures patients have access to their medical data. Finally, the Public Health and Clinical Data Exchange objective supports the ongoing systematic collection, analysis, and interpretation of data that may be used in the prevention and controlling of disease through the estimation of health status and behavior. The integration of health IT systems into the national network of health data tracking and promotion improves the efficiency, timeliness, and effectiveness of public health surveillance. We stated our belief that it is important to keep these core goals, primarily because these objectives promote interoperability between health care providers and health IT systems to support safer, more coordinated care while ensuring patients have access to their medical data.

Under the proposed scoring methodology, MIPS eligible clinicians would be required to report certain measures from each of the four objectives, with performance-based scoring occurring at the individual measure-level. Each measure would be scored based on the MIPS eligible clinician's performance for that measure, based on the submission of a numerator and denominator, except for the measures associated with the Public Health and Clinical Data Exchange objective, which require ''yes or no'' submissions. Each measure would contribute to the MIPS eligible clinician's total Promoting Interoperability performance category score. The scores for each of the individual measures would be added together to calculate the Promoting Interoperability performance category score of up to 100 possible points for each MIPS eligible clinician. In general, the Promoting Interoperability performance category score makes up 25 percent of the MIPS final score. If a MIPS eligible clinician fails to report on a required measure or claim an exclusion for a required measure if applicable, the clinician would receive a total score of zero for the Promoting Interoperability performance category.

We also considered an alternative approach in which scoring would occur at the objective level, instead of the individual measure level, and MIPS eligible clinicians would be required to report on only one measure from each objective to earn a score for that objective. Under this scoring methodology, instead of six required measures, the MIPS eligible clinician total Promoting Interoperability performance category score would be based on only four measures, one measure from each objective. Each objective would be weighted similarly to how the objectives are weighted in our proposed methodology, and bonus points would be awarded for reporting any additional measures beyond the required four. We solicited public comment on this alternative approach, and whether additional flexibilities should be considered, such as allowing MIPS eligible clinicians to select which measures to report on within an objective and how those objectives should be weighted, as well as whether additional scoring approaches or methodologies should be considered.

In our proposed scoring methodology, the e-Prescribing objective would contain three measures each weighted differently to reflect their potential availability and applicability to the clinician community. In addition to the existing e-Prescribing measure, we proposed to add two new measures to the e-Prescribing objective: Query of Prescription Drug Monitoring Program (PDMP); and Verify Opioid Treatment Agreement. For more information about these two proposed measures, we refer readers to section III.H.3.h.(5)(f) of the proposed rule (83 FR 35922 through 35925). The e-Prescribing measure would be required for reporting and weighted at 10 points because we believed it would be applicable to most MIPS eligible clinicians. In the event that a MIPS eligible clinician meets the criteria and claims the exclusion for the e-Prescribing measure in 2019, the 10 points available for that measure would be redistributed equally among the two measures under the Health Information Exchange objective:

- Support Electronic Referral Loops By Sending Health Information Measure (25 points).
- Support Electronic Referral Loops By Receiving and Incorporating Health Information (25 points).

We solicited public comment on whether this redistribution is appropriate for 2019, or whether the points should be distributed differently.

The Query of PDMP and Verify Opioid Treatment Agreement measures would be optional for the MIPS performance period in 2019. These new measures may not be available to all MIPS eligible clinicians for the MIPS performance period in 2019 as they may not have been fully developed by their health IT vendor, or not fully implemented in time for data capture and reporting. Therefore, we did not propose to require these two new measures in 2019, although MIPS eligible clinicians may choose to report them and earn up to 5 bonus points for each measure. We proposed to require these measures beginning with the MIPS performance period in 2020, and we solicited public comment on this proposal.

Due to varying state requirements, not all MIPS eligible clinicians would be able to e-prescribe controlled substances, and thus, these measures would not be available to them. For these reasons, in the CY 2019 PFS proposed rule (83 FR 35915 through 35916) we proposed an exclusion for these two measures beginning with the MIPS performance period in 2020. The exclusion would provide that any MIPS eligible clinician who is unable to report the measure in accordance with applicable law would be excluded from reporting the measure, and the 5 points assigned to that measure would be redistributed to the e-Prescribing measure.

As the two new opioid measures become more broadly available in CEHRT, we proposed each of the three measures within the e-Prescribing objective would be worth 5 points beginning with the MIPS performance period in 2020. Requiring these two measures would add 10 points to the maximum total score for the Promoting Interoperability performance category as these measures would no longer be eligible for optional bonus points. To maintain a maximum total score of 100 points, beginning with the MIPS performance period in 2020, we proposed to reweight the e-Prescribing measure from 10 points down to 5 points, and reweight the Provide Patients Electronic Access to Their Health Information measure from 40 points down to 35 points as illustrated in Table 38. We proposed that if the MIPS eligible clinician qualifies for the e-Prescribing exclusion and is excluded from reporting all three of the measures associated with the e-Prescribing objective as described in section III.H.3.h.(5)(f) of the proposed rule, (83 FR 35921) the 15 points for the e-Prescribing objective would be redistributed evenly among the two measures associated with the Health Information Exchange objective and the Provide Patients Electronic Access to their Health Information measure by adding 5 points to each measure.

We refer readers to section III.I.3.h.(5)(f) of this final rule, where we discuss the Promoting Interoperability performance category measures, for a discussion of the comments we received regarding the above-referenced proposed scoring methodology for the e-Prescribing objective and associated measures. After consideration of the public comments we received, we are finalizing our proposed scoring for the E-Prescribing objective as proposed but with the modifications discussed at the end of this section III.I.3.h.(5)(f) of the preamble of this final rule. The e-Prescribing measure is finalized with modification, the Query of PDMP measure is finalized with modification, and the Verify Opioid Treatment Agreement measure is finalized with modification. In addition, we refer readers to section III.I.3.h.(5)(f)(ii) of the preamble of this final rule where we discuss our reasons for adopting the Query of PDMP measure with modification and the Verify Opioid Treatment Agreement measure with modification.

For the Health Information Exchange objective, we proposed to change the name of the existing Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information measure, and proposed a new measure which combines the functionality of the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures into a new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. For more information about the proposed measure and measure changes, we refer readers to section III.I.3.h.(5)(f) of the proposed final rule (83 FR 35925 through 35928). MIPS eligible clinicians would be required to report both of these measures, each worth 20 points toward their total Promoting Interoperability performance category score. These measures are weighted heavily to emphasize the importance of sharing health information through interoperable exchange in an effort to promote care coordination and better patient outcomes. Similar to the two new measures in the e-Prescribing objective, the new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure may not be available to all MIPS eligible clinicians as it may not have been fully developed by their health IT vendor, or not fully implemented in time for a MIPS performance period in 2019. For these reasons, we proposed two exclusions for the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure:

1. Any MIPS eligible clinician who is unable to implement the measure for a MIPS performance period in 2019 would be excluded from this measure.

2. Any MIPS eligible clinician who receives fewer than 100 transitions of care or referrals or has fewer than 100 encounters with patients never before encountered during the performance period would be excluded from this measure.

We note that these two exclusions for the measure were proposed in different sections of the proposed rule (83 FR 35916, 35927).

In the event that a MIPS eligible clinician claims an exclusion for the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, the 20 points would be redistributed to the Support Electronic Referral Loops by Sending Health Information measure, and that measure would then be worth 40 points. We solicited public comment on whether this redistribution is appropriate, or whether the points should be redistributed to other measures instead.

We refer readers to section III.I.3.h.(5)(f) of this final rule, where we discuss the Promoting Interoperability performance category measures, for a discussion of the comments we received regarding the above-referenced proposed scoring methodology for the Health Information Exchange objective and associated measures. We did not receive any comments regarding the redistribution of points if an exclusion is claimed for the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. After consideration of the comments that we received, we are finalizing our proposals for the Health Information Exchange objective as proposed. In addition, measure specification details can be found in section III.I.3.h.(5)(f) of the preamble of this final rule.

In the CY 2019 PFS proposed rule (83 FR 359186), we proposed to weight the

one measure in the Provider to Patient Exchange objective, Provide Patients Electronic Access to Their Health Information, at 40 points toward the total Promoting Interoperability performance category score in 2019 and 35 points beginning in 2020. We proposed that this measure would be weighted at 35 points beginning in 2020 to account for the two new opioid measures, which would be worth 5 points each beginning in 2020 as proposed. We stated our belief that this objective and its associated measure get to the core of improved access and exchange of patient data in Promoting Interoperability and are the crux of the Promoting Interoperability performance category. This exchange of data between health care provider and patient is imperative in order to continue to improve interoperability, data exchange and improved health outcomes. We stated that it is important for patients to have control over their own health information, and through this highly weighted objective we are aiming to show our dedication to this effort.

We solicited comment on these proposals and our summary and response are below.

Comment: A few commenters supported CMS' proposed weighting of the Provide Patients Electronic Access to Their Health Information measure.

Response: We appreciate the support regarding the proposed weight of this measure. We believe that it is important to give patients access to their data and therefore the measure deserves to be highly weighted.

Comment: A few commenters stated that an allocation of 40 points to a single measure (Provide Patient Electronic Access to Their Health Information) is too high. Commenters stated that if the points are redistributed to other measures because exclusions are claimed, especially if an exclusion is claimed on more than one measure, the emphasis on the remaining measures will increase.

Response: We believe that it is essential for patients to have access to their health information and the assignment of 40 points to this measure reflects the importance we place on patient's access to their health information.

After consideration of the comments, we are finalizing with modification the proposals for the Provider to Patient Exchange objective. The Provide Patients Electronic Access to Their Health Information measure will be worth up to 40 points beginning in CY 2019. We had proposed that the measure would be worth up to 35 points beginning in CY 2020, but we are not finalizing that proposal because we are not requiring the Verify Opioid Treatment Agreement measure beginning in CY 2020 as proposed, which would have been worth up to 5 points. For additional measure information, we refer readers to section III.I.3.h.(5)(f) of the preamble of this final rule.

The measures under the Public Health and Clinical Data Exchange objective are reported using ''yes or no'' responses and thus we proposed to score those measures on a pass/fail basis in which the MIPS eligible clinician would receive the full 10 points for reporting two ''yes'' responses, or for submitting a ''yes'' for one measure and claiming an exclusion for another. If there are no ''yes'' responses and two exclusions are claimed, the 10 points would be redistributed to the Provide Patients Electronic Access to Their Health Information measure. A MIPS eligible clinician would receive zero points for reporting ''no'' responses for the measures in this objective if they do not submit a ''yes'' or claim an exclusion for at least two measures under this objective. We proposed that for this objective, the MIPS eligible clinician would be required to report on two measures of their choice from the following list of measures: Immunization Registry Reporting, Electronic Case Reporting, Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting. To account for the possibility that not all of the measures under the Public Health and Clinical Data Exchange objective may be applicable to all MIPS eligible clinicians, we proposed to establish exclusions for these measures as described in section III.H.3.h.(5)(f) of the proposed rule (83 FR 35929 through 35930). If a MIPS eligible clinician claims two exclusions, the 10 points for this objective would be redistributed to the Provide Patients Electronic Access to their Health Information measure under the Provider to Patient Exchange objective, making that measure worth 50 points in 2019 and 45 points beginning in 2020. Reporting more than two measures for this objective would not earn the MIPS eligible clinician any additional points. We refer readers to section III.H.3.h.(5)(f) of the proposed rule (83 FR 35929 through 35930) in regard to the proposals for the Public Health and Clinical Data Exchange objective and its associated measures.

We solicited comment on these proposals and our summary and response are below.

Comment: A commenter suggested that MIPS eligible clinicians should be eligible to earn more points for reporting on more than two public health and clinical data exchange measures.

Response: We appreciate the suggestion but decline to implement it at this time. We are limiting bonus point opportunities to brand new measures, such as those associated with the e-Prescribing objective, in an effort to maintain simplicity and avoid confusion in our scoring methodology.

Comment: Some commenters questioned whether they could receive credit for reporting to more than one registry for a measure.

Response: We believe that a clinician who is in active engagement with two different public health agencies or clinical data registries for purposes of the same measure would accomplish the same policy goal as our proposal to report on two measures. It is also consistent with the policy we established in the CY 2018 Quality Payment Program final rule for reporting on the measures associated with the Public Health and Clinical Data Registry Reporting Objective for the performance score and bonus score (82 FR 53663–53664). In addition, allowing MIPS eligible clinicians to report to two different public health agencies or clinical data registries of their choice promotes flexibility in reporting and allows them to focus on the public health measures that are most relevant to them and their patient populations. Therefore, we will be adopting our proposal with modification to allow clinicians the flexibility to report to two different public health agencies or clinical data registries for purposes of the same measure.

After consideration of the public comments we received, we are finalizing our proposals for the Public Health and Clinical Data Exchange objective with modifications. MIPS eligible clinicians must report to two different public health agencies or clinical data registries for any of the following measures: Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, Public Health Registry Reporting, and Clinical Data Registry Reporting. MIPS eligible clinicians may report to two different public health agencies or clinical data registries for purposes of the same measure if they choose. For additional measure information, we refer readers to section III.I.3.h.(5)(f) of this final rule.

In the CY 2019 PFS proposed rule (83 FR 359186), we proposed that the Protect Patient Health Information objective and its associated measure, Security Risk Analysis, would remain part of the requirements for the

Promoting Interoperability performance category, but would no longer be scored as a measure and would not contribute to the MIPS eligible clinician's Promoting Interoperability performance category score. To earn any score in the Promoting Interoperability performance category, we proposed a MIPS eligible clinician would have to report that they completed the actions included in the Security Risk Analysis measure at some point during the calendar year in which the performance period occurs. We stated our belief that the Security Risk Analysis measure involves critical tasks and noted that the HIPAA Security Rule requires covered entities to conduct a risk assessment of their health care organization. This risk assessment will help MIPS eligible clinicians comply with HIPAA's administrative, physical, and technical safeguards. Therefore, we stated that every MIPS eligible clinician should already be meeting the requirements for this objective and measure as it is a requirement of HIPAA. We indicated that we still believe this objective and its associated measure are imperative in ensuring the safe delivery of patient health data. As a result, we would maintain the Security Risk Analysis measure as part of the Promoting Interoperability performance category, but we would not score the measure.

The following is a summary of the public comments received on the proposals for the Protect Patient Health Information objective and its associated measure, Security Risk Analysis and our responses.

Comment: A commenter stated that the Security Risk Analysis measure has historically been challenging for physicians. The commenter did not support the annual reporting of this measure to be required to achieve any score in the Promoting Interoperability category. To overcome what the commenter described as the burdensome nature of this measure, the commenter indicated that MIPS eligible clinicians need additional support and resources to aid in their understanding of how to conduct a security risk analysis that is compliant with CMS's standards.

Response: The Security Risk Analysis measure has been a required measure since the beginning of the EHR Incentive programs in 2011 through the transition to MIPS starting in 2017. The requirement remains that the actions included in the measure must be performed once during the calendar year in which the performance period occurs. We appreciate the commenter's interest in additional educational materials for clinicians on how they can improve the privacy and security of their health information. We refer them to *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/2016_SecurityRiskAnalysis.pdf*. HHS Office for Civil Rights (OCR) has issued guidance on conducting a security risk analysis in accordance with the HIPAA Security Rule (*http://www.hhs.gov/hipaa/forprofessionals/security/guidance/guidance-risk-analysis/index.html*). Additional free tools and resources available to assist MIPS eligible clinicians include a Security Risk Assessment (SRA) Tool developed by the Office of National Coordinator for Health Information Technology (ONC) and OCR at *http://www.healthit.gov/providersprofessionals/security-risk-assessment-tool*. We believe that performing an annual security risk assessment will help identify security weaknesses and may provide opportunities to improve the security of the MIPS eligible clinician's electronic systems.

Comment: Several commenters stated that if the Security Risk Analysis measure is required, then MIPS eligible clinicians should receive credit for doing it. The commenters recommended that the technological, encryption, and other cybersecurity components of the security risk analysis should be shifted to the health IT vendor and should not be a burden placed on MIPS eligible clinicians.

Response: As we discussed in the proposed rule (83 FR 35916), we do not believe that the Security Risk Analysis measure should be scored because it includes actions already required under HIPAA and will help MIPS eligible clinicians comply with HIPAA's administrative, physical, and technical safeguards. We do not believe points should be awarded because MIPS eligible clinicians should have already been performing these actions. In addition, while a health IT vendor's products must possess the relevant privacy and security capabilities be certified, we believe that MIPS eligible clinicians must also conduct security risk assessments to make sure that vulnerabilities are identified and remediated. In addition, successful completion of a security risk analysis is required to earn a score in the Promoting Interoperability performance category.

Comment: The majority of commenters supported CMS' proposal to require MIPS eligible clinicians to attest to the completion of the actions of the Security Risk Analysis measure with no associated score in order to be eligible to receive an overall score in the Promoting Interoperability performance category. They stated that this measure is essential to safely transmitting their patient data and successfully participating in the Promoting Interoperability performance category.

Response: As discussed in the preceding response, we agree that this measure should not be scored.

After consideration of the public comments, we are finalizing our proposal to require MIPS eligible clinicians to attest that they completed the actions included in the Security Risk Analysis measure at some point during the calendar year in which the MIPS performance period occurs. MIPS eligible clinicians who fail to complete these actions or fail to attest will not earn any score for the Promoting Interoperability performance category, regardless of whether they report on other measures for this category.

As we proposed at 83 FR 35916, similar to how MIPS eligible clinicians currently submit data, the MIPS eligible clinician would submit their numerator and denominator data for each measure, and a ''yes or no'' response for each of the two reported measures under the Public Health and Clinical Data Exchange objective. The numerator and denominator for each measure would then translate to a performance rate for that measure and would be applied to the total possible points for that measure. For example, the e-Prescribing measure was proposed to be worth 10 points. A numerator of 200 and denominator of 250 would yield a performance rate of (200/250) = 80 percent. This 80 percent would be applied to the 10 total points available for the e-Prescribing measure to determine the measure score. A performance rate of 80 percent for the e-Prescribing measure would equate to a measure score of 8 points (performance rate * total possible measure points = points awarded toward the total Promoting Interoperability performance category score; 80 percent * 10 = 8 points). To calculate the Promoting Interoperability performance category score, the measure scores would be added together, and the total sum would be divided by the total possible points (100). The total sum cannot exceed the total possible points. This calculation results in a fraction from zero to 1, which can be formatted as a percent. For further clarification we refer readers to the scoring example that we included in the proposed rule (83 FR 35917).

When calculating the performance rates, measure and objective scores, and the Promoting Interoperability performance category score, we would generally round to the nearest whole

number. For example if a MIPS eligible clinician received a score of 8.53 the nearest whole number would be 9. Similarly, if the MIPS eligible clinician received a score of 8.33 the nearest whole number would be 8. In the event that the MIPS eligible clinician receives a performance rate or measure score of less than 0.5, as long as the MIPS eligible clinician reported on at least one patient for a given measure, a score of 1 would be awarded for that measure. We stated that we believed this is the best method for the issues that might arise with the decimal points and is the easiest for computations.

In order to meet statutory requirements and HHS priorities, the MIPS eligible clinician would need to report on all of the required measures across all objectives in order to earn any score at all for the Promoting Interoperability performance category. Failure to report any required measure, or reporting a ''no'' response on a ''yes or no'' response measure, unless an exclusion applies would result in a score of zero. We solicited public comment on the proposed requirement to report on all required measures, or whether reporting on a smaller subset of optional measures would be appropriate.

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TABLE 39: Proposed Scoring Methodology for the MIPS Performance Period in 2019

Objectives	Measures	Maximum Points
e-Prescribing	e-Prescribing	10 points
	Bonus: Query of Prescription Drug Monitoring Program (PDMP)	5 points bonus
	Bonus: Verify Opioid Treatment Agreement	5 points bonus
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Health Information	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Choose two of the following: Immunization Registry Reporting Electronic Case Reporting Public Health Registry Reporting Clinical Data Registry Reporting Syndromic Surveillance Reporting	10 points

TABLE 40: Proposed Scoring Methodology Beginning with MIPS Performance Period in 2020

Objectives	Measures	Maximum Points
e-Prescribing	e-Prescribing	5 points
	Query of Prescription Drug Monitoring Program (PDMP)	5 points
	Verify Opioid Treatment Agreement	5 points
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Health Information	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	35 points
Public Health and Clinical Data Exchange	Choose two of the following: Immunization Registry Reporting Electronic Case Reporting Public Health Registry Reporting Clinical Data Registry Reporting Syndromic Surveillance Reporting	10 points

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In the proposed rule (83 FR 35917), we sought public comment on whether these measures are weighted appropriately, or whether a different weighting distribution, such as equal distribution across all measures would be better suited to this program and this proposed scoring methodology. We also sought public comment on other scoring methodologies such as the alternative we considered and described earlier in this section.

We solicited comment on these proposals and our summary of these comments and responses are below.

Comment: Some commenters expressed concern that CMS has gone back to an ''all or nothing'' approach, which existed in the original meaningful use program. Commenters indicated that under CMS' proposal, clinicians would be required to report on all required measures within each of the four objectives. Failure to report on one measure without claiming an exclusion would result in a score of zero. Other commenters stated that the proposed new structure is still essentially an ''all or nothing'' approach, which they do not support. Instead, they suggested that MIPS eligible clinicians who do not or cannot attest to a measure should not receive points for that particular measure, but they should still earn points for all of the other measures that they are able to submit data for.

Response: We tried to reduce confusion and clinician burden by proposing to reduce the number of measures that MIPS eligible clinicians are required to report and provide an opportunity for MIPS eligible clinicians to earn points by redistributing the points to other measures when an exclusion is claimed. We do not agree that this scoring structure is an all or nothing approach due to the reduction of measures, the requirement of a one in the numerator for numerator/denominator measures or a ''yes'' for yes/no measures, and the redistribution of points when an exclusion is claimed. We do not agree with the suggestion that MIPS eligible clinicians that do not or cannot attest to measures should not receive points since the measures have been reduced to six required measures which will reduce administrative burden and allow MIPS eligible clinicians to focus more on their patients. We believe it would disadvantage clinicians if we did not redistribute the points for measures when an exclusion is claimed. We believe the proposed scoring methodology promotes the goals of the performance category to focus on interoperability, improving patient access to health information and aligning the performance category with the Medicare Promoting Interoperability Program for eligible hospitals and CAHs.

Comment: One commenter agreed with the CMS proposal to give a MIPS eligible clinician a Promoting Interoperability performance category score of ''zero'' for failure to report on any one required measure, but recommended that CMS create an exclusion process with identified circumstances where partial credit for the measure may be applied, but such partial credit should be the exception and not the norm and should be evaluated on a case-by-case basis.

Response: We appreciate the suggestion but believe it would further complicate scoring when we are trying to simplify it to the greatest extent possible. Our intention with our proposals for the scoring methodology was to reduce clinician burden. We do not believe that a process to address individual scenarios is feasible for us to implement at this time, but will take this comment into consideration for future rulemaking.

Comment: One commenter requested clarification of our proposal to require MIPS eligible clinicians to report on all of the required measures across all objectives in order to earn any score at all for the Promoting Interoperability performance category. The commenter questioned if failure to report any required measure would result in a zero for that measure or a zero for the Promoting Interoperability performance category.

Response: The clinician would earn a score of zero for the entire Promoting Interoperability performance category.

Comment: Some commenters expressed concern with the time required to incorporate new measures into CEHRT (an average of 1,000 hours per measure per product) and requested that measures changes be done judiciously to minimize the burden to developers and to MIPS eligible clinicians who must implement the new measures.

Response: The proposed scoring methodology primarily would eliminate or revise existing measures, which should only require consolidation of existing workflows and actions. In addition, the certification criteria and standards for EHR technology would remain the same as finalized in the October 16, 2015 final rule titled ''2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications'' (80 FR 62602 through 62759).

Comment: One commenter stated that we should not require a minimum numerator of 1 for any of the performance measures, but instead we should require all program participants to report on all of the performance measures, with an exclusion available for each measure in case their CEHRT does not support the measure. If the exclusion is claimed, the participant would receive a 0 on that measure, and the exclusion status would be published on Physician Compare.

Response: We disagree with the commenter's suggested approach. CEHRT presently has the capability to support all of the proposed measures with the exception of the Query of Prescription Drug Monitoring measure and the Verify Opioid Treatment Agreement measure, which would be optional in the 2019 MIPS performance period. For more information on what will be posted on Physician Compare, see section III.I.3.l. of this final rule.

Comment: One commenter suggested an alternative intermediate solution where each measure would be worth up to 10 points for a total of 110 points (90 for the existing performance measures plus e-Prescribing plus a second registry measure).

Response: We appreciate this suggestion, but we believe that removing several of the existing performance score measures will help to reduce burden for MIPS eligible clinicians.

Comment: Many commenters supported CMS' proposal to reduce the number of measures to be reported as part of the Promoting Interoperability performance category.

Response: We believe the reduction in reporting will relieve health care provider burden through a more flexible, performance-based approach.

Comment: Some commenters supported the CMS effort to reduce the complexity of the scoring methodology. Some commenters stated that the proposed scoring methodology reduces clinician burden by eliminating confusing base and performance scores in favor of scoring at the individual measure level, with relevant measure exclusions. Some commenters supported the overall reduction of measures in this category through the elimination of burdensome measures. Another commenter indicated that the proposed scoring methodology and measure set is a huge improvement and does a lot to streamline the requirements of the Promoting Interoperability performance category. Commenters supported the move to a

single set of measures because it will help alleviate confusion by MIPS eligible clinicians. Many commenters supported CMS' proposed scoring methodology in which MIPS eligible clinicians would be required to report certain measures from each of the four objectives, with performance-based scoring occurring at the individual measure-level.

Response: We appreciate the many commenters who supported the proposed scoring methodology and agree it will reduce burden.

Comment: A few commenters stated they favored a system that provides the flexibility for MIPS eligible clinicians to select the measures most relevant to their practice and patient population and are the least burdensome to implement.

Response: We believe the proposed scoring methodology approach, including the reduction of measures to reduce reporting burden and our goal to provide patients with access to their health information promotes the goals of the Promoting Interoperability performance category. Providing flexibility to choose measures that do not promote increased focus on interoperability or improving patient access to health information will deemphasize the goals of the Promoting Interoperability performance category. We received many comments indicating that there were too many measures so to address that we have reduced and combined measures to reduce MIPS eligible clinician burden.

Comment: One commenter supported this specific proposal to streamline and simplify the Promoting Interoperability performance category, but cautioned CMS against further implementation of major category overhauls. Significant changes, even those intended to reduce physician reporting burden, can increase burden when they require yet another round of health care provider and staff education to understand how to maximize performance under a redesigned category scoring methodology. Solo practitioners and small group practices in particular have indicated that substantial category changes are significant burdens for their practices.

Response: We appreciate the commenter's support for our proposal and will take the recommendation against further implementation of major category overhaul into consideration in future rulemaking. We note that in the CY 2018 Quality Payment Program final rule (82 FR 53682–53683), we finalized a significant hardship exception for the Promoting Interoperability performance category for MIPS eligible clinicians who are in small practices.

Comment: A few commenters disagreed with our proposal to combine the Request/Accept Summary of Care measure with the Clinical Information Reconciliation measure and they proposed that each measure remain separate and be worth 10 points, rather than having them combined and worth 20 points.

Response: We thank commenters for their suggestion but we decline to adopt it. For the reasons discussed in section III.I.3.h.(5)(f) of this final rule, we believe it is appropriate to combine these measures and have the point value reflect the combination.

Comment: Many commenters recommended that we establish a threshold of 50 points to align with the Medicare Promoting Interoperability Program for eligible hospitals and CAHs.

Response: Although our proposed scoring methodology did not include a point threshold, we appreciate this comment and will take it into consideration as we develop future proposals.

Comment: A commenter supported the proposed weighting of the measures but recommended that CMS consider adding additional measures that would promote the integration of clinical and administrative data toward the goal of creating substantive longitudinal patient records.

Response: We appreciate the support and appreciate the suggestion. In the proposed rule we did request comments (83 FR 35931 through 35932) on potential new measures as well as ways to link the quality, improvement activities, and the Promoting Interoperability performance categories. We plan to use the comments we received to inform future proposals that focus on integration.

Comment: Some commenters thanked CMS for aligning the measures in the inpatient and outpatient settings because it will reduce burden.

Response: We appreciate commenter's support of our proposal to align the MIPS Promoting Interoperability performance category measures with the Medicare Promoting Interoperability Program measures for eligible hospitals and CAHs.

Comment: Some commenters stated that CMS should not implement the alternative scoring approach that was considered and discussed in the proposed rule because it would allow MIPS eligible clinicians to report on fewer measures and still earn the same credit which is a lowering of the bar for achieving interoperability. Many commenters suggested that the Public Health and Clinical Data Exchange objective would be deemphasized by reducing the reporting requirement to only one measure.

Response: We agree and will not be implementing the alternative that we considered. Our primary proposal focuses on interoperability and improving patient access to health information and we believe that the objectives and measures we have chosen will help to fulfill these goals. We agree that reporting to two different public health agencies or clinical data registries for any of the measures from the Public Health and Clinical Data Exchange objective will help to build bi-directional data exchange between clinicians and public health agencies and clinical data registries. We believe that our proposal will enable MIPS eligible clinicians to push themselves on measures that are the most applicable to how they deliver care to patients.

Comment: Many commenters supported CMS' alternative approach to scoring in which scoring would occur at the objective level, instead of the individual measure level, and MIPS eligible clinicians would be required to report on only one measure from each objective to earn a score for that objective.

Some commenters stated that requiring MIPS eligible clinicians to report on every single measure or claim an exclusion creates an unfair burden. Other commenters supported the alternative approach because they believe it is less rigid and provides MIPS eligible clinicians with more flexibility to report measures that are part of their workflow.

Response: We have taken commenters' feedback into consideration as we have constructed our final policy as outlined in section III.I.3.h.(5)(d) of this final rule. We decline to finalize the alternative approach to scoring. In addition, the other objectives containing more than one measure are the Electronic Prescribing objective and the Health Information Exchange objective. For the Electronic Prescribing objective, we note that both the Query of PDMP and Verify Opioid Treatment Agreement measures are optional for reporting for CY 2019; therefore we believe this objective could require reporting on only one measure as opposed to multiple measures. We continue to believe that the objective and measure set that we selected will enable MIPS eligible clinicians to focus on interoperability and improving patient access to health information.

Comment: A commenter recommended that CMS only require that MIPS eligible clinicians attest to satisfying each measure for a least 1 patient instead of using a performance rate.

Response: We disagree. We believe that a performance-based scoring mechanism will enable MIPS eligible clinicians who perform well on measures to differentiate themselves from other MIPS eligible clinicians who submitted data with lower results for the Promoting Interoperability performance category.

Comment: One commenter suggested that if a MIPS eligible clinician cannot fulfill a measure that an exclusion process be created where partial credit can be earned. They recommended that partial credit be granted on a case-by-case basis.

Response: We do not believe that finalizing a process to address individual scenarios is feasible for us to implement at this time. We may take this comment into consideration in our development of future rulemaking.

Comment: One commenter supported all of the proposed measures as long as there is no minimum threshold requirement and no performance measurement.

Response: The Promoting Interoperability performance category sets a very low minimum threshold requirement for measures. We believe that the minimum reporting requirements we set (a one in the numerator for numerator/denominator measures, a ''yes'' for yes/no measures, unless an exclusion is claimed) are appropriate. We believe that a performance based scoring system as we are implementing for the Promoting Interoperability performance category will enable high performing MIPS eligible clinicians to distinguish themselves from others and potentially earn a higher upward adjustment.

Comment: One commenter urged CMS to allow MIPS eligible clinicians to ''pick and choose'' measures from a ''menu'' of objectives and measures. Other commenters recommended that the Promoting Interoperability performance category not be limited to a small set of measures. The commenters recommended more flexibility by allowing MIPS eligible clinicians to select from a larger list of measures.

Response: We disagree because we allowed considerable choice for years one and two and received significant feedback about how complicated it was for clinicians to understand the requirements for the base and performance scores. We continue to believe that a reduced set of measures will reduce burden for clinicians and will enable them to focus more on patient care. As we have received significant commenters support on our proposal to align the Promoting Interoperability requirements and measures with the Medicare Promoting Interoperability Program measures for eligible hospitals and CAHs, we decline to retain measures so that MIPS eligible clinicians have flexibility in selecting measures.

Comment: A commenter stated that if CMS does not remove the ''all or nothing'' scoring requirement, we recommend that the proposals related to re-weighting measures when a MIPS eligible clinician claims an exclusion be modified because they are confusing.

Response: While we understand that concern, we believe that if a MIPS eligible clinician meets the requirements of an exclusion, then the points for the excluded measure should be redistributed to another measure. We will develop educational tools to assist MIPS eligible clinicians to understand our redistribution policy.

Comment: A commenter stated that MIPS eligible clinicians rely on their EHR systems to help them with program participation. They warned that if these proposed changes are finalized in November 2018 for the 2019 performance period, the systems will not be updated until mid-2019 at the earliest. They requested a full calendar year's notice before any changes would become applicable.

Response: We disagree that a full calendar year's notice is necessary. The proposed new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information, includes two exclusions in CY 2019, as described in section III.I.3.h.(5)(f) of the preamble of this final rule. For the Electronic Prescribing objective, we note that both the Query of PDMP and Verify Opioid Treatment Agreement measures are optional for reporting for CY 2019.The criteria for all of the remaining measures (numerator/denominator or yes/no measures) would remain the same and are supported by 2015 Edition CEHRT.

Summary of Final Scoring Methodology: As discussed above, after consideration of the comments we received, we are finalizing our proposed performance-based scoring methodology for the Promoting Interoperability performance category beginning with the performance period in CY 2019, with modifications, as described below.

For additional measure-specific information, we refer readers to section III.I.3.h.(5)(f) the preamble of this final rule.

Promoting Interoperability Score: We are finalizing that MIPS eligible clinicians are required to report certain measures from each of the four objectives, with performance-based scoring occurring at the individual measure-level. Each measure is scored based on the MIPS eligible clinician's performance for that measure, except for the measures associated with the Public Health and Clinical Data Exchange objective, which require a yes/no attestation. Each measure will contribute to the MIPS eligible clinician's total Promoting Interoperability performance category score. The scores for each of the individual measures are added together to calculate the total Promoting Interoperability performance category score of up to 100 possible points for each MIPS eligible clinician. To calculate the Promoting Interoperability performance category score, the measure scores are added together, and the total sum is divided by the total possible points (100). The total sum cannot exceed the total possible points. This calculation results in a fraction from zero to 1, which can be formatted as a percent. For a MIPS eligible clinician to earn a score greater than zero for the Promoting Interoperability performance category, in addition to completing the actions included in the Security Risk Analysis measure, the MIPS eligible clinician must submit their complete numerator and denominator or yes/no data for all required measures. The numerator and denominator for each performance measure will translate to a performance rate for that measure and will be applied to the total possible points for that measure. The MIPS eligible clinician must report on all of the required measures across all of the objectives in order to earn any score at all. Failure to report any required measure, or reporting a ''no'' response on a yes/no response measure, unless an exclusion is claimed will result in a Promoting Interoperability performance category score of zero.

Security Risk Analysis Measure: We are finalizing our proposal that MIPS eligible clinicians must attest to having completed the actions included in the Security Risk Analysis measure at some point during the calendar year in which the MIPS performance period occurs. The Security Risk Analysis measure is not scored and does not contribute any points to the MIPS eligible clinician's total score for the objectives and measures.

Electronic Prescribing Objective Scoring: We are finalizing the Electronic

Prescribing objective as proposed with the following modifications. The e-Prescribing measure is worth up to 10 points in CYs 2019 and 2020. We are modifying the points for CY 2020 to reflect the modification to our proposal for the Query of Prescription Drug Monitoring Program (PDMP) measure in CY 2020. The Query of PDMP measure is optional in CY 2019 and worth 5 bonus points. We are not establishing a policy for the Query of PDMP measure for CY 2020 in this final rule and intend to address this measure in future rulemaking. The Verify Opioid Treatment Agreement measure is optional in CY 2019 and 2020, and worth five bonus points. We intend to reevaluate the status of the Verify Opioid Treatment Agreement measure for subsequent years in future rulemaking. An exclusion is available for the e-Prescribing measure as described in section III.I.3.h.(5)(f) of the preamble of this final rule. If an exclusion is claimed for the e-Prescribing measure for CY 2019, the 10 points for the e-Prescribing measure will be redistributed equally among the measures associated with the Health Information Exchange objective. Since the Query of PDMP and Verify Opioid Treatment Agreement measures are optional and eligible for bonus points, no exclusions are available.

Health Information Exchange Objective Scoring: We are finalizing the Health Information Exchange objective as proposed. The Support Electronic Referral Loops by Sending Health Information measure is worth up to 20 points. An exclusion is available for this measure, as described in section III.I.3.h.(5)(f) of the preamble of this final rule, although we did not address in the proposed rule how the points would be redistributed in the event the exclusion is claimed. We intend to propose in next year's rulemaking how the points will be redistributed if an exclusion is claimed. The new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information, is worth up to 20 points. Exclusions are available for this measure, as described in section III.I.3.h.(5)(f) of this final rule. If an exclusion is claimed, the 20 points would be redistributed to the other measure within this objective, the Support Electronic Referral Loops by Sending Health Information measure, which would be worth up to 40 points. We will address in future rulemaking how the points will be redistributed if exclusions are claimed for both the Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure.

Provider to Patient Exchange Objective Scoring: We are finalizing the Provider to Patient Exchange objective with modifications. The Provide Patients Electronic Access to Their Health Information measure is worth up to 40 points beginning with the MIPS performance period in CY 2019. No exclusions are available for this measure.

Public Health and Clinical Data Exchange Objective Scoring: We are finalizing the Public Health and Clinical Data Exchange objective as proposed with the following modifications. MIPS eligible clinicians must submit a yes/no response for two different public health agencies or clinical data registries for any of the measures associated with the Public Health and Clinical Data Exchange objective to earn 10 points for the objective. Failure to report on two different public health agencies or clinical data registries or submitting a ''no'' response for a measure will earn a score of zero. Exclusions available for this objective are discussed in section III.I.3.h.(5)(f) of the preamble of this final rule. If an exclusion is claimed for one measure, but the MIPS eligible clinicians submits a ''yes'' response for another measure, they would earn the 10 points for the Public Health and Clinical Data Exchange objective. If a MIPS eligible clinician claims exclusions for both measures they select to report on, the 10 points would be redistributed to the Provide Patients Electronic Access to Their Health Information measure under the Provider to Patient Exchange objective.

Tables 41 and 42 reflect the final policy for the objectives, measures, and maximum points available for the MIPS performance periods in CY 2019 and CY 2020. Please note, the maximum points available do not include points that would be redistributed in the event an exclusion is claimed:

Tables 41 and 42 illustrate our final performance-based scoring methodology.

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TABLE 41: Scoring Methodology for the MIPS Performance Period in 2019

Objectives	Measures	Maximum Points
e-Prescribing	e-Prescribing**	10 points
	Bonus: Query of Prescription Drug Monitoring Program (PDMP)	5 point bonus
	Bonus: Verify Opioid Treatment Agreement	5 point bonus
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information**	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Health Information**	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report to two different public health agencies or clinical data registries for any of the following: Immunization Registry Reporting** Electronic Case Reporting** Public Health Registry Reporting** Clinical Data Registry Reporting** Syndromic Surveillance Reporting**	10 points

** Exclusion available.

TABLE 42: Scoring Methodology for the MIPS Performance Period in 2020

Objectives	Measures	Maximum Points
e-Prescribing	e-Prescribing**	10 points
	Bonus: Verify Opioid Treatment Agreement	5 point bonus
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information**	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Health Information**	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report to two different public health agencies or clinical data registries for any of the following: Immunization Registry Reporting** Electronic Case Reporting** Public Health Registry Reporting** Clinical Data Registry Reporting** Syndromic Surveillance Reporting**	10 points

** Exclusion available.

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We proposed to codify the proposed new scoring methodology in new paragraphs (b)(4)(ii) and (iii) under § 414.1380 and we are finalizing the proposed regulation text with modification.

(e) Promoting Interoperability/ Advancing Care Information Objectives and Measures Specifications for the 2018 Performance Period

The Advancing Care Information (now Promoting Interoperability) performance category Objectives and Measures for the 2018 performance period are as follows. For more information, we refer readers to the CY 2017 Quality Payment Program and CY 2018 Quality Payment Program final rules (81 FR 77227 through 77229, and 82 FR 53674 through 53680, respectively).

Objective: Protect Patient Health Information.

Objective: Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the

implementation of appropriate technical, administrative, and physical safeguards.

Security Risk Analysis Measure: Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data created or maintained by CEHRT in accordance with requirements in §§ 164.312(a)(2)(iv) and 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the MIPS eligible clinician's risk management process.

Objective: Electronic Prescribing.

Objective: Generate and transmit permissible prescriptions electronically.

e-Prescribing Measure: At least one permissible prescription written by the MIPS eligible clinician is queried for a drug formulary and transmitted electronically using CEHRT.

Denominator: Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the performance period.

Numerator: The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.

Exclusion: Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.

Objective: Patient Electronic Access.

Objective: The MIPS eligible clinician provides patients (or patient-authorized representative) with timely electronic access to their health information and patient-specific education.

Patient Access Measure: For at least one unique patient seen by the MIPS eligible clinician: (1) The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programing Interface (API) in the MIPS eligible clinician's CEHRT.

Denominator: The number of unique patients seen by the MIPS eligible clinician during the performance period.

Numerator: The number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications of the API in the MIPS eligible clinician's CEHRT.

Patient-Specific Education Measure: The MIPS eligible clinician must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to at least one unique patient seen by the MIPS eligible clinician.

Denominator: The number of unique patients seen by the MIPS eligible clinician during the performance period.

Numerator: The number of patients in the denominator who were provided electronic access to patient-specific educational resources using clinically relevant information identified from CEHRT during the performance period.

Objective: Coordination of Care Through Patient Engagement.

Objective: Use CEHRT to engage with patients or their authorized representatives about the patient's care.

View, Download, Transmit (VDT) Measure: During the performance period, at least one unique patient (or patient-authorized representatives) seen by the MIPS eligible clinician actively engages with the EHR made accessible by the MIPS eligible clinician by either: (1) Viewing, downloading or transmitting to a third party their health information; or (2) accessing their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the MIPS eligible clinician's CEHRT; or (3) a combination of (1) and (2).

Denominator: Number of unique patients seen by the MIPS eligible clinician during the performance period.

Numerator: The number of unique patients (or their authorized representatives) in the denominator who have viewed online, downloaded, or transmitted to a third party the patient's health information during the performance period and the number of unique patients (or their authorized representatives) in the denominator who have accessed their health information through the use of an API during the performance period.

Secure Messaging Measure: For at least one unique patient seen by the MIPS eligible clinician during the performance period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative).

Denominator: Number of unique patients seen by the MIPS eligible clinician during the performance period.

Numerator: The number of patients in the denominator for whom a secure electronic message is sent to the patient (or patient-authorized representative) or in response to a secure message sent by the patient (or patient-authorized representative), during the performance period.

Patient-Generated Health Data Measure: Patient-generated health data or data from a non-clinical setting is incorporated into the CEHRT for at least one unique patient seen by the MIPS eligible clinician during the performance period.

Denominator: Number of unique patients seen by the MIPS eligible clinician during the performance period.

Numerator: The number of patients in the denominator for whom data from non-clinical settings, which may include patient-generated health data, is captured through the CEHRT into the patient record during the performance period.

Objective: Health Information Exchange.

Objective: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other health care providers into their EHR using the functions of CEHRT.

Send a Summary of Care Measure: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider (1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

Denominator: Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician.

Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was created using CEHRT and exchanged electronically.

Exclusion: Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.

Request/Accept Summary of Care Measure: For at least one transition of care or referral received or patient encounter in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician receives or retrieves and incorporates into the patient's record an electronic summary of care document.

Denominator: Number of patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition or referral or has never before encountered the patient and for which an electronic summary of care record is available.

Numerator: Number of patient encounters in the denominator where an electronic summary of care record received is incorporated by the clinician into the CEHRT.

Exclusion: Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.

Clinical Information Reconciliation Measure: For at least one transition of care or referral received or patient encounter in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician performs clinical information reconciliation. The MIPS eligible clinician must implement clinical information reconciliation for the following three clinical information sets: (1) Medication. Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy. Review of the patient's known medication allergies; and (3) Current Problem list. Review of the patient's current and active diagnoses.

Denominator: Number of transitions of care or referrals during the performance period for which the MIPS eligible clinician was the recipient of the transition or referral or has never before encountered the patient.

Numerator: The number of transitions of care or referrals in the denominator where the following three clinical information reconciliations were performed: Medication list; medication allergy list; and current problem list.

Objective: Public Health and Clinical Data Registry Reporting.

Objective: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.

Immunization Registry Reporting Measure: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

Syndromic Surveillance Reporting Measure: The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care setting.

Electronic Case Reporting Measure: The MIPS eligible clinician is in active engagement with a public health agency to electronically submit case reporting of reportable conditions.

Public Health Registry Reporting Measure: The MIPS eligible clinician is in active engagement with a public health agency to submit data to public health registries.

Clinical Data Registry Reporting Measure: The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.

(f) Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians

(i) Measure Summary Overview

In the CY 2019 PFS proposed rule (83 FR 35920 through 35932), we proposed to adopt beginning with the performance period in 2019 the existing Promoting Interoperability objectives and measures as finalized in the CY 2018 Quality Payment Program final rule (82 FR 53674 through 53680) with several proposed changes as discussed herein, including the addition of new measures, removal of some of the existing measures, and modifications to the specifications of some of the existing measures. We did not propose to continue the Promoting Interoperability transition objectives and measures (see 82 FR 53674 through 53676) beyond the 2018 MIPS performance period because the 2015 Edition of CEHRT will be required beginning with the MIPS performance period in 2019. Our intent for these proposed changes is to ensure the measures better focus on the effective use of health IT, particularly for interoperability, and to address concerns stakeholders have raised through public forums and in public comments related to the perceived burden associated with the current measures in the program. As stated in the CY 2017 Quality Payment Program final rule (81 FR 77216) our priority is to finalize reporting requirements for the Promoting Interoperability performance category that incentivizes performance and reporting with minimal complexity and reporting burden. In addition, we acknowledged that while we believe all of the measures of the Promoting Interoperability performance category are important, we must also balance the need for these data with data collection and reporting burden (81 FR 77221).

In CY 2017, we initiated an informal process outside of rulemaking for submission of new Promoting Interoperability performance category measures for potential inclusion in the Year 3 Quality Payment Program proposed rule. We prioritized measures that build on interoperability and health information exchange, the advanced use of CEHRT using 2015 Edition Standards and Certification Criteria, improve program efficiency and flexibility, measure patient outcomes, emphasize patient safety, and support improvement activities and quality performance categories of MIPS. In addition, and as we indicated in the CY 2018 Quality Payment Program proposed rule (82 FR 30079), we sought new measures that may be more broadly applicable to MIPS eligible clinicians who are Nurse Practitioners (NPs), Physician Assistants (PAs), Certified Registered Nurse Anesthetists (CRNAs) and Clinical Nurse Specialists (CNSs).

During this initial submission period, various MIPS eligible clinicians, stakeholders and health IT developers submitted new measures for consideration via an application posted on the CMS website, now hosted at *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/CallForMeasures.html*. Through our review process, which included representation from the ONC, as well as various stakeholder listening sessions, we identified measure submissions that met our criteria and aligned with the Promoting Interoperability performance category goals and priorities, as well as broader HHS initiatives related to the opioid crisis.[20] As a result of this process, we proposed two measures, Query of PDMP and Verify Opioid Treatment Agreement.

We proposed to remove six measures from the Promoting Interoperability objectives and measures beginning with the performance period in 2019. Two of

[20] *https://www.hhs.gov/opioids/about-the-epidemic/index.html*; *https://www.healthit.gov/opioids*.

the measures we proposed to remove—Request/Accept Summary of Care and Clinical Information Reconciliation—would be replaced by the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, which combines the functionalities and goals of the two measures it is replacing. Four of the measures—Patient-Specific Education; Secure Messaging; View, Download, or Transmit; and Patient-Generated Health Data—would be removed because they have proven burdensome to MIPS eligible clinicians in ways that were unintended and may detract from clinicians' progress on current program priorities. We stated that although the measures proposed for removal would no longer need to be submitted if we finalize the proposal to remove them, MIPS eligible clinicians may still continue to use the standards and functions of those measures based on the preferences of their patients and their practice needs. We stated our belief that this burden reduction would enable MIPS eligible clinicians to focus on new measures that further interoperability, advances of innovation in the use of CEHRT and the exchange of health care information.

As discussed in the proposed scoring methodology in section III.H.3.h.(5)(f) of the proposed rule, we proposed to add three new measures to the Promoting Interoperability objectives and measures beginning with the performance period in 2019. For the e-Prescribing objective, we proposed the two new measures referenced earlier, Query of PDMP and Verify Opioid Treatment Agreement, both of which support HHS initiatives related to the treatment of opioid and substance use disorders by helping health care providers avoid inappropriate prescriptions, improving coordination of prescribing amongst health care providers and focusing on the advanced use of CEHRT. For the Health Information Exchange objective, we proposed a new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information, which builds upon and replaces the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures, while furthering interoperability and the exchange of health information.

We also proposed to modify some of the existing Promoting Interoperability performance category objectives and measures beginning with the performance period in 2019. We proposed to rename the Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information. In addition, we proposed to rename the Patient Electronic Access objective to Provider to Patient Exchange, and proposed to rename the remaining measure, Provide Patient Access to Provide Patients Electronic Access to Their Health Information. We proposed to eliminate the Coordination of Care Through Patient Engagement objective and all of its associated measures as described earlier. Finally, we proposed to rename the Public Health and Clinical Data Registry Reporting objective to Public Health and Clinical Data Exchange and require reporting on at least two measures of the MIPS eligible clinician's choice from the following: Immunization Registry Reporting; Syndromic Surveillance Reporting, Electronic Case Reporting; Public Health Registry Reporting; and Clinical Data Registry Reporting. In addition, we proposed exclusion criteria for each of these measures.

Finally, we solicited comment on a potential new measure Health Information Exchange Across the Care Continuum under the Health Information Exchange objective in which a MIPS eligible clinician would send an electronic summary of care record, or receive and incorporate an electronic summary of care record, for transitions of care and referrals with a health care provider other than a MIPS eligible clinician. The measure would include health care providers in care settings including but not limited to long term care facilities and post-acute care providers such as skilled nursing facilities, home health, and behavioral health settings.

As we stated in the proposed rule (83 FR 35921) we understand from previous listening sessions that EHR vendors and developers will need time to develop, test and implement new measures, and MIPS eligible clinicians will need time to implement as well as establish and test their processes and workflows. As indicated above and in the discussion of the proposed scoring methodology in section III.H.3.h.(5)(d) of the proposed rule, we proposed three new measures (Query of PDMP, Verify Opioid Treatment Agreement, and Support Electronic Referral Loops by Receiving and Incorporating Health Information). We proposed that the Query of PDMP and Verify Opioid Treatment Agreement measures would be optional for the performance period in 2019 and bonus points may be earned for reporting on them. We proposed that the Support Electronic Referral Loops by Receiving and Incorporating Health Information would be required beginning with the performance period in 2019 with exclusions available. We proposed to require the Query of PDMP and Verify Opioid Treatment Agreement measures beginning with the performance period in 2020, and we solicited public comment on this proposal.

We noted that the proposals under the Health Information Exchange objective require only consolidation of existing workflows and actions, while certification criteria and standards remain the same as in the CY 2018 Quality Payment Program final rule (82 FR 53677 through 53678). Therefore, we stated our belief that MIPS eligible clinicians could potentially implement this new measure for the performance period in 2019.

The following is a summary of the comments we received on our proposals.

Comment: One commenter stated that for some measures MIPS eligible clinicians and group practices should be able to get credit for actions that are taken outside of the 90-day performance period.

Response: Since the inception of the Quality Payment Program, we have limited the ability to increment the numerator and denominator of measures to actions occurring during the performance period chosen, with the exception of the Security Risk Analysis measure for which the relevant actions may occur any time during the calendar year. The MIPS eligible clinician may select a MIPS performance period that exceeds the 90-day minimum up to a maximum of the full calendar year if they choose. (82 FR 53670).

(ii) Measure Proposals for the e-Prescribing Objective

In the CY 2019 PFS proposed rule (83 FR 35921 through 35925), we proposed two new measures under the e-Prescribing objective. In the CY 2017 Quality Payment Program final rule, we stated that MIPS eligible clinicians will have the option to include or not include controlled substances in the definition of ''permissible prescriptions'' at their discretion where feasible and allowable by law in the jurisdiction where they provide care (81 FR 77227). We believe it is important to consider other requirements specific to electronic prescribing of controlled substances for health care providers to take into account and how this may interact with the proposals under this rulemaking. We are committed to combatting the opioid epidemic by making it a top priority for the agency and aligning its efforts with the HHS opioid initiative to combat misuse and promote programs that support treatment and recovery support services.

We proposed to add two new measures to the e-Prescribing objective that are based on electronic prescriptions for controlled substances (EPCS): Query of PDMP; and Verify Opioid Treatment Agreement. These measures build upon the meaningful use of CEHRT as well as the security of electronic prescribing of Schedule II controlled substances while preventing diversion. For both measures, we proposed to define opioids as Schedule II controlled substances under 21 CFR 1308.12, as they are recognized as having a high potential for abuse with potential for severe psychological or physical dependence. We also proposed to apply the same policies for the existing e-Prescribing measure to both the Query of PDMP and Verify Opioid Treatment Agreement measures, including the requirement to use CEHRT as the sole means of creating the prescription and for transmission to the pharmacy. We stated that MIPS eligible clinicians have the option to include or exclude controlled substances in the e-Prescribing measure denominator as long as they are treated uniformly across patients and all available schedules and in accordance with applicable law. However, because the intent of these two new measures is to improve prescribing practices for controlled substances, MIPS eligible clinicians would have to include Schedule II opioid prescriptions in the numerator and denominator or claim the applicable exclusion. Additionally, we noted the intent of the proposed measures is not to dissuade the prescribing or use of opioids for patients with medical diagnoses or conditions that benefit from their use, such as patients diagnosed with cancer or those receiving hospice. We solicited comment on the impact that implementing this measure could have on patients who receive opioids due to medical diagnoses such as cancer or receiving hospice care as well as treatment of patients under a program involving substance abuse education, treatment, or prevention under 42 CFR part 2.

Additionally, we solicited comment on the federal and state statutory and regulatory requirements that may impact implementation of the Query of PDMP and Verify Opioid Treatment Agreement measures.

We stated that in the event we finalize the new scoring methodology that we proposed in section III.H.3.h.(5)(d) of the proposed rule, MIPS eligible clinicians who claim the exclusion under the existing e-Prescribing measure would automatically receive an exclusion for all three of the measures under the e-Prescribing objective; they would not have to also claim exclusions for the other two measures, Query of PDMP and Verify Opioid Treatment Agreement. We are not finalizing this proposal because we are finalizing the two new measures (Query of PDMP and Verify Opioid Treatment Agreement) are optional, so exclusions would not be necessary for them.

(A) Query of Prescription Drug Monitoring Program (PDMP) Measure

As we stated in the proposed rule (83 FR 35922 through 35923), a PDMP is an electronic database that tracks prescriptions of controlled substances at the State level. PDMPs play an important role in patient safety by assisting in the identification of patients who have multiple prescriptions for controlled substances or may be misusing or overusing them. Querying the PDMP is important for tracking the prescribed controlled substances and improving prescribing practices. The ONC, Centers for Disease Control and Prevention (CDC), Department of Justice (DOJ) and Substance Abuse and Mental Health Services Administration (SAMHSA) have had integral roles in the integration and expansion of PMDPs with health information technology systems. For example, the ONC and SAMHSA collaboratively led the ''Enhancing Access'' project to improve health care provider access to PDMP data utilizing health IT.[21] Likewise, the CDC conducted a process and outcome evaluation of the PDMP EHR Integration and Interoperability Expansion (PEHRIIE) program funded by SAMHSA for nine states between FY 2012 and 2016. The PEHRIIE program goals were to integrate PDMPs into health IT and improve the comprehensiveness of PDMPs through initiating and/or improving interstate data exchange.[22] In addition, the Bureau of Justice Assistance's Harold Rogers Prescription Monitoring Program supports Prescription Drug Monitoring Program Information Exchange (PMIX) through funding, the goal of PMIX is to help states implement a cost-effective solution to facilitate interstate data sharing among PDMPs.[23] Integration of the PDMP with health information technology systems supports improves access to PDMP data, minimizes changes to current workflow and overall burden and optimizes prescribing practices. The intent of the Query of the PDMP measure is to build upon the current PDMP initiatives from Federal partners focusing on prescriptions generated and dispensing of opioids.

Proposed Measure Description: For at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a Prescription Drug Monitoring Program (PDMP) for prescription drug history, except where prohibited and in accordance with applicable law.

We stated that we recognize both the utility and value of addressing PDMP EHR integration and further recognizes the majority of states mandate use of State prescription monitoring programs (PMPs) requiring prescribers/dispensers to access PMP.[24] According to the CDC, State-level policies that enhance PDMPs or regulate pain clinics helped several states drive down opioid prescriptions and overdose deaths.[25] We stated that we are also further aware of the varying integration approaches underway including efforts to integrate a state PDMP into a health information exchange or EHR or other efforts to enhance a user interface of some type, such as risk assessment tools or red flags. We noted federal evaluation resources available to inform integration efforts[26] and believe integration is critical for enhancing health care provider workflow, access to critical PDMP data, and improving clinical care including prescription management.

We proposed that the query of the PDMP for prescription drug history must be conducted prior to the electronic transmission of the Schedule II opioid prescription. MIPS eligible clinicians would have flexibility to query the PDMP using CEHRT in any manner allowed under their State law.

Although the query of the PDMP may currently be burdensome for some MIPS eligible clinicians as part of their current workflow practice, we stated our belief that querying the PDMP is beneficial to optimal prescribing practices and foresee progression toward fully automated queries of the PDMP building upon the current initiatives at the State level.

We proposed to include in this measure all permissible prescriptions and dispensing of Schedule II opioids regardless of the amount prescribed during an encounter in order for MIPS

[21] *https://www.healthit.gov/PDMP* and *https://www.healthit.gov/sites/default/files/work_group_document_integrated_paper_final_0.pdf.*

[22] *https://www.cdc.gov/drugoverdose/pdf/pehriie_report-a.pdf.*

[23] *https://www.bja.gov/funding/Category-5-awards.pdf.*

[24] *http://www.namsdl.org/library/14D3122C-96F5-F53E-E8F23E906B4DE09D/.*

[25] *https://www.cdc.gov/drugoverdose/policy/successes.html.*

[26] *https://www.cdc.gov/drugoverdose/pdf/pehriie_report-a.pdf.*

eligible clinicians to identify multiple health care provider episodes (physician shopping), prescriptions of dangerous combinations of drugs, prescribing rates and controlled substances prescribed in high quantities. We requested comment on these policy proposals, including whether additional queries should be performed and under which circumstances. In addition we solicited comment on whether the query should have additional constraints concerning when it should be performed.

Denominator: Number of Schedule II opioids electronically prescribed using CEHRT by the MIPS eligible clinician during the performance period.

Numerator: The number of Schedule II opioid prescriptions in the denominator for which data from CEHRT is used to conduct a query of a PDMP for prescription drug history except where prohibited and in accordance with applicable law. A numerator of at least one is required to fulfill this measure.

Exclusion (beginning in 2020): Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids in accordance with applicable law during the performance period. We proposed that the exclusion criteria would be limited to prescriptions of Schedule II opioids as the measure action is limited to prescriptions of Schedule II opioids only and does not include any other types of electronic prescriptions. We also requested comment on the proposed exclusion criteria and whether there are circumstances which may justify other exclusions for the Query of PDMP measure and what those circumstances might be including medical diagnoses such as cancer or patients under care of hospice.

We noted that we also understand that PDMP integration is not currently in widespread use for CEHRT, and many MIPS eligible clinicians may require additional time and workflow changes at the point of care before they can meet this measure without experiencing significant burden. For instance, many MIPS eligible clinicians will likely need to manually enter the data into CEHRT to document the completion of the query of the PDMP action. In addition, some MIPS eligible clinicians may also need to conduct manual calculation of the measure. Even for those MIPS eligible clinicians that have achieved successful integration of a PDMP with their EHR, this measure may not be machine calculable, for instance, in cases where the MIPS eligible clinician follows a link within the EHR to a separate PDMP system. For the purposes of meeting this measure, we noted there is no existing certification criteria for the query of a PDMP. However, we stated our belief that the use of structured data captured in the CEHRT can support querying a PDMP through the broader use of health IT. We solicited public comment on whether ONC should consider adopting standards and certification criteria to support the query of a PDMP, and if such criteria were to be adopted, on what timeline should CMS require their use to meet this measure.

We noted the NCPDP SCRIPT 2017071 standard for e-prescribing is now available and can help to support PDMP and EHR integration. We solicited public comment, especially from health care providers and health IT developers on whether they believe use of this standard can support MIPS eligible clinicians seeking to report on this measure, and whether HHS should encourage use of this standard through separate rulemaking.

We solicited comment on the challenges associated with querying the PDMP with and without CEHRT integration and whether this proposed measure should require certain standards, methods or functionalities to minimize burden.

In including EPCS as a component of the measure as proposed, we acknowledged and sought input on perceived and real technological barriers as part of its effective implementation including but not limited to input on two-factor authentication and on the effective and appropriate uses of technology, including the use of telehealth modalities to support established patient and health care provider relationships subsequent to in-person visit(s) and for prescribing purposes.

We also proposed that in order to meet this measure, a MIPS eligible clinician must use the capabilities and standards as defined for CEHRT at 45 CFR 170.315(a)(10)(ii) and (b)(3).

The following is a summary of the comments we received on these proposals.

Comment: One commenter stated that the measure is overly burdensome because view-only data is not sufficient for clinicians and data should be in a format that is acceptable by the receiving EHR system.

Response: We agree that if data exchanged is not supported in a computable format, it may create increased burden to the MIPS eligible clinician. Although we believe the Query of PDMP measure is a necessary step to combat the opioid crisis by taking advantage of health IT capabilities, we agree that the lack of EHR integration with PDMPs is an obstacle to widespread adoption of this measure. We will continue to work with our colleagues across HHS and with stakeholders to develop necessary standards and complementary resources to promote the advancement of PDMP functionality. Over time, we believe the continued advancement of this measure will help further patient safety and reduce provider burden. We are providing bonus points for this measure in CY 2019 and will propose our policy for CY 2020 in future rulemaking.

Comment: Some commenters supported this new measure but stated that there is little or no time for health IT developers to update their products, receive certification and roll these products out to users. Commenters requested that CMS give more lead-time for these type of changes and have the Query of PDMP measure be optional in the 2019 and 2020 MIPS performance periods.

Other commenters stated that while PDMPs play an important role in identifying high-risk patients, and recommended that CMS move more slowly with requiring the measure until PDMPs are more fully integrated into EHRs and clinician workflows.

Response: We acknowledge that there is currently no certified functionality within CEHRT specific to connecting to a PDMP and that support for integration between PDMP systems and EHRs varies widely across States due to variations in laws and technical approaches. We believe that functionality currently in CEHRT may support integration with PDMP systems. While we understand the concern that there is not specific certified functionality to meet this measure, we stated in the proposed rule (83 FR 35923) that MIPS eligible clinicians have the flexibility to query the PDMP in any manner allowed under their State law. We also stated (83 FR 35923) that in order to meet the measure, MIPS eligible clinicians must use the capabilities of their CEHRT defined at § 170.315(a)(10)(ii) and (b)(3).

The certification criteria defined at § 170.315(b)(3) supports this measure because it allows a MIPS eligible clinician to create a new prescription, change a prescription, cancel a prescription, refill a prescription, request fill status notifications and request and receive medication history information to and from pharmacies. PDMPs collect, monitor, and analyze electronically transmitted prescribing and dispensing data submitted by pharmacies and dispensing practitioners. Additionally, the CEHRT criteria defined at § 170.315(a)(10)(ii) defines drug formulary checks, which

are the most useful when utilized with e-Prescribing. These criteria ensure the availability of structured data to support PDMPs through the broader use of health IT and may increase the efficiency and safety of opioid prescribing, while potentially reducing the cost of care.

We are aware of the need for additional time to implement this measure and thus we are making it optional in CY 2019 and will propose our policy for this measure for CY 2020 in future rulemaking.

Comment: One commenter stated that CMS must recognize that the Query of PDMP measure may not provide a complete picture of the patient's medication history.

Response: We agree that the Query of PDMP measure may not provide a complete picture of the patient's medication history; however, it can provide the clinician with information to make a more informed clinical decision, and we believe it is a valuable tool to consider in caring for patients.

Comment: One commenter recommended that CMS and ONC work together to develop a set of national standards for PDMPs, so that the information can be exchanged across a variety of States. Another commenter recommended CMS and ONC develop standards to allow access to a PDMP through a HIE.

Response: We understand States have varying technical approaches for PDMPs and that some states are pursuing strategies that utilize HIEs to help clinicians access PDMPs. We believe these strategies are an important way to increase interoperability and support clinicians' ability to connect with PDMP systems.

We will continue to work with ONC and other stakeholders to encourage the development of standards, which facilitate increased interoperability between PDMPs and other systems, including HIEs and clinician health IT systems.

Comment: A commenter stated that a State lacks a state-wide PDMP and requested an exclusion for MIPS eligible clinicians who do not have a State PDMP to query. Another commenter requested an exclusion for MIPS eligible clinicians who do not prescribe any Schedule II opioids during a 90-day performance period, because the lack of such exclusion could result in MIPS eligible clinicians prescribing an unnecessary Schedule II opioid just to avoid earning a zero for the Promoting Interoperability performance category. One commenter requested that in addition to the proposed exclusion CMS should add an exclusion for MIPS eligible clinicians in states that do not support PDMP integration using the NCPDP SCRIPT or SMART on FHIR standard.

Response: We decline to add any exclusions to the Query of PDMP measure at this time. For CY 2019, exclusions are not available, as the measure is optional.

Comment: Some commenters stated the development of interfaces to connect EHRs to a PDMP vendor solution is underway, but there is a cost to access the PDMP gateway. Other commenters noted that some states charge clinicians fees to use a PDMP and a mandatory measure using PDMPs could add considerable financial burden.

Response: Our goal of burden reduction includes consideration of costs associated with meeting the Promoting Interoperability performance category requirements. We will continue to listen to feedback related to costs and mitigate burden wherever possible and as practicable within the MIPS programs. We will also continue to work with HHS partners and other stakeholder in the creation, harmonization, and promotion of free and open source interoperability standards for EHRs and PDMPs, and we encourage PDMPs across the country to connect to the free and open source RxCheck, a fully operational national hub that enables states to securely and efficiently share PDMP data.

Comment: A few commenters stated that this measure should be Yes/No reporting instead of reporting a numerator and denominator since some states require health care providers to download current PDMP results that are not incorporated into CEHRT. The commenter further stated that having this measure as a numerator/denominator will create significant challenges to capture and calculate the performance of this measure.

Response: We decline to change the format of the measure to a Yes/No metric as we believe that a numerator/denominator reporting format captures the intent of the measure, which is to identify multiple provider episodes (physician shopping), prescriptions of dangerous combinations of drugs, prescribing rates and controlled substances prescribed in high quantities. We believe MIPS eligible clinicians need to demonstrate their performance in meeting these opioid measures.

Comment: A commenter questioned what documentation is required to indicate that they fulfilled the Query of PDMP measure. The commenter stated that in the 2020 MIPS performance period, when the measure is required, MIPS eligible clinicians will need time to figure out how to generate the appropriate documentation.

Response: We understand that many clinicians may be required to manually calculate this measure, and we plan to issue guidance regarding the documentation to retain. This may include MIPS eligible clinicians with EHR-integrated PDMPs, who still have to manually calculate the measure due to the lack of automated functionality. Due to challenges with reporting on this new measure, we will determine through future rulemaking the status of this measure for the 2020 MIPS performance period and beyond.

Comment: A commenter requested that the denominator of the measure be changed from ''electronically prescribed'' to all prescribed Schedule II opioids because entities that are barred from e-prescribing controlled substances would still benefit from incorporating PDMP queries into their workflows.

Response: As we stated in the proposed rule (83 FR 35922), intent of the Query of the PDMP measure is to build upon current PDMP initiatives from federal partners focusing on prescriptions generated and dispensing of opioids. The objectives and measures for the Promoting Interoperability performance category focus on the use of CEHRT. Therefore we decline to expand the denominator of the measure to include Schedule II opioids that are not electronically prescribed.

Comment: One commenter requested clarification as to whether the numerator is intended to capture PMDP queries or user acknowledgement of conducting a PDMP query.

Response: The numerator captures instances were a MIPS eligible clinician conducts a query of a PDMP for prescription medication history, except where prohibited and in accordance with the applicable law. We understand that many clinician systems may not have the ability to capture the number of PDMP queries in an automated fashion, and that these clinicians may need to capture the data and calculate the measure manually. The intent of the measure is to identify multiple provider episodes (physician shopping), prescriptions of dangerous combinations of drugs, prescribing rates and controlled substances prescribed in high quantities.

Comment: A commenter stated that many state PDMPs are not ready to implement direct integration of the PDMP with the EHR. Many commenters stated that this functionality needs to be a part of CEHRT, so that prescribers do not need to leave their EHR and log into a separate system to conduct the query

of the PDMP. Commenters suggested that CMS redesign the measure so that only direct integration is included.

Response: We agree that there are issues associated with the integration of the PDMP with CEHRT and that is why we will establish our policies for the measure for CY 2020 and beyond in future rulemaking.

Comment: One commenter recommended that CMS allow MIPS eligible clinicians to use a health information exchange to access the Schedule II opioid prescription drug history and earn extra points.

Response: We have stated that clinicians may query the PDMP in any fashion allowed under applicable state law, which would include the use of HIEs to access PDMP data.

Comment: A commenter recommended CMS and ONC work together with PDMPs, PDMP health IT vendors, and key standards development organizations (NCPDP and HL7 in particular) to address the interoperability and integration issues when using PDMPs. We note that, while NCPDP provides medication history query specifications that CEHRT support as part of their electronic prescribing capabilities, none of the PDMPs currently support these. The commenter suggested that consideration should be given whether comprehensive interoperability with PDMPs to support both clinicians and patients would benefit from the use of HL7 FHIR© standards.

Response: We recognize that interoperability and integration efforts are in various stages. CMS and ONC continue to work in tandem and with our stakeholders toward our shared goal of interoperability. We encourage work by PDMPs, pharmacies, and health IT developers to use existing and emerging open source standards to ensure greater interoperability between PDMPs and health IT systems and within efficient clinician workflows. The adoption and implementation of these open source standards is important not only for PDMP query functionality but for also other relevant tools, such as automated clinical decision support, that facilitate more informed prescribing practices and improved patient outcomes.

Comment: The commenter stated their state does not let the PDMP be fully integrated with the electronic medical record. The commenter also questioned how CMS envisions clinicians attesting to querying of the PDMP, and it would be helpful to have more guidance from CMS.

Response: If you choose to submit data for CY 2019 for the Query of PDMP measure, you will submit your numerator and denominator. We plan to provide additional information in future rulemaking regarding this measure in CY 2020 and beyond.

Comment: A commenter stated that some states are not planning for EHR systems to interface with a PDMP and even those that are planning for this functionality may face a lengthy process to develop the ability for an EHR to integrate with a PDMP.

Response: We will use this input to help inform our future work and ongoing collaborative efforts with our HHS colleagues, and with other public- and private-sector partners, as appropriate. We will seek comment and suggestions in future rulemaking to ascertain if additional exclusions are needed for MIPS eligible clinicians located in one of the States where PDMPs are not integrated with EHRs.

Comment: Some commenters supported the intent of this measure but did not support the measure as written because it lacks standards. Commenters suggested that CMS work with ONC to develop a national standard for PDMPs.

Response: We will continue to collaborate with our colleagues across HHS, and with other public-and private-sector partners as appropriate.

Comment: A commenter addressed the impact the Query of PDMP measure may have on patients who receive opioids due to medical diagnoses such as cancer or receiving hospice. The commenter stated that patients with cancer, in hospice care and/or end of life patients should be excluded from this measure. The commenter also stated that CMS needed to do more work to define ''cancer patient,'' and whether this included cancer survivors or those with an active cancer diagnosis.

Response: We decline to add an exclusion for this for the 2019 MIPS performance period because the measure is optional and not required. If we propose to require this measure in future years, we may consider this suggestion for an exclusion.

After consideration of the comments we received, we are finalizing the Query of PDMP measure with modification:

Measure Description: For at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law.

For the purposes of this measure, we are defining opioids as Schedule II controlled substances under 21 CFR 1308.12. We are finalizing the proposal to apply the same policies for the existing e-Prescribing measure to the Query of PDMP measure, including the requirement to use CEHRT as the sole means of creating the prescription and for transmission to the pharmacy. The query of the PDMP for prescription drug history must be conducted prior to the electronic transmission of the Schedule II opioid prescription. MIPS eligible clinicians would have flexibility to query the PDMP using CEHRT in any manner allowed under their State law. This measure includes all permissible prescriptions and dispensing of Schedule II opioids regardless of the amount prescribed during an encounter in order for MIPS eligible clinicians to identify multiple health care provider episodes (physician shopping), prescriptions of dangerous combinations of drugs, prescribing rates and controlled substances prescribed in high quantities. To meet this measure, a MIPS eligible clinician must use the capabilities and standards as defined for CEHRT at §§ 170.315(a)(10)(ii) and (b)(3).

Denominator: Number of Schedule II opioids electronically prescribed using CEHRT by the MIPS eligible clinician during the performance period.

Numerator: The number of Schedule II opioid prescriptions in the denominator for which data from CEHRT is used to conduct a query of a PDMP for prescription drug history except where prohibited and in accordance with applicable law. A numerator of at least one is required to fulfill this measure.

As this measure is optional in CY 2019, we are not finalizing exclusions for it. We will propose our policy for the Query of a PDMP measure for CY 2020 in future rulemaking.

(B) Verify Opioid Treatment Agreement Measure

As we stated in the proposed rule at 83 FR 35923, the intent of this measure is for MIPS eligible clinicians to identify whether there is an existing opioid treatment agreement when they electronically prescribe a Schedule II opioid using CEHRT if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days. We stated that we believe seeking to identify an opioid treatment agreement will further efforts to coordinate care between health care providers and foster a more informed review of patient therapy. The intent of the treatment agreement is to clearly outline the responsibilities of both patient and MIPS eligible clinician in the treatment plan. Such a treatment plan can be integrated into care coordination and care plan activities

and documents as discussed and agreed upon by the patient and MIPS eligible clinician. An opioid treatment agreement is intended to support and to enable further coordination and the sharing of substance use disorder (SUD) data with consent, as may be required of the individual.

We stated that we understand from stakeholder feedback during listening sessions that there are varied opinions regarding opioid treatment agreements amongst health care providers. Some are supportive of their use, indicating that treatment agreements are an important part of the prescription of opioids for pain management, and help patients understand their role and responsibilities for maintaining compliance with terms of the treatment. Other health care providers object to their use citing ethical concerns, and creation of division and trust issues in the health care provider–patient relationship. Other concerns stem from possible disconnect between the language and terminology used in the agreement and the level of comprehension on the part of the patient. Because of the debate among practitioners, we requested comment on the challenges this proposed measure may create for MIPS eligible clinicians, how those challenges might be mitigated, and whether this measure should be included as part of the Promoting Interoperability performance category. We also acknowledged challenges related to prescribing practices and multiple State laws which may present barriers to the uniform implementation of this proposed measure. We solicited public comment on the challenges and concerns associated with opioid treatment agreements and how they could impact the feasibility of the proposal.

Proposed Measure Description: For at least one unique patient for whom a Schedule II opioid was electronically prescribed by the MIPS eligible clinician using CEHRT during the performance period, if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days within a 6-month look-back period, the MIPS eligible clinician seeks to identify the existence of a signed opioid treatment agreement and incorporates it into the patient's electronic health record using CEHRT.

We proposed this measure would include all Schedule II opioids prescribed for a patient electronically using CEHRT by the MIPS eligible clinician during the performance period, as well as any Schedule II opioid prescriptions identified in the patient's medication history request and response transactions during a 6-month look-back period, where the total number of days for which a Schedule II opioid was prescribed for the patient is at least 30 days.

We stated that there also may be MIPS eligible clinician burdens specific to identifying the existence of a treatment agreement which could require additional time and changes to existing workflows, determining what constitutes a treatment agreement due to a lack of a definition, standard or electronic format and manual calculation of the measure. We note that there is no certified capability specific to verification and incorporation of an opioid treatment agreement, however, clinicians must use the capabilities and standards defined for CEHRT at §§ 170.315(a)(10) and (b)(3) and 170.205(b)(2) to meet the measure. In addition, limitations in the completeness of care team information may limit the ability of a MIPS eligible clinician to identify all potential sources for querying and obtaining information on a treatment agreement for a specific patient. There are currently pilots in development focused on increasing connectivity and data exchange among health care providers to better integrate behavioral health information, for instance, pilots taking place as part of the federal Demonstration Program for Certified Community Behavioral Health Clinics (CCBHC) [27] includes criteria on how CCBHCs should use health IT to coordinate services and track data on quality measures. Participants in such pilots would potentially have the means necessary to leverage health IT connectivity to query behavioral health data resources and health care providers within their region to identify the existence of an opioid treatment agreement and to successfully integrate patient information from the hospital stay into the care plan for the patient. We solicited comment on other similar pathways to facilitate the identification and exchange of treatment agreements and opioid abuse treatment planning.

We proposed the 6-month look-back period would begin on the date on which the MIPS eligible clinician electronically transmits their Schedule II opioid prescription using CEHRT and provided an illustrative example of this policy in the proposed rule.

We proposed a 6-month look-back period to identify more egregious cases of potential overutilization of opioids and to cover timeframes for use outside the performance period. In addition, we proposed that the 6-month look-back period would utilize at a minimum the industry standard NCDCP SCRIPT v10.6 medication history request and response transactions codified at § 170.205(b)(2)). As ONC has stated (80 FR 62642), adoption of the requirements for NCDCP SCRIPT v10.6 does not preclude developers from incorporating and using technology standards or services not required by regulation in their health IT products.

We did not propose to define an opioid treatment agreement as a standardized electronic document; nor did we propose to define the data elements, content structure, or clinical purpose for a specific document to be considered a ''treatment agreement.'' For this measure, we solicited comment on what characteristics should be part of an opioid treatment agreement including data, content and clinical purpose into CEHRT, including which functionalities could be utilized to accomplish this. We noted that a variety of standards available in CEHRT might support the electronic exchange of opioid abuse related treatment data, such as use of the Consolidated Clinical Document Architecture (C–CDA) care plan template that is currently optional in CEHRT.

We also solicited comment on methods or processes for incorporation of the treatment agreement into CEHRT, including which functionalities could be utilized to accomplish this task.

We solicited comment on whether there are specific data elements that are currently standardized that should be incorporated via reconciliation and if the ''patient health data capture'' functionality (§ 170.315(e)(3)) could be used to incorporate a treatment plan that is not a structured document with structured data elements.

Denominator: Number of unique patients for whom a Schedule II opioid was electronically prescribed by the MIPS eligible clinician using CEHRT during the performance period and the total duration of Schedule II opioid prescriptions is at least 30 cumulative days as identified in the patient's medication history request and response transactions during a 6-month look-back period.

Numerator: The number of unique patients in the denominator for whom the MIPS eligible clinician seeks to identify a signed opioid treatment agreement and, if identified, incorporates the agreement in CEHRT. A numerator of at least one is required to fulfill this measure.

Exclusion (beginning in 2020): Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids in accordance with applicable law during the performance period.

[27] *https://www.samhsa.gov/section-223.*

We proposed that the exclusion criteria would be limited to prescriptions of Schedule II opioids as the measure action is limited to electronic prescriptions of Schedule II opioids only and does not include any other types of electronic prescriptions.

We requested comment on the proposed exclusion criteria and whether there are additional circumstances that should be added to the exclusion criteria and what those circumstances might be including medical diagnoses such as cancer or patients under care of hospice.

We solicited comment on whether these types of agreements could create a burden on clinicians and patients, particularly clinicians who serve patients with cancer or those practicing in hospice, as well as the patients they serve.

We also proposed that, in order to meet this measure, a MIPS eligible clinician must use the capabilities and standards as defined for CEHRT at §§ 170.315(a)(10) and (b)(3) and 170.205(b)(2).

As discussed earlier, we recognize that many health care providers are only beginning to adopt electronic prescriptions for controlled substances (EPCS) at this time. Although we have proposed two new measures which combine EPCS with other actions, we requested comment on whether stakeholders would be interested in a measure focused only on the number of Schedule II opioids prescribed and the successful use of EPCS for permissible prescriptions electronically prescribed.

We solicited comment about the feasibility of such a measure, and whether stakeholders believe this would help to encourage broader adoption of EPCS.

The following is a summary of the comments we received on these proposals.

Comment: A few commenters supported the new Verify Opioid Treatment Agreement measure, but stated concern about the amount of time available for EHR vendors to update systems to meet the requirements of the measure and request CMS give more lead-time for these type of changes. Another commenter requested that CMS remove the requirement to use the capabilities and standards of CEHRT to verify if an opioid treatment agreement exists.

Response: We recognize the measure is technically complex and may require updates to a MIPS eligible clinician's EHR systems in order to effectively perform the functionality associated with this measure. However, we believe there are MIPS eligible clinicians who are already using health IT to verify whether there is an opioid treatment agreement in place before electronically prescribing opioids. We also believe it is important to continue to improve prescribing practices for controlled substances using currently available methods as part of existing workflow practices, and that this particular measure can help lead to improvement in prescribing practices.

As discussed in the proposed rule, we believe there are some ways in which certified health IT may be able to support the electronic exchange of opioid related treatment data, such as use of the C–CDA care plan template that is currently optional in CEHRT. This template contains information on health concerns, goals, interventions, health status evaluation & outcomes sections that could support the development of an opioid treatment agreement. In addition, the ''patient health data capture'' functionality which is part of the 2015 Edition certification criteria (§ 170.315(e)(3)) could be used to incorporate a treatment plan that is not a structured document with structured data elements.

We note that there is no capability within certified health IT to support verification of an opioid treatment agreement. We stated (83 FR 35925) that in order to meet the measure, MIPS eligible clinicians must use the capabilities and standards defined for CEHRT at §§ 170.315(a)(10) and (b)(3) and 170.205(b)(2). The certification criteria defined at § 170.315(a)(10) defines drug formulary checks and preferred drug check lists for a given patient and medication, which are the most useful when utilized with e-Prescribing. These criteria may enable health IT to provide structured data to support querying and may increase the efficiency and safety of opioid prescribing, while potentially reducing the cost of care and confronting the opioid crisis.

The certification criteria defined at § 170.315(b)(3) supports this measure because it allows a health care provider to create a new prescription, change a prescription, cancel a prescription, refill a prescription, request fill status notifications and request and receive medication history information. Additionally, certification criteria defined at § 170.205(b)(2) adopts the NCPDP SCRIPT Standard v10.6 standards and associated implementation specifications for electronic prescribing.

While we understand the above regulations do not specifically define certification criteria and standards for the Verify Opioid Treatment Agreement measure, we believe they may help provide a framework for MIPS eligible clinicians who would like to implement the measure.

Comment: Several commenters expressed concern regarding the calculation of the denominator and potential data inaccuracies because the data is from third party systems and the ability of the EHR to calculate the performance rate is reliant on the quality of the data received. The commenters stated there are no standards regarding the type or format of data that is received. Therefore, the EHR system may be incomplete, making the calculation inaccurate. The commenters recommended that the Verify Opioid Treatment Agreement measure be revised to acknowledge that the EHR will be able to calculate prescription duration only with data supplied.

In addition, a commenter stated the measure is highly problematic and prone to error calculation because the denominator is based on patients who are receiving an electronic prescription for a Schedule II opioid medication and have a total of 30 or more cumulative prescription days on the Schedule II opioid being prescribed in a 6-month look back period. The commenter stated that neither the NCPDP 10.6 Medication History Query nor the NCPDP 2017071 Medication History Query has a required, discrete data field to capture the prescription days. The commenter requested CMS not finalize the measure and not proceed with making the measure optional until it can be better defined. The commenter also stated that if the measure is finalized, that CMS should change its denominator proposal to be based on doses prescribed, as opposed to prescription days.

Response: We understand the measure would be technically complex and potentially burdensome for MIPS eligible clinicians to implement and that the results of the measure may be affected by data quality and availability issues. We may consider modifications to the denominator in future rulemaking.

In addition, as opioid treatment agreements become more widely adopted, we believe this measure may help to encourage health IT vendors to develop innovative solutions to capture data and reduce workflow complexities.

Comment: A commenter requested clarification of the meaning of ''incorporates the agreement'' in CEHRT, as there are no standards about what data elements are included in opioid treatment agreements. The commenter also requested the numerator be changed to the number of

unique patients in the denominator for whom the MIPS eligible clinician has a signed opioid treatment agreement in CEHRT.

Response: As we did not define standards, data elements, content structure or clinical purpose for a specific document to be considered an ''opioid treatment agreement,'' we also did not define what needs to be incorporated into the CEHRT to meet the measure. Rather the intent of an opioid treatment agreement is to support and enable further care coordination and shared decision making. Therefore, we leave it to the discretion of the MIPS eligible clinician to determine what is considered an opioid treatment agreement and how to capture this in their CEHRT.

We decline to change the numerator to those patients for whom the MIPS eligible clinician has a signed opioid treatment agreement in CEHRT. The goal of this measure is to encourage MIPS eligible clinicians to seek to identify an existing opioid treatment agreement for those patients for whom they have prescribed Schedule II opioids, rather than those patients for whom they have successfully identified and incorporated an opioid treatment agreement.

Comment: Many commenters suggested CMS align the requirements of this measure with the similar measure for eligible hospitals and CAHs under the Medicare Promoting Interoperability Program, so that the Verify Opioid Treatment Agreement measure would be optional in the 2019 and 2020 MIPS performance periods.

Response: We appreciate the suggestion to align the requirements of the Verify Opioid Treatment Agreement measure in the Promoting Interoperability performance category with the Medicare Promoting Interoperability Program for eligible hospitals and CAHs. CMS received many similar concerns and feedback on the Verify Opioid Treatment Agreement measure proposal for eligible hospitals and CAHs, which we discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20528 through 20530). The concerns noted by commenters on both the FY 2019 IPPS/LTCH PPS proposed rule and the CY 2019 PFS proposed rule included the varied opinions on the effectiveness of opioid treatment agreements, lack of specified certification standards and criteria, and the complexities of implementing such a measure.

We understand these concerns and believe additional time is necessary to implement this measure before we make it required. Therefore, we are aligning with the Medicare Promoting Interoperability Program for eligible hospitals and CAHs and making the Verify Opioid Treatment Agreement measure optional for the 2019 and 2020 MIPS performance periods. We will include proposals for this measure for future years in future rulemaking.

Comment: Several commenters questioned whether MIPS eligible clinicians who do not prescribe opioids are allowed to claim an exclusion, or is the exclusion limited to those who cannot prescribe opioids because of applicable law.

Response: We are not finalizing the Verify Opioid Treatment Agreement measure as proposed and therefore are not finalizing the exclusion we proposed at 83 FR 35925, which would have allowed any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids in accordance with applicable law during the performance period to claim an exclusion.

Because we are finalizing the measure as optional for both the 2019 and 2020 performance periods, we decline to offer any additional exclusions for this measure.

Comment: One commenter suggested that this measure overlaps with existing quality and improvement activities and thus CMS should work to allow MIPS eligible clinicians who report on measures and activities under the quality and improvement activities performance categories to automatically receive credit in the Promoting Interoperability performance category.

Response: We appreciate the suggestion and are currently considering possible ways that points could be earned across multiple performance categories. We refer readers to our request for comment (83 FR 35932) where we requested input on ways to link these three performance categories.

Comment: A commenter appreciated that the measure is intended to verify whether an opioid treatment agreement exists, rather than mandating the creation of an opioid treatment agreement.

Response: We believe it is important for MIPS eligible clinicians to be able to use an existing opioid treatment agreement if one exists, rather than creating a potentially duplicative agreement.

After consideration of the comments received, we are adopting our proposal for the addition of the Verify Opioid Treatment Agreement measure with modification:

Measure Description: For at least one unique patient for whom a Schedule II opioid was electronically prescribed by the MIPS eligible clinician using CEHRT during the performance period, if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days within a 6-month look-back period, the MIPS eligible clinician seeks to identify the existence of a signed opioid treatment agreement and incorporates it into the patient's electronic health record using CEHRT.

We define opioids as Schedule II controlled substances under 21 CFR 1308.12. We are finalizing the proposal to apply the same policies for the existing e-Prescribing measure to the Verify Opioid Treatment Agreement measure, including the requirement to use CEHRT as the sole means of creating the prescription and for transmission to the pharmacy. This measure includes all Schedule II opioids prescribed for a patient electronically using CEHRT by the MIPS eligible clinician during the performance period, as well as any Schedule II opioid prescriptions identified in the patient's medication history request and response transactions during a 6-month look-back period, where the total number of days for which a Schedule II opioid was prescribed for the patient is at least 30 days.

The 6-month look-back period begins on the date on which the MIPS eligible clinician electronically transmits their Schedule II opioid prescription using CEHRT. The 6-month look-back period must utilize at a minimum the industry standard NCDCP SCRIPT v10.6 medication history request and response transactions codified at § 170.205(b)(2)).

To meet this measure, a MIPS eligible clinician must use the capabilities and standards as defined for CEHRT at §§ 170.315(a)(10) and (b)(3) and 170.205(b)(2).

Denominator: Number of unique patients for whom a Schedule II opioid was electronically prescribed by the MIPS eligible clinician using CEHRT during the performance period and the total duration of Schedule II opioid prescriptions is at least 30 cumulative days as identified in the patient's medication history request and response transactions during a 6-month look-back period.

Numerator: The number of unique patients in the denominator for whom the MIPS eligible clinician seeks to identify a signed opioid treatment agreement and, if identified, incorporates the agreement in CEHRT. A numerator of at least one is required to fulfill this measure.

This measure will be optional in the CY 2019 and 2020 performance periods, so we are not finalizing the proposed exclusion for CY 2020.

(iii) Measures for the Health Information Exchange Objective

As we stated in the proposed rule (83 FR 35925) the Health Information Exchange measures for MIPS eligible clinicians hold particular importance because of the role they play within the care continuum. In addition, these measures encourage and leverage interoperability on a broader scale and promote health IT-based care coordination. However, through our review of the existing measures, we determined that we could potentially improve the measures to further reduce burden and better focus the measures on interoperability in health care provider to health care provider exchange. Such modifications would address a number of concerns raised by stakeholders including:

- Supporting the implementation of effective health IT supported workflows based on a specific organization's needs;
- Reducing complexity and burden associated with the manual tracking of workflows to support health IT measures; and
- Emphasizing within these measures the importance of using health IT to support closing the referral loop to improve care coordination.

We stated that we believe we can potentially improve the existing Health Information Exchange measures to streamline measurement, remove redundancy, reduce complexity and burden, and address stakeholders' concerns about the focus and impact of the measures on the interoperable use of health IT.

In the CY 2019 PFS proposed rule (83 FR 35925 through 35928), we proposed several changes to the current measures under the Health Information Exchange objective. First, we proposed to change the name of the Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information. We also proposed to remove the Clinical Information Reconciliation measure and combine it with the Request/Accept Summary of Care measure to create a new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information. This proposed new measure would include actions from both the Request/Accept Summary of Care measure and Clinical Information Reconciliation measure.

(A) Modifications to the Send a Summary of Care Measure

We proposed to change the name of the Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information measure (83 FR 35925 through 35926), to better reflect the emphasis on completing the referral loop and improving care coordination.

Through public comment and stakeholder correspondence, we have become aware that in the health care industry there is some misunderstanding of the scope of transitions and referrals which must be included in the denominator of this measure. In the event that a MIPS eligible clinician is the recipient of a transition of care or referral, and subsequent to providing care the MIPS eligible clinician transitions or refers the patient back to the referring provider of care, this transition of care should be included in the denominator of the measure for the MIPS eligible clinician. We expect this will help build upon the current provider to provider communication via electronic exchange of summary of care records created by CEHRT required under this measure, further promote interoperability and care coordination with additional health care providers, and prevent redundancy in creation of a separate measure.

In the past, stakeholders have raised concerns that the summary care records shared according to the C–CDA standard included excessive information not relevant to immediate care needs, which increased burden on health care providers. Under the ONC Health IT Certification Program 2015 Edition, CEHRT must have the capability to exchange all of the information in the CCDS as part of a summary care record structured according to the C–CDA standard. We previously finalized in the final rule titled ''Medicare and Medicaid Programs Electronic Health Record Incentive Program—Stage 2: Health Information Technology, Standards Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology'' (hereafter referred to as the ''Stage 2 final rule'') (77 FR 53991 through 53993) that health care providers must transmit all of the CCDS information as part of this summary care record, if known, and that health care providers must always transmit information about the problem list, medications, and medication allergies, or validate that this information is not known.

As finalized in the final rule titled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017; Final Rule'' (hereafter referred to as the ''2015 EHR Incentive Programs final rule'') (80 FR 62852 through 62861), our policy allows health care providers to constrain the information in the summary care record to support transitions of care. For instance, we encouraged health care providers to send a list of items that he or she believes to be pertinent and relevant to the patient's care, rather than a list of all problems, whether active or resolved, that have ever populated the problem list. Although a current problem list must always be included, the health care provider can use his or her judgment in deciding which items historically present on the problem list, medical history list (if it exists in CEHRT), or surgical history list are relevant given the clinical circumstances.

We also wish to encourage MIPS eligible clinicians to use the document template available within the C–CDA which contains the most clinically relevant information required by the receiver. Accordingly, we proposed that MIPS eligible clinicians may use any document template within the C–CDA standard for purposes of the measures under the Health Information Exchange objective. Although a MIPS eligible clinician's CEHRT must be capable of sending the full C–CDA upon request, we believe this additional flexibility will help support clinicians' efforts to ensure the information supporting a transition is relevant.

For instance, when the MIPS eligible clinician is referring to another health care provider the recommended document is the ''Referral Note'' which is designed to communicate pertinent information from a MIPS eligible clinician who is requesting services of another health care provider of clinical or non-clinical services. When the receiving health care provider sends back the information, the most relevant C–CDA document template may be the ''Consultation Note,'' which is generated by a request from a clinician for an opinion or advice from another clinician. Although the 2015 Edition transition of care certification criterion only requires testing to the Continuity of Care Document and Referral Note document templates, we proposed to allow MIPS eligible clinicians the flexibility to use additional C–CDA templates most appropriate to their clinical workflows. Clinicians would need to work with their health IT developer to determine appropriate technical workflows and implementation. For more information about the C–CDA and associated templates, see *http://www.hl7.org/documentcenter/public/standards/dstu/*

CDAR2_IG_CCDA_CLINNOTES_R1_DSTUR2.1_2015AUG.zip.

The following is a summary of the comments we received on these proposals.

Comment: A commenter stated that renaming the measure creates too much confusion and inconvenience because there are too many MIPS eligible clinicians and locations per clinician to keep track of, which undermines the quality of care provided to patients. Other commenters stated that MIPS eligible clinicians are accustomed to the current name and changing the name will only contribute to confusion.

Response: We respectfully decline to retain the current name as we believe that the proposed new name, Support Electronic Referral Loops by Sending Health Information measure, better reflects the emphasis on completing the referral loop and improving care coordination. We also believe that it is important to align measure names across the Medicare Promoting Interoperability Program and the Promoting Interoperability performance category to reduce confusion and burden for health care providers.

Comment: A commenter requested that this measure be modified or removed from the Promoting Interoperability performance category because there is a limited number of specialists that are able to receive the summary of care.

Response: While we understand that there may be challenges associated with this measure, we believe that the sharing of health information with other health care providers treating patients is imperative to improving the quality of care. While we understand that some specialists may be lagging behind in their adoption of CEHRT, the numbers of specialists using CEHRT continues to rise over time. We continue to believe that the use of paper records will continue to diminish and that use of CEHRT will continue to increase. Including this measure as a requirement of the Promoting Interoperability performance category will incentivize clinicians to electronically share the summary of care.

Comment: One commenter addressed our proposal to allow MIPS eligible clinicians to use any document template within the C–CDA for the measures associated with this objective and requested that CMS not expect clinicians to manually select C–CDA templates or portions of templates when sending documents because it adds workflow steps and interferes with solutions that automate sending of information. The commenter recommended that CMS investigate the Integrated Healthcare Enterprise (IHE) summary sections profile for potential future adoption. Other commenters supported allowing MIPS eligible clinicians and groups to determine which data is most appropriate to be shared.

Response: We believe that this additional flexibility allowing MIPS eligible clinicians to use any document template within the C–CDA will help support MIPS eligible clinicians efforts to ensure the information supporting a transition of care is relevant and note that the use of any additional template would be optional for MIPS eligible clinicians. Although MIPS eligible clinicians must have the capability to send the full CCDA upon request, they may choose to send just the items that are pertinent and relevant to the patient's care. The ability to select the most appropriate template will enable the most clinically relevant information to be transmitted. We will work with ONC to consider other suggestions regarding the adoption of other health IT standards and may consider the suggestion to include the IHE summary sections profile in future rulemaking.

Comment: A few commenters requested that CMS allow for flexibility to use any C–CDA formats available to meet the HIE measures to create and electronically send summary of care records.

Response: We believe the proposal to allow MIPS eligible clinicians to use any document template within the C–CDA will provide further flexibility for health care providers to focus on clinically relevant information. We note that CEHRT supports the ability to send and receive C–CDA documents according to Releases 1.1 and 2.1 to support interoperability and exchange. The 2015 Edition transitions of care certification criterion at § 170.315(b)(1) requires Health IT Modules to support the Continuity of Care Document, Referral Note, and (inpatient settings only) Discharge Summary document templates.

While MIPS eligible clinicians' CEHRT must be capable of sending the full C–CDA upon request, we believe this additional flexibility to utilize different functionality within the C–CDA will help support clinicians efforts to ensure the information supporting a transition is relevant. We note that in the use of a document template the clinician would need to work with their developer to determine appropriate technical workflows and implementation.

Comment: Some commenters supported allowing MIPS eligible clinicians and groups to determine which data is most appropriate to be shared. A few commenters agreed with use of any C–CDA document templates available within the C–CDA which contains the most clinically relevant information that may be required by the recipient of the transition or referral. The commenters stated this proposal supports increased flexibility, enables increased information sharing between care providers, and will help providers better understand their patient's history.

Response: We appreciate the feedback by the commenter and agree that this proposal will provide further flexibility for health care providers to focus on clinically relevant information and decrease burden associated with reporting requirements.

Comment: Commenters questioned whether there was an exclusion for the Support Electronic Referral Loops by Sending Health Information measure. A few commenters stated that the lack of an exclusion will unfairly disadvantage MIPS eligible clinicians and practices that are unable to send at least one received summary of care.

Response: While we proposed to change the name of the Send a Summary of Care measure, we did not propose changes to the numerator, denominator or exclusion for the measure. The exclusion remains for this measure.

Exclusion: Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.

After consideration of the comments received, we are finalizing the proposal to change the name of the Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information measure. We are also finalizing the proposal that MIPS eligible clinicians may use any document template within the C–CDA standard for purposes of the measures under the Health Information Exchange objective.

(B) Removal of the Request/Accept Summary of Care Measure

We proposed to remove the Request/Accept Summary of Care measure (83 FR 35926) based on our analysis of the existing measure and in response to stakeholder input.

We stated that, through review of implementation practices based on stakeholder feedback, we believe that the existing Request/Accept Summary of Care measure is not feasible for machine calculation in the majority of cases. The intent of the measure is to identify when MIPS eligible clinicians are engaging with other providers of

care or care team members to obtain up-to-date patient health information and to subsequently incorporate relevant data into the patient record. However, stakeholders have noted the measure specification does not effectively further this purpose. Specifically, the existing measure specification results in unintended consequences where health care providers implement either:

(1) A burdensome workflow to document the manual action to request or obtain an electronic record, for example, clicking a check box to document each phone call or similar manual administrative task, or

(2) A workflow which is limited to only querying internal resources for the existence of an electronic document.

Neither of these two implementation options is desirable when the intent of the measure is to incentivize and encourage health care providers to implement effective workflows to identify, receive, and incorporate patient health information from other health care providers into the patient record.

In addition, our analysis identified that the definition of incorporate within the Request/Accept Summary of Care measure is insufficient to ensure an interoperable result. When this measure was initially finalized in the 2015 EHR Incentive Programs final rule at 80 FR 62860, we did not define ''incorporate'' as we believed it would vary amongst health care provider's workflows, patient population and the referring health care provider. In addition, we noted that the information could be included as an attachment, as a link within the EHR, as imported structured data or reconciled within the record and not exclusively performed through use of CEHRT. Further, stakeholder feedback highlights the fact that the requirement to incorporate data is insufficiently clear regarding what data must be incorporated.

Our intention was that ''incorporate'' would relate to the workflows undertaken in the process of clinical information reconciliation further defined in the Clinical Information Reconciliation measure (80 FR 62852 through 62862). Taken together, the three measures under the Health Information Exchange objective were intended to support the referral loop through sending, receiving, and incorporating patient health data into the patient record. However, stakeholder feedback on the measures suggests that the separation between receiving and reconciling patient health information is not reflective of clinical and care coordination workflows. Further, stakeholders noted, that when approached separately, the incorporate portion of the Request/Accept Summary of Care measure is both inconsistent with and redundant to the Clinical Information Reconciliation measure which causes unnecessary burden and duplicative measure calculation.

The following is a summary of the comments we received on these proposals.

Comment: Commenters supported the removal of this measure, and stated they appreciated CMS' acknowledgement of the challenges of the current Request/Accept Summary of Care measure.

Response: We believe that removing the measure will reduce burden.

Comment: One commenter stated that it is confusing for CMS to state in the proposed rule that measures will be removed, when they are truly just re-named. The commenter stated that the Request/Accept Summary of Care measure and the Clinical Information Reconciliation measure would not be removed. Rather, they would be combined into a new measure named Support Electronic Referral Loops by Receiving and Incorporating Health Information.

Response: While we appreciate this comment, the result of our proposals would be to replace two measures with one measure, resulting in a reduction in the number of measures.

Comment: A commenter requested that CMS maintain the current separate Request/Accept Summary of Care and Clinical Information Reconciliation measures instead of replacing them with the combined measure because MIPS eligible clinicians understand the separate measures.

Response: We disagree and believe that reducing the number of measures reduces burden for MIPS eligible clinicians. Also the proposed measures, Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Incorporating Health Information, align with our focus on the exchange of health care information and aligns with the measures for the Medicare Promoting Interoperability Program.

After consideration of the comments received, we are removing the Request/Accept Summary of Care Measure as proposed.

(C) Removal of the Clinical Information Reconciliation Measure

We proposed to remove the Clinical Information Reconciliation measure (83 FR 35927) to reduce redundancy, complexity, and MIPS eligible clinician burden.

We stated that we believe the Clinical Information Reconciliation measure is redundant in regard to the requirement to ''incorporate'' electronic summaries of care in light of the requirements of the Request/Accept Summary of Care measure. In addition, the measure is not fully health IT based as the exchange of health care information is not required to complete the measure action and the measure specification is not limited to only the reconciliation of electronic information in health IT supported workflows. We stated in the 2015 EHR Incentive Programs final rule at 80 FR 62861 that the clinical information reconciliation process could involve both automated and manual reconciliation to allow the receiving health care provider to work with both electronic data received as well as the patient to reconcile their health information. Further, stakeholder feedback from hospitals, clinicians, and health IT developers indicates that because the measure is not fully based on the use of health IT to meet the measurement requirements, health care providers must engage in burdensome tracking of manual workflows. While the overall activity of clinical information reconciliation supports quality patient care and should be a part of effective clinical workflows, the process to record and track each individual action places unnecessary burden on MIPS eligible clinicians.

The following is a summary of the comments we received on these proposals.

Comment: Commenters supported the removal of the Clinical Information Reconciliation measure and its incorporation with the Request/Accept Summary of Care measure. Some commenters stated that removal of the Clinical Information Reconciliation measure would reduce burden.

Response: We appreciate the support for our proposal and agree that it will reduce burden.

After consideration of the comments received, we are removing the Clinical Information Reconciliation measure as proposed.

(D) Support Electronic Referral Loops by Receiving and Incorporating Health Information Measure

We proposed to add the following new measure for inclusion in the Health Information Exchange objective: Support Electronic Referral Loops by Receiving and Incorporating Health Information (FR 83 35927). This measure would build upon and replace the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures.

Proposed name of measure and description: Support Electronic Referral Loops by Receiving and Incorporating Health Information: For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, medication allergy, and current problem list.

We proposed to combine two existing measures, the Request/Accept Summary of Care measure and the Clinical Information Reconciliation measure, in this new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure to focus on the exchange of health care information as the current Clinical Information Reconciliation measure is not reliant on the exchange of health care information to complete the measure action. We did not propose to change the actions associated with the existing measures; rather, we proposed to combine the two measures to focus on the exchange of the health care information, reduce administrative burden, and streamline and simplify reporting.

CMS and ONC worked together to define the following for this measure:

Denominator: Number of electronic summary of care records received using CEHRT for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.

Numerator: The number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication—Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy—Review of the patient's known medication allergies; and (3) Current Problem List—Review of the patient's current and active diagnoses.

Exclusions: (1) Any MIPS eligible clinician who is unable to implement the measure for a MIPS performance period in 2019 would be excluded from this measure. (2) Any MIPS eligible clinician who receives fewer than 100 transitions of care or referrals or has fewer than 100 encounters with patients never before encountered during the performance period would be excluded from this measure.

We note that these two exclusions for the measure were proposed in different sections of the proposed rule (83 FR 35916, 35927).

We requested comment on the proposed exclusion criteria and whether there are additional circumstances that should be added to the exclusion criteria and what those circumstances might be.

For the proposed measure, the denominator would increment on the receipt of an electronic summary of care record after the MIPS eligible clinician engages in workflows to obtain an electronic summary of care record for a transition, referral or patient encounter in which the MIPS eligible clinician has never before encountered the patient. The numerator would increment upon completion of clinical information reconciliation of the electronic summary of care record for medications, medication allergies, and current problems. The MIPS eligible clinician would no longer be required to manually count each individual non-health-IT-related action taken to engage with other providers of care and care team members to identify and obtain the electronic summary of care record. Instead, the proposed measure would focus on the result of these actions when an electronic summary of care record is successfully identified, received, and reconciled with the patient record. We stated that we believe this approach would allow MIPS eligible clinicians to determine and implement appropriate workflows supporting efforts to receive the electronic summary of care record consistent with the implementation of effective health IT information exchange at an organizational level.

Finally, we proposed to apply our existing policy for cases in which the MIPS eligible clinician determines no update or modification is necessary within the patient record based on the electronic clinical information received, and the MIPS eligible clinician may count the reconciliation in the numerator without completing a redundant or duplicate update to the record. We welcomed public comment on methods by which this specific action could potentially be electronically measured by the MIPS eligible clinician's health IT system—such as incrementing on electronic signature or approval by an authorized health care provider—to mitigate the risk of burden associated with manual tracking of the action, such as having to click check boxes.

We welcomed public comment on these proposals. We solicited comment on methods and approaches to quantify the reduction in burden for MIPS eligible clinicians implementing streamlined workflows for this proposed health IT-based measure. We also solicited comment on the impact these proposed modifications may have for health IT developers in updating, testing, and implementing new measure calculations related to these proposed changes. Specifically, we solicited comment on whether ONC should require developers to recertify their EHR technology as a result of the changes proposed, or whether they should be able to make the changes and engage in testing without recertification, and on the appropriate timeline for such requirements factoring in the proposed continuous 90 day performance period within the calendar year for clinicians. Finally, we solicited comment on whether this proposed new measure that combines the Request/Accept Summary of Care and Clinical Information Reconciliation measures should be adopted, or whether either or both of the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures should be retained in lieu of this proposed new measure.

We stated that in the event we finalize the new scoring methodology we proposed in section III.H.3.h.(5)(d) of the proposed rule, an exclusion would be available for MIPS eligible clinicians who cannot implement the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure for a performance period in CY 2019 and an exclusion for MIPS eligible clinician who receives fewer than 100 transitions of care or referrals or has fewer than 100 encounters with patients never before encountered during the performance period.

We also proposed that, in order to meet this measure, a MIPS eligible clinician must use the capabilities and standards as defined for CEHRT at § 170.315(b)(1) and (2).

We solicited comment on these proposals and our summary and response are below.

Comment: A commenter stated that the incorporation of clinical information within the C–CDA into the receiving clinician's CEHRT is limited by the CEHRT and not the clinician. The commenter recommended that the measure be eliminated and requested that CMS work with ONC to strengthen interoperability requirements.

Response: We are working with ONC to explore and potentially implement many initiatives to strengthen interoperability. We understand that there may be limitations with 2015 CEHRT but we believe that EHR developers and vendors will update their products so the CEHRT will calculate the combined measure and not further burden the MIPS eligible clinician.

Comment: Many commenters supported the proposal to combine the Clinical Information Reconciliation measure with the Request/Accept Summary of Care measure into the proposed Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. Some commenters agreed that the proposed measure will allow MIPS eligible clinicians to focus on the exchange of health care information and reconcile the data in patients' medical records.

Response: We appreciate the commenter's support for efforts to improve processes and technology solutions around closing referral loops. We believe that the combined measure focuses on the exchange of health care information and reduces administrative burden. We also believe that this measure will help incentivize further innovation around interoperable exchange of information to support these processes.

Comment: Some commenters disagreed with our proposal to combine the Clinical Information Reconciliation measure with the Request/Accept Summary of Care measure stating that clinical information reconciliation is important and it should remain a stand-alone measure. They indicated that combining the Clinical Information Reconciliation measure with another measure diminishes its importance. Other commenters stated that combining these measures into one is onerous for both front line staff responsible for running reports, as well as EHR developers and clinicians hoping to improve scores, since they will not fully know which measure to target. Some commenters stated that the name change is extremely confusing. Other commenters stated that this new measure is more burdensome and it will be harder to specifically target issues within the measure because two workflows will be combined.

Response: We believe that the current separation of the measures is burdensome and redundant in the action of incorporation of the summary of care record. In addition, we listened to stakeholder' concerns regarding the separate Request/Accept Summary of Care and Clinical Information Reconciliation measures, which indicated that the separation between receiving and reconciling patient health information is not reflective of clinical and care coordination workflows and the incorporation aspect is redundant to both measures. We agree the process of clinical information reconciliation includes both automated and manual reconciliation to allow the receiving health care provider to work with both the electronic data provided with any necessary review, and to work directly with the patient to reconcile their health information. In addition, we believe that combining the measures of Request/Accept Summary of Care and Clinical Information Reconciliation retains the focus on interoperability and exchange of health information as opposed to the separation of the measures where health information exchange and interoperability was not a focus for clinical information reconciliation.

Comment: One commenter noted the measure exclusion (Any MIPS eligible clinician who receives fewer than 100 transitions of care or referrals or has fewer than 100 encounters with patients never before encountered during the performance period) is causing greater hardship for those clinicians that refer out more than 100 times and therefore must report this measure. While most primary care clinicians refer out more than 100 times in a 90-day period, many specialists do not. If a specialist can claim an exclusion, and therefore, not set up direct messaging capabilities, it may affect the performance on the measure of clinicians that are referring to those specialists if they cannot find someone they refer to that has the capability.

Response: The use of direct messaging is not required to fulfill this measure. Our intent has been to promote and facilitate a wide range of options for the transmission of an electronic summary of care document. Examples of acceptable transmission methods include secure email, Health Information Service Provider (HISP), query-based exchange or use of third party HIE.

Comment: Commenters supported the exclusions for Support Electronic Referrals Loops by Receiving and Incorporating Health Information.

Response: We appreciate the support and believe the exclusions will benefit MIPS eligible clinicians who are unable to implement the measure because they do not refer or transition patients or because they cannot implement the measure for the 2019 MIPS performance period.

After consideration of the public comments we received, we are finalizing the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure as proposed. We are finalizing the proposal to apply the existing policy for cases in which the MIPS eligible clinician determines no update or modification is necessary within the patient record based on the electronic clinical information received, and the MIPS eligible clinician may count the reconciliation in the numerator without completing a redundant or duplicate update to the record.

We are finalizing a MIPS eligible clinician must use the capabilities and standards as defined for CEHRT at § 170.315(b)(1) and (b)(2).

We are adopting the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure as follows:

- *Measure Description: Support Electronic Referral Loops by Receiving and Incorporating Health Information:* For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, mediation allergy, and current problem list.

Denominator: Number of electronic summary of care records received using CEHRT for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.

Numerator: The number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication—Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy—Review of the patient's known medication allergies; and (3) Current Problem List—Review of the patient's current and active diagnoses.

Exclusions: (1) Any MIPS eligible clinician who is unable to implement the measure for a MIPS performance period in 2019 would be excluded from this measure.

(2) Any MIPS eligible clinician who receives fewer than 100 transitions of care or referrals or has fewer than 100 encounters with patients never before encountered during the performance period.

(iv) Measures for the Provider to Patient Exchange Objective

The Provider to Patient Exchange objective for MIPS eligible clinicians builds upon the goal of improved access and exchange of patient data, patient centered communication and coordination of care using CEHRT. We proposed a new scoring methodology in section III.H.3.h.(5)(d) of the proposed rule, under which we proposed to rename the Patient Electronic Access objective to Provider to Patient Exchange, remove the Patient-Specific Education measure and rename the Provide Patient Access measure to Provide Patients Electronic Access to Their Health Information. In addition, we proposed to remove the Coordination of Care through Patient Engagement objective and all associated measures. The existing Promoting Interoperability performance category Patient Electronic Access objective includes two measures and the existing Coordination of Care through Patient Engagement objective includes three measures.

We reviewed the Promoting Interoperability performance category requirements and determined that these proposals could reduce program complexity and burden and better focus on leveraging the most current health IT functions and standards for patient flexibility of access and exchange of information.

In the CY 2019 PFS proposed rule (83 FR 35928 through 35929), we proposed the Provider to Patient Exchange objective would include one measure, the existing Provide Patient Access measure, which we proposed to rename to Provide Patients Electronic Access to Their Health Information.

(A) Modifications To Provide Patient Access Measure

We proposed to change the name of the Provide Patient Access measure to Provide Patients Electronic Access to Their Health Information measure (83 FR 35928) to better reflect the emphasis on patient engagement in their health care and patient's electronic access of their health information through use of APIs.

We proposed to change the measure name to emphasize electronic access of patient health information as opposed to use of paper-based actions and limit the focus to only health IT solutions to encourage adoption and innovation in use of CEHRT (80 FR 62783 through 62784). In addition, we are committed to promoting patient engagement with their healthcare information and ensuring access in an electronic format.

We solicited comment on these proposals and our summary and response are below.

Comment: A commenter supported the new name for the measure but recommended that CMS not require widespread use of APIs for at least 3 years after the final standard for the measure has been published.

Response: We decline to provide additional time to implement this measure. In the 2015 Edition final rule, ONC finalized certification criteria that will enable clinicians using 2015 Edition CEHRT to share information through an API consistent with the requirements of this measure (80 FR 62675). As discussed, we believe that eligible clinicians have already implemented, or are prepared to implement, this functionality as part of the 2015 Edition of CEHRT for 2019 and will be able to fulfill this measure.

Comment: One commenter recommended that CMS establish an exclusion for this measure if the MIPS eligible clinician cannot successfully identify an application that meets their security needs. Another requested an exclusion if the MIPS eligible clinician's EHR does not have the ability to have a portal. A commenter cautioned that CMS must address the risks that this measure poses for systems security and the confidentiality of health information because of its use of APIs and recommended that CMS provide an exclusion for this measure for MIPS eligible clinicians that cannot successfully identify an application that meets their security needs. The commenter also recommended that CMS work with the OCR and the FTC to develop an extensive education program so that consumers can be aware of how application companies may use their data.

Response: We decline to implement exclusion criteria for the Provide Patients Electronic Access to Their Health Information measure as we believe MIPS eligible clinicians should work with their health IT vendors to identify applications that meet their security needs. While we appreciate stakeholder concerns regarding security issues, we believe there are already applications available to consumers that could satisfy security requirements. The 2015 Edition of CEHRT enables clinicians to provide patients with timely access to their health information and make the patient's health information available for the patient (or patient authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the application programming interfaces (API) in the MIPS eligible clinician's CEHRT.

We appreciate commenters' interest in additional educational materials for patients on how they can improve the privacy and security of their health information. We will take this comment into consideration as we consider what other consumer-facing materials are helpful, and we direct commenters to resources currently available from HHS (for example, content and materials such as those available at *https://www.hhs.gov/hipaa/for-individuals/right-to-access/index.html*) and FTC (for example, content and materials such as those available at *https://www.consumer.ftc.gov/topics/online-security*) websites.

Comment: A few commenters requested that CMS confirm that this measure focuses on MIPS eligible clinicians making the information available to patients and does not account for patient use.

Response: The Provide Patients Electronic Access to Their Health Information measure does not require that patients actually access their information. Patients should be able to access their health information on demand, and we encourage MIPS eligible clinicians to maintain the appropriate functionalities for patient access to their health information at all times unless the system is undergoing scheduled maintenance, which should be limited.

Comment: A commenter stated that changing the names of measures with essentially the same meaning is confusing to MIPS eligible clinicians. The Provide Patients Electronic Access to Their Health Information measure should simply be called the Provide Patients Electronic Access measure.

Response: We did not intend to confuse MIPS eligible clinicians. We believe that the name change effectively focuses the electronic aspect of the measure and our focus on leveraging advanced use of HIT. We also believe it is important to align the names of the measures of the Promoting Interoperability performance category with the Medicare Promoting Interoperability Program for eligible hospitals and CAHs. Many health care providers have noted frustration with the differing requirements between the two programs and we believe that through alignment we can reduce much of that frustration.

After consideration of the comments we received, we finalizing the new name, Provide Patients Electronic Access to Their Health Information, as proposed.

(B) Removal of the Patient-Generated Health Data Measure

We proposed to remove the Patient-Generated Health Data (PGHD) measure (83 FR 35928) to reduce complexity and focus on the goal of using advanced EHR technology and functionalities to advance interoperability and health information exchange.

As finalized in the 2015 EHR Incentive Programs final rule at 80 FR 62851, the measure is not fully health IT based as we did not specify the manner in which health care providers would incorporate the data received. Instead, we finalized that health care providers could work with their EHR developers to establish the methods and processes that work best for their practice and needs. We indicated that this could include incorporation of the information using a structured format (such as an existing field in the EHR or maintaining an isolation between the data and the patient record such as incorporation as an attachment, link or text reference which would not require the advanced use of CEHRT). Although we continue to believe that incorporating this data is valuable, we prioritized only those actions which are completed electronically using certified health IT.

We solicited comment on these proposals and our summary and response are below.

Comment: Several commenters disagreed with our proposal to remove this measure as it is essential for encouraging the collection and use of patient-reported outcomes. The commenters urged CMS to retain this measure to encourage MIPS eligible clinicians to establish workflows to collect and integrate these critical data into their medical records, thereby promoting interoperability and patient-centered care. One commenter stated that the removal of this measure signals that patient and caregiver engagement has taken a backseat to provider to provider care coordination. Another stated that the measure is crucial for healthcare to be truly interoperable and person-centered.

Response: Functions and standards related to measures that are no longer required for the Promoting Interoperability performance category may still hold value for some health care providers and may be utilized as best suits their practice and the preferences of their patient population. The removal of measures is not intended to discourage the use of the standards, the implementation of best practices, or conducting and tracking the information for providers' own quality improvement goals.

Comment: Another commenter stated that that the measure did not accomplish its intended goal since we did not specify the manner in which health care providers would incorporate the data received.

Response: We agree that it is important to encourage providers to obtain data generated by patients, for instance, through the use of consumer-facing devices, and utilize this data to inform decision-making and provide more effective patient-centered care. While we are finalizing removal of the Patient-Generated Health Data measure for the reasons discussed in the proposed rule, we will continue to consider ways to encourage this activity.

Comment: Many commenters supported the removal of this measure. A commenter supported the removal of this measure because it is burdensome and takes valuable time away from patient care. Another commenter supported the removal of this measure but mentioned that allowing the transmission of key health data such as home blood pressure readings, finger-stick glucose levels, and other vitals is still beneficial to the patient. This functionality should thus remain available in CEHRT. Another suggested that CMS promote the use of patient-generated health data collected via remote monitoring by encouraging the development of open APIs across CEHRT developers.

Response: While we are removing the measure from the Promoting Interoperability performance category, the functionality is not being removed from 2015 Edition CEHRT. We will continue to work with ONC to encourage the development of innovative API functionality that supports exchange of patient-generated health data.

After consideration of the public comments we received, we are removing the Patient-Generated Health Data measure as proposed.

(C) Removal of the Patient-Specific Education Measure

We proposed to remove the Patient-Specific Education measure (83 FR 35928) as it has proven burdensome to MIPS eligible clinicians in ways that were unintended and detracts from their progress on current program priorities.

The Patient-Specific Education measure was finalized as a performance score measure for MIPS eligible clinicians in the CY 2017 Quality Payment Program final rule with the intent of improving patient health, increasing transparency and engaging patients in their care (81 FR 77228 through 77237).

We stated that we believe that the Patient-Specific Education measure does not align with the current emphasis of the Promoting Interoperability performance category to increase interoperability, or reduce burden for MIPS eligible clinicians. In addition to not including interoperability as a core focus, stakeholders have indicated that this measure does not capture many of the innovative activities around providing patient education, for instance new approaches to integrating patient education within clinical decision support modules. As a result of this lack of alignment, this measure could potentially increase clinician burden.

We solicited comment on this proposal and our summary and response are below.

Comment: Many commenters supported the removal of this measure. A commenter supported the removal of this measure because it is burdensome. Other commenters stated that reporting on this measure takes valuable time away from patient care and leads to clinician frustration and ultimately contributes to burnout. Another commenter agreed with the removal of the measure because it does not align with promoting interoperability.

Response: We appreciate the commenters' support for the removal of this measure.

Comment: Several commenters disagreed with the removal of this measure. One commenter stated that the removal of this measure signals that patient and caregiver engagement has taken a backseat to provider to provider care coordination. Another commenter stated that the measure is vital to improved health literacy that empowers patient self-care which reduces unnecessary utilization and decreases costs. One commenter stated the measure should be used to provide patients with information about relevant clinical trials, medication adherence tools, and opioid management strategies. A few commenters stated that providing patients with relevant education materials raises their health literacy and enables them to be more active in managing their own health. Several commenters recommended that the measure be available for bonus points.

Response: We disagree that the Patient-Specific Education measure should be retained as a required measure. While we believe that there are

merits to the Patient-Specific Education measure as identified by the commenters, we affirm our position that the Patient-Specific Education measure does not align with the current emphasis of the Promoting Interoperability performance category which aims to increase interoperability, leverage the most current health IT functions and standards and reduce burden for MIPS eligible clinicians. We also decline to offer bonus points for this measure. We note that bonus points should be reserved for brand new measures to help to ease the transition to becoming a required measure.

After consideration of the public comments we received, we are removing of the Patient-Specific Education measure as proposed.

(D) Removal of the Secure Messaging Measure

We proposed to remove the Secure Messaging measure (82 FR 35929) as it has proven burdensome to MIPS eligible clinicians in ways that were unintended and detracts from MIPS eligible clinicians' progress on current program priorities.

The Secure Messaging measure was finalized in the CY 2017 Quality Payment Program final rule with the intent to build upon the policy goals of Stage 2 under the EHR Incentive Programs of using CEHRT for health care provider-patient communication (81 FR 77227 through 77236). We stated that we believe that the Secure Messaging measure does not align with the current emphasis of the Promoting Interoperability performance category to increase interoperability or reduce burden for MIPS eligible clinicians. In addition, we stated that we believe there is burden associated with tracking secure messages, including the unintended consequences of workflows designed for the measure rather than for clinical and administrative effectiveness.

We solicited comment on this proposal and our summary and response are below.

Comment: Some commenters opposed the removal of this measure because it supports meaningful improvements in interoperability. Other commenter noted that it must remain a required measure because it ensures that patients can communicate confidentially with their health care providers. Some commenters stated that some health care providers rely on secure messaging to communicate with patients in an effective and timely manner.

Response: We believe that there is a significant burden associated with tracking secure messages. Although we are not requiring the measure, the functionality remains in 2015 Edition CEHRT so MIPS eligible clinicians may continue to utilize the functionality if they choose.

Comment: Many commenters supported the removal of this measure. Some commenters stated that they supported the removal of this measure because it is burdensome, and reporting on this measure takes valuable time away from patient care and leads to clinician frustration and ultimately contributes to burnout.

Response: We agree that this measure may detract from MIPS eligible clinicians' progress on current program priorities such as increasing interoperability and reducing burden.

After consideration of the public comments we received, we are removing the Secure Messaging measure as proposed.

(E) Removal of the View, Download or Transmit Measure

We proposed to remove the View, Download or Transmit measure (83 FR 35929) as it has proven burdensome to MIPS eligible clinicians in ways that were unintended and detracts from their progress on current program priorities.

We stated that we have received MIPS eligible clinician and stakeholder feedback through correspondence, public forums, and listening sessions indicating there is ongoing concern with measures which require patient action for successful submission. We have noted that data analysis on the patient action measures supports stakeholder concerns that barriers exist which impact a clinician's ability to meet them. Stakeholders have indicated that successful submission of the measure is reliant upon the patient, who may face barriers to access which are outside a clinician's control.

After additional review, we noted that successful performance predicated solely on a patient's action has inadvertently created burdens to MIPS eligible clinicians and detracts from progress on Promoting Interoperability measure goals of focusing on patient care, interoperability and leveraging advanced used of health IT. Therefore, we proposed to remove the View, Download or Transmit measure.

We solicited comment on this proposal and our summary and response are below.

Comment: Commenters supported the removal of this measure. One commenter stated that the View, Download, and Transmit measure is challenging because many practices that care for a much older population of patients are at a disadvantage for this measure because many of those patients do not own a computer or even have an email address and in some cases, do not own a cell phone. Another commenter appreciated the proposal to remove this measure and noted that CMS should not hold MIPS eligible clinicians accountable for actions beyond their control.

Response: Previous stakeholder feedback through correspondence, public forums, and listening sessions indicated there is ongoing concern with measures which require health care providers to be accountable for patient actions such as viewing, downloading, or transmitting. We further understand that there are barriers which could negatively impact a MIPS eligible clinician's ability to successfully meet a measure requiring patient action, such as location in remote, rural areas and access to technology including computers, internet and/or email. We believe that removing the patient action measures will allow for focus on program goals of increasing interoperability and patient access to their health information.

Comment: One commenter expressed concern about the removal of this measure and noted that it will limit the effectiveness of driving meaningful improvements in interoperability. One commenter stated that the removal of this measure signals that patient and caregiver engagement has taken a backseat to provider to provider care coordination.

Response: We disagree that the removal of this measure devalues patient and caregiver engagement as we are weighting the Provide Patients Electronic Access to their Health Information measure at 40 points, the highest of any measure in the Promoting Interoperability performance category in recognition of the value of patients having electronic access to their health information. We are removing the View, Download, Transmit measure because of the burden it places on MIPS eligible clinicians to be accountable for patient action.

After consideration of the public comments we received, we are removing the View, Download or Transmit measure as proposed.

In summary, we are removing the Coordination of Care Through Patient Engagement objective and its associated measures: View, Download or Transmit; Secure Messaging; and Patient-Generated Health Data. We are renaming the Patient Electronic Access objective to Provider to Patient Exchange objective and removing the Patient-Specific Education measure. We are renaming the Provide Patient Access

measure to Provide Patients Electronic Access to their Health Information.

(v) Modifications to the Public Health and Clinical Data Registry Reporting Objective and Measures

In connection with the scoring methodology proposed in section III.H.3.h.(5)(d) of the proposed rule, in the CY 2019 PFS proposed rule (83 FR 35929 through 35931), we proposed changes to the Public Health and Clinical Data Registry Reporting objective and five associated measures.

We stated that we believe that public health reporting through EHRs will extend the use of electronic reporting solutions to additional events and care processes, increase timeliness and efficiency of reporting and replace manual data entry.

We proposed to change the name of the objective to Public Health and Clinical Data Exchange and proposed exclusions for each of the associated measures.

Under the new scoring methodology proposed in section III.H.3.h.(5)(d) of the proposed rule, we proposed that a MIPS eligible clinician would be required to submit two of the measures of the clinician's choice from the five measures associated with the objective: Immunization Registry Reporting, Syndromic Surveillance Reporting, Electronic Case Reporting, Public Health Registry Reporting, and Clinical Data Registry Reporting.

In prior rulemaking, we recognized the goal of increasing interoperability through public health registry exchange of data (80 FR 62771). We stated that we continue to believe that public health reporting is valuable in terms of health information exchange between MIPS eligible clinicians and public health and clinical data registries. For example, when immunization information is directly exchanged between EHRs and registries, patient information may be accessed by all of a patient's health care providers for improved continuity of care and reduced health care provider burden, as well as supporting population health monitoring.

We also proposed exclusion criteria for each of the Public Health and Clinical Data Exchange measures beginning with the performance period in 2019. Under the scoring methodology for the Promoting Interoperability performance category for the performance period in 2018 (82 FR 53676 through 53677), the measures associated with the Public Health and Clinical Data Registry Reporting objective are not required for the base score, and thus we did not establish exclusion criteria for them. However, we understand that some MIPS eligible clinicians may not be able to report to public health agencies or clinical data registries due to their scope of practice. Therefore, we proposed the following measure exclusions based on the exclusions finalized in previous rulemaking under the EHR Incentive Programs (80 FR 62862 through 62871).

Measure: Immunization Registry Reporting.

Proposed Exclusions: Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Immunization Registry Reporting measure if the MIPS eligible clinician:

1. Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period.

2. Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the performance period.

3. Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.

Measure: Syndromic Surveillance Reporting.

Proposed Exclusions: Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Syndromic Surveillance Reporting measure if the MIPS eligible clinician:

1. Is not in a category of health care providers from which ambulatory syndromic surveillance data is collected by their jurisdiction's syndromic surveillance system.

2. Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the CEHRT definition at the start of the performance period.

3. Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from MIPS eligible clinicians as of 6 months prior to the start of the performance period.

Measure: Electronic Case Reporting.

Proposed Exclusions: Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Electronic Case Reporting measure if the MIPS eligible clinician:

1. Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the performance period.

2. Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the performance period.

3. Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the performance period.

Measure: Public Health Registry Reporting.

Proposed Exclusions: Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Public Health Reporting measure if the MIPS eligible clinician;

1. Does not diagnose or directly treat any disease or condition associated with a public health registry in the MIPS eligible clinician's jurisdiction during the performance period.

2. Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the performance period.

3. Operates in a jurisdiction where no public health registry for which the MIPS eligible clinician is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the performance period.

Measure: Clinical Data Registry Reporting.

Proposed Exclusions: Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Clinical Data Registry Reporting measure if the MIPS eligible clinician;

1. Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the performance period.

2. Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the performance period.

3. Operates in a jurisdiction where no clinical data registry for which the MIPS eligible clinician is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the performance period.

We solicited comment on the proposed exclusions and whether there are circumstances that would require

additional exclusion criteria for the measures.

In addition, we stated that we intend to propose in future rulemaking to remove the Public Health and Clinical Data Exchange objective and measures no later than CY 2022, and solicited public comment on whether MIPS eligible clinicians will continue to share such data with public health entities once the Public Health and Clinical Data Exchange objective is removed, as well as other policy levers outside of the Promoting Interoperability performance category that could be adopted for continued reporting to public health and clinical data registries, if necessary. As noted above, although we believe that these registries provide the necessary monitoring of public health nationally and contribute to the overall health of the nation, we are also focused on reducing burden and identifying other appropriate venues in which reporting to public health and clinical data registries could be reported. We solicited public comment on the role that each of the public health and clinical data registries should have in the future of the Promoting Interoperability performance category and whether the submission of this data should still be required.

Lastly, we solicited public comment on whether the Promoting Interoperability performance category is the best means for promoting sharing of clinical data with public health entities.

We solicited comment on these proposals and our summary and response are below.

Comment: One commenter stated that these measures should be optional as they continue to remain difficult for MIPS eligible clinicians due to the lack of availability of interoperable public health registries. Another commenter noted that the measures should be a bonus and not required as they note that the path for participation is convoluted and will require an onerous amount of effort on the part of the clinician. Commenters also noted issues with AHRQ's Registry of Patient Registries such as difficulty searching for registries that would fulfill the Promoting Interoperability performance category's requirement.

Response: We disagree as we are trying to simplify scoring by limiting bonus opportunities to brand new measures. Hence we are offering bonus points for reporting the two new measures under the e-Prescribing objective but not the ''new'' measure under the Health Information Exchange objective because it is simply the combination of two existing measures. We know that there are some improvements that need to be made to AHRQ's Registry of Patient Registries and we are working with AHRQ and CDC to improve the search capabilities so that available registries can be easily located.

Comment: Many commenters opposed CMS' intent to remove the Public Health and Clinical Data Exchange objective and measures in the future and noted that interoperability of public health data is still evolving and incentivizes MIPS eligible clinicians to share data with public health agencies. One commenter encouraged CMS to reconsider removing the objective and measures for the following reasons: Many states do not have other policy levers outside the Promoting Interoperability programs and performance category to encourage or enforce public health reporting; CMS and States have spent many years now, using HITECH Act funding, supporting improvements to public health systems and HIEs to encourage health care providers to submit public health data, and thus, the reporting should continue; and in some states public health reporting is one of the driving use cases for participants to connect to their statewide HIE and removing these measures would remove an incentive to encourage health care providers to participate in HIEs. Another commenter expressed concerns about CMS' intention to remove the Public Health and Clinical Data Exchange objectives and measures noting that it is a significant policy lever for those who have yet to engage in this aspect of the program.

Response: We understand the importance of reporting to public health and clinical data registries. We are continuing to focus on burden reduction, as well as other platforms and venues for reporting data to public health and clinical data registries outside of the Promoting Interoperability performance category. We will continue to monitor the data we compile specific to the public health reporting requirements and take the commenters' concerns into consideration in future rulemaking.

Comment: One commenter requested clarification of whether a MIPS eligible clinician can submit to two different registries for purposes of the same measure and get credit for submitting to two registries, or must they report to different registries for purposes of two different measures to receive full credit for the objective.

Response: Although we proposed that a MIPS eligible clinician must report on two measures of their choice to fulfill the Public Health and Clinical Data Registry Reporting objective, we agree that a MIPS eligible clinician should be able to report to two different public health agencies or clinical data registries for purposes of the same measure. Therefore, as previously discussed in section III.H.3.(5)(d) of this final rule, we are finalizing the proposal with modification so that a MIPS eligible clinician may earn full credit for this objective by reporting to two different public health agencies or clinical data registries for purposes of the same measure.

Comment: Some commenters agreed with the Public Health and Clinical Data Exchange reporting requirements proposed, stating they would continue to advance interoperability and improve early detection of outbreaks as well as promote population health strategies.

Response: We appreciate the support for our proposal and believe that public health reporting through EHRs will extend the use of electronic reporting solutions to additional events and care processes and increase the timeliness and efficiency of reporting.

Comment: A few commenters supported the proposed exclusions for the Public Health and Clinical Data Exchange measures. One commenter suggested that the first exclusion for the Immunization Registry Reporting measure be modified to 100 or less immunizations in a performance period.

Response: We decline to expand the first exclusion for the Immunization Registry Reporting measure because if the MIPS eligible clinician is performing any immunizations we believe that the information should be reported to an immunization registry.

Comment: One commenter recommended that CMS specify that exclusions may only be claimed if a MIPS eligible clinician meets exclusions for all of the measures associated with the Public Health and Clinical Data Exchange objective and has made all possible efforts to report on the measures for this objective. The commenter suggested that participation in this objective should be encouraged instead of claiming exclusions, which would not improve interoperability or support improvements to population health. Commenters also stated that public health reporting also supports added value for individuals and reporters by enabling bidirectional information exchange between clinical care and public health.

Response: We agree that MIPS eligible clinicians should try to find public health registries with which they can be in active engagement. We understand the concerns of the commenters and are committed to reducing provider burden

while increasing flexibility. As previously discussed in section III.H.3.(5)(d) of this final rule, we believe the ability to report to two different public health agencies or clinical data registries will promote flexibility in reporting and enables MIPS eligible clinicians to focus on the measures that are most relevant to them and their patient population.

After consideration of the comments we received, we are finalizing our proposals with modification. We are changing the name of the objective to Public Health and Clinical Data Exchange and adopting exclusions for each of the associated measures. As previously discussed in section III.H.3.(5)(d) of this final rule, we are adopting a final policy to allow MIPS eligible clinicians to earn full credit for this objective by reporting to two different public health agencies or clinical data registries for any of the measures associated with the objective.

We may use the comments that we received on the removal of the Public Health and Clinical Data Exchange objectives and measures to inform future rulemaking.

To assist readers in identifying the requirements of CEHRT for the Promoting Interoperability performance category objectives and measures under the scoring methodology we are finalizing in section III.I.3.h.(5)(d) of this final rule, we include Table 43, which includes the 2015 Edition certification criteria required to meet the objectives and measures.

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TABLE 43: Promoting Interoperability Objectives and Measures and Certification Criteria for the 2015 Edition

Objective	Measure	2015 Edition
Protect Patient Health Information.	Security Risk Analysis	The requirements are a part of CEHRT specific to each certification criterion[28].
e-Prescribing	e-Prescribing	§170.315(b)(3)(Electronic Prescribing). §170.315(a)(10) (Drug-Formulary and Preferred Drug List checks)
	Query of PDMP	§170.315(a)(10) (Drug-Formulary and Preferred Drug List checks) and (b)(3) (Electronic Prescribing)
	Verify Opioid Treatment Agreement	§170.315(a)(10) (Drug-Formulary and Preferred Drug List checks) (b)(3) (Electronic Prescribing), and §170.205(b)(2) (Electronic Prescribing Standard)
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	§170.315(b)(1) (Transitions of Care)
	Support Electronic Referral Loops by Receiving and Incorporating Health Information	§170.315(b)(1) (Transitions of Care) §170.315(b)(2) (Clinical Information Reconciliation and Incorporation)
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	§170.315(e)(1) (View, Download, and Transmit to 3rd Party) §170.315(g)(7) (Application Access—Patient Selection) §170.315(g)(8) (Application Access—Data Category Request) §170.315(g)(9) (Application Access—All Data Request) The three criteria combined are the ''API'' certification criteria.
Public Health and Clinical Data Exchange	Immunization Registry Reporting	§170.315(f)(1) (Transmission to Immunization Registries)
	Syndromic Surveillance Reporting	§170.315(f)(2) (Transmission to Public Health Agencies—Syndromic Surveillance) Urgent Care Setting Only
	Electronic Case Reporting	§170.315(f)(5) (Transmission to Public Health Agencies—Electronic Case Reporting)
	Public Health Registry Reporting	EPs may choose one or more of the following: § 170.315(f)(4) (Transmission to Cancer Registries) §170.315(f)(7) (Transmission to Public Health Agencies—Health Care Surveys)
	Clinical Data Registry Reporting	No 2015 Edition health IT certification criteria at this time.

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(vi) Request for Comment—Potential New Measures Health Information Exchange Across the Care Continuum

We are working to introduce additional flexibility to allow MIPS eligible clinicians a wider range of options in selecting measures that are most appropriate to their setting, patient population, and clinical practice improvement goals. For this reason, in the CY 2019 PFS proposed rule (83 FR 35931) we solicited comment on a potential concept for future rulemaking to add two additional measure options related to health information exchange for MIPS eligible clinicians.

We received many comments in response to our request, and we will consider them as we develop future policy regarding the potential new measures that focus on health information exchange across the care continuum.

[28] References from Title 45.

(g) Improvement Activities Bonus Score Under the Promoting Interoperability Performance Category and Future Reporting Considerations

In the CY 2017 Quality Payment Program final rule (81 FR 77202), we discussed our approach to the measurement of the use of CEHRT to allow MIPS eligible clinicians and groups the flexibility to implement CEHRT in a way that supports their clinical needs. Toward that end, we adopted a policy for the 2017 and 2018 performance periods (81 FR 77202–77209 and 82 FR 53664–53670) and codified it at § 414.1380(b)(4)(i)(C)(*2*) to award a bonus score to MIPS eligible clinicians who use CEHRT to complete certain activities in the improvement activities performance category based on our belief that the use of CEHRT in carrying out these activities could further the outcomes of clinical practice improvement.

In the CY 2019 PFS proposed rule (83 FR 35932 through 35935), we proposed significant changes to the scoring methodology and measures beginning with the performance period in 2019. In connection with these changes, we did not propose to continue the bonus for completing certain improvement activities using CEHRT for the performance period in 2019 and subsequent performance periods. As discussed in section III.H.3.h.(5)(b) of the proposed rule, we shifted the focus of this performance category to put a greater emphasis on interoperability and patient access to health information, and we stated that we do not believe awarding a bonus for performing an improvement activity using CEHRT would directly support those goals. While we continued to believe that the use of CEHRT in completing improvement activities is extremely valuable and vital to the role of CEHRT in practice improvement, awarding a bonus in the Promoting Interoperability performance category would not be appropriate in light of the new direction we wanted to take, and we solicited comment on other ways to promote the use of CEHRT.

We invited comments on our decision not to propose to continue the bonus for completing certain improvement activities using CEHRT for the performance period in 2019 and subsequent performance periods, and our responses are below.

Comment: Commenters supported our decision not to continue the bonus points for completing improvement activities using CEHRT.

Response: We appreciate the support and although we are discontinuing the bonus points, we will continue to seek other opportunities to promote the use of CEHRT.

Comment: Some commenters stated that they opposed our decision not to continue the bonus points for completing improvement activities using CEHRT stating that providing bonus points in the Promoting Interoperability performance category represented CMS' understanding that health IT can play an invaluable role in improving outcomes and incentivized MIPS eligible clinicians to incorporate health IT into their practice workflows and clinical activities. The commenters requested that CMS continue to incentivize—but not require—clinicians to use health IT as they accomplish improvement activities.

Response: We are limiting bonus points to brand new measures in the Promoting Interoperability performance category such as the Verify Opioid Treatment Agreement measure. We are exploring opportunities that would allow MIPS eligible clinicians to earn credit across multiple MIPS performance categories. We continue to believe that the use of health IT, telehealth, and connection of patients to community-based services is important. We encourage the use of health IT as we understand it is an important aspect of the care delivery processes described in many of the established improvement activities found at *https://qpp.cms.gov/*. In addition, we encourage stakeholders to submit new improvement activities through the Annual Call for Activities that encourage the use of health IT.

After consideration of the comments received, we are not continuing the bonus points for completing improvement activities using CEHRT.

We acknowledged that the omission of this bonus could be viewed as increasing burden, and sought to counteract that concern by evaluating other methods to reduce burden to offset this potential increase. We have also considered various ways to align and streamline the different performance categories under the MIPS. In lieu of the improvement activities bonus score, we have looked extensively at ways to link three of the performance categories—quality, improvement activities and Promoting Interoperability—to reduce burden and create a more cohesive and closely linked MIPS program. One possibility we have identified is to establish several sets of new multi-category measures that would cut across the different performance categories and allow MIPS eligible clinicians to report once for credit in all three performance categories. Our goal would be to establish several of combined measures so MIPS eligible clinicians could report once for credit across all three performance categories. We only solicited comment on this concept, as we are still evaluating the appropriate measure combinations and feasibility of a multi-category model.

Furthermore, we stated that to promote measurement that provides clinicians with measures that are meaningful to their practices, we intend to consider proposing in future rulemaking MIPS public health priority sets across the four performance categories (quality, improvement activities, Promoting Interoperability, and cost), and solicited comments on this topic.

We thank commenters for their views and we will consider their views as we develop future policy proposals.

(h) Additional Considerations

(i) Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists

In prior rulemaking (82 FR 30079), we discussed our belief that certain types of MIPS eligible clinicians (NPs, PAs, CNSs, and CRNAs) may lack experience with the adoption and use of CEHRT. Because many of these non-physician clinicians were or are not eligible to participate in the Medicare or Medicaid EHR Incentive Program (now known as the Promoting Interoperability Program), we stated that we have little evidence as to whether there are sufficient measures applicable and available to these types of MIPS eligible clinicians under the advancing care information (now known as Promoting Interoperability) performance category. We established a policy for the performance periods in 2017 and 2018 under section 1848(q)(5)(F) of the Act to assign a weight of zero to the advancing care information performance category in the MIPS final score if there are not sufficient measures applicable and available to NPs, PAs, CRNAs, and CNSs. We will assign a weight of zero only in the event that an NP, PA, CRNA, or CNS does not submit any data for any of the measures specified for the advancing care information performance category, but if they choose to report, they will be scored on the advancing care information performance category like all other MIPS eligible clinicians and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act. We stated our intention to use data from the first performance period (2017) to further evaluate the participation of

these MIPS eligible clinicians in the advancing care information performance category and consider for subsequent years whether the measures specified for this category are applicable and available to these MIPS eligible clinicians. In the CY 2019 PFS proposed rule (83 FR 35933), we stated that as we have not yet analyzed the data for the first MIPS performance period, it would be premature to propose to alter our treatment of these MIPS eligible clinicians in year 3.

Accordingly, we proposed to continue this policy for the performance period in 2019 and to codify the policy at § 414.1380(c)(2)(i)(A)(5). We requested public comments on this proposal.

The following is a summary of the comments we received on this proposal.

Comment: One commenter suggested that PAs and NPs not have their Promoting Interoperability performance category reweighted with possible exceptions for small PA and NP-owned practices. The commenter indicated that PAs have been using CEHRT for years and should be held to the same standards and expectations as physicians.

Response: We agree that the goal is to have all MIPS eligible clinicians use CEHRT. However, we believe that at this point in time it is premature to determine whether there are sufficient measures applicable and available to NPs, PAs, CNSs, and CRNAs. We plan to analyze performance data as it becomes available to inform future rulemaking. We note that if NPs and PAs choose to report data for the Promoting Interoperability performance category, they will be scored like all other MIPS eligible clinicians and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act regardless of their Promoting Interoperability performance category score.

After consideration of the comments we received, we will continue the policy for NPs, PAs, CRNAs, and CNSs for the performance period in 2019 as proposed. We are codifying the policy at § 414.1380(c)(2)(i)(A)(5) as proposed.

(ii) Physical Therapists, Occupational Therapists, Clinical Social Workers, and Clinical Psychologists

As discussed in section III.H.3.a. of the proposed rule, in accordance with section 1848(q)(1)(C)(i)(II) of the Act, we proposed to add the following clinician types to the definition of a MIPS eligible clinician, beginning with the performance period in 2019: Physical therapists; occupational therapists; clinical social workers; and clinical psychologists (83 FR 35883 through 35884). For the reasons discussed in prior rulemaking and in the preceding section III.H.3.h.(5)(f) of the proposed rule, we proposed(83 FR 35933) to apply the same policy we adopted for NPs, PAs, CNSs, and CRNAs for the performance periods in 2017 and 2018 to these new types of MIPS eligible clinicians for the performance period in 2019. Because many of these clinician types were or are not eligible to participate in the Medicare or Medicaid Promoting Interoperability Program, we stated that we have little evidence as to whether there are sufficient measures applicable and available to them under the Promoting Interoperability performance category. Thus, we proposed to rely on section 1848(q)(5)(F) of the Act to assign a weight of zero to the Promoting Interoperability performance category if there are not sufficient measures applicable and available to these new types of MIPS eligible clinicians (physical therapists, occupational therapists, clinical social workers, and clinical psychologists). We encouraged all of these new types of MIPS eligible clinicians to report on these measures to the extent they are applicable and available; however, we understand that some of them may choose to accept a weight of zero for this performance category if they are unable to fully report the Promoting Interoperability measures. We stated that we believe this approach is appropriate for their first performance period (in 2019) based on the payment consequences associated with reporting, the fact that many of these types of MIPS eligible clinicians may lack experience with EHR use, and our current uncertainty as to whether we have proposed sufficient measures that are applicable and available to these types of MIPS eligible clinicians. We would use their first performance period to further evaluate the participation of these MIPS eligible clinicians in the Promoting Interoperability performance category and would consider for subsequent years whether the measures specified for this category are applicable and available to these MIPS eligible clinicians.

We stated that these MIPS eligible clinicians may choose to submit Promoting Interoperability performance category measures if they determine that these measures are applicable and available to them; however, if they choose to report, they would be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians and the performance category would be given the weighting prescribed by section 1848(q)(5)(E) of the Act regardless of their Promoting Interoperability performance category score.

We proposed to codify this policy at § 414.1380(c)(2)(i)(A)(*4*).

The following is a summary of the comments we received on this proposal.

Comment: A few commenters stated that they are very pleased that CMS proposed to assign a weight of zero to the Promoting Interoperability performance category for physical and occupational therapists. The commenters stated that this is appropriate because the four included objectives have minimal relevance to therapy. Additionally, commenters noted that PTs and OTs have not received any financial incentives or support for implementing CEHRT, and therefore, it would be inappropriate to require them to report on measures for the Promoting Interoperability performance category.

Response: We will continue to monitor participation of physical therapists, occupational therapists, and clinical psychologists to evaluate whether there are sufficient measures applicable and available to them. Our intention is not to continue the proposed policy in perpetuity. We believe that for increased interoperability and health information exchange it is important for all types of MIPS eligible clinicians to use CEHRT, and we aim to adopt measures for the Promoting Interoperability performance category that are available and applicable to all types of MIPS eligible clinicians.

Comment: A commenter recommended that these types of clinicians not be automatically reweighted and instead recommended the creation of some sort of methodology to encourage health IT utilization and interoperability goals for these clinician types.

Response: We disagree. We believe these specialties may not have sufficient measures applicable and available to them. We believe that through enabling these specialties to report if they are able or be reweighted if they are not, will give these specialties more time if they need it as they may not be familiar with the use of CEHRT. The reweighting will not be forever, but will be in place until we can determine through data analysis that these specialties are reporting in sufficient numbers to require their participation in the Promoting Interoperability performance category.

After consideration of the comments that we received, we are adopting our proposal with modification. In section

III.I.3.a. of this final rule, we are adopting a final policy to add the following types of clinicians to the definition of MIPS eligible clinician: Physical therapist, occupational therapist. qualified speech-language pathologist, qualified audiologist, clinical psychologist, and registered dietitian or nutritional professional. For the reasons discussed in the proposed rule, we will apply the same policy we adopted for NPs, PAs, CNSs, and CRNAs for the performance periods in 2017 and 2018 to each of these new types of MIPS eligible clinicians for the performance period in 2019. We are not adopting a policy related to clinical social workers because they are not being added as MIPS eligible clinicians at this time. We are finalizing the proposed regulation text at § 414.1380(c)(2)(i)(A)(*4*) to reflect these modifications.

(6) APM Scoring Standard for MIPS Eligible Clinicians Participating in MIPS APMs

(a) Overview

As codified at § 414.1370, MIPS eligible clinicians, including those participating in MIPS APMs, are subject to MIPS reporting requirements and payment adjustments, unless excluded on another basis.

In the CY 2017 Quality Payment Program rule, we finalized the APM scoring standard, which is designed to reduce reporting burden for participants in certain APMs by reducing the need for duplicative data submission to MIPS and their respective APMs, and to avoid potentially conflicting incentives between those APMs and the MIPS.

We established at § 414.1370(c) that the MIPS performance period under § 414.1320 applies for the APM scoring standard. We finalized under § 414.1370(f) that, under the APM scoring standard, MIPS eligible clinicians will be scored at the APM entity group level and each MIPS eligible clinician will receive the APM Entity's final MIPS score. In the CY 2019 PFS proposed rule, we proposed to amend § 414.1370(f)(2) to state that if the APM Entity group is excluded from MIPS, all eligible clinicians within that APM Entity group are also excluded from MIPS.

The MIPS final score under the APM scoring standard is comprised of the four MIPS performance categories as finalized at § 414.1370(g): Quality; cost; improvement activities; and advancing care information. In 2018, these performance categories are scored at 50 percent, 0 percent, 30 percent, and 20 percent, respectively.

(b) Summary of Proposals

In the CY 2019 PFS proposed rule, we discussed the following proposed policies:

- We proposed to revise § 414.1370(b)(3) to clarify the requirement for MIPS APMs to assess performance on quality measures and cost/utilization.
- We proposed to modify the Shared Savings Program quality reporting requirements by expanding the reporting exception for solo practitioners such that, beginning in 2019, in the case of a Shared Savings Program ACO's failure to report quality measures as required by the Shared Saving Program, we will allow a solo practitioner to report on any available MIPS measures, including individual measures.
- We proposed to clarify that, beginning in 2019, the complete reporting requirement for Web Interface reporters be modified to specify that if an APM Entity fails to complete reporting for Web Interface measures but successfully reports the CAHPS for ACOs survey, we will score the CAHPS for ACOs survey and apply it towards the APM Entity's quality performance category score. In this scenario, the Shared Savings Program TIN-level reporting exception will not be triggered and all MIPS eligible clinicians within the ACO will receive the APM Entity score.
- We clarified that we will consider each distinct track of an APM and whether it meets the criteria necessary to be a MIPS APM under § 414.1370(b)(1). We further clarified the term ''track'' to refer to a distinct arrangement through which an APM Entity participates in the APM, and that such participation is mutually exclusive of the APM Entity's participation in another ''track'' within the same APM.
- We clarified our interpretation of the rule at § 414.1370(b)(4)(i) for APMs that begin after the first day of the MIPS performance period for the year (currently January 1), where quality measures tied to payment must be reported for purposes of the APM from the first day of the MIPS performance period, and indicated that we consider the first performance year for an APM to begin as of the first date for which eligible clinicians and APM entities participating in the model must report on quality measures under the terms of the APM.
- We proposed to remove the Promoting Interoperability (formerly advancing care information) full-TIN reporting requirement for participants in the Shared Savings Program to allow individual TIN/NPIs to report for the Promoting Interoperability performance category.
- We explained how performance feedback may be accessed by ACO participant TINs in the Shared Savings Program.
- We proposed to update the MIPS APM measure sets that apply for purposes of the APM scoring standard.

(c) MIPS APM Criteria

In the CY 2017 Quality Payment Program final rule, we established at § 414.1370(b) that for an APM to be considered a MIPS APM, it must satisfy the following criteria: APM Entities must participate in the APM under an agreement with CMS or by law or regulation, the APM must require that APM Entities include at least one MIPS eligible clinician on a participation list, the APM must base payment incentives on performance (either at the APM entity or eligible clinician level) on cost/utilization and quality measures, and the APM must be neither a new APM for which the first performance period begins after the first day of the MIPS performance year, nor an APM in the final year of operation for which the APM scoring standard is impracticable.

As stated in the CY 2019 PFS proposed rule (83 FR 35934), it has come to our attention that there may have been some ambiguity in the third criterion at § 414.1370(b)(3). We have received questions as to whether the criterion requires MIPS APMs to base payment incentives on performance on cost/utilization ''measures'', or whether it requires more generally that MIPS APMs base payment incentives on ''cost/utilization.'' Because we did not address this exact point in prior rulemaking and our intended policy is not strictly clear from the regulation text, we clarified in the CY 2019 PFS proposed rule that we intended the word ''measures'' at § 414.1370(b)(3) to modify only ''quality'' and not ''cost/utilization.'' To make this criterion clear, we proposed to modify the regulation to specify that a MIPS APM must be designed in such a way that participating APM Entities are incentivized to reduce costs of care or utilization of services, or both. This proposed change to § 414.1370(b)(3) would make it clear that a MIPS APM could take into account performance in terms of cost/utilization using model design features other than the direct use of cost/utilization measures.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

Comment: We received several comments supporting our proposal to modify the criterion at § 414.1370(b)(3) to clarify that the word ''measures'' only modifies the word ''quality'' and not ''cost/utilization.'' Commenters stated that as proposed, this revision would mean that a MIPS APM could take into account performance in terms of cost/utilization using a cost/utilization measure and/or through other model design features. One commenter noted appreciation of this clarification and stated that this update to § 414.1370(b)(3) will allow participating APM Entities more flexibility when reporting cost/utilization information. Further, this commenter stated that our proposed clarification is consistent with CMS's intent and the implied intent of MACRA. Another commenter expressed appreciation for this clarification and noted that this may increase participation in MIPS.

Response: We agree with commenters that the policy as intended and clarified allows for flexibility in how reporting cost/utilization information is reported. We continue to believe that accounting for cost/utilization performance can be accomplished by taking model design features into account and it is unnecessary to rely solely on cost/utilization measures. Therefore, we are finalizing our proposal to modify § 414.1370(b)(3) to specify that a MIPS APM must be designed in a way that participating APM Entities are incentivized to reduce costs of care or utilization of services, or both. We continue to believe that this change to the regulation text will clarify our intent that a MIPS APM could take into account performance in terms of cost/utilization using model design features other than the direct use of cost/utilization measures. We are revising § 414.1370(b)(3), as proposed, to state that the APM bases payment on performance (either at the APM entity or eligible clinician level) on quality measures and cost/utilization.

We also proposed to clarify that we will consider each distinct track of an APM and whether it meets the criteria, in this final rule, to be a MIPS APM, and that it is possible for an APM to have tracks that are MIPS APMs and tracks that are not MIPS APMs. However, we specified that we will not further consider whether the individual APM Entities or MIPS eligible clinicians participating within a given track each satisfy all of the MIPS APM criteria.

For purposes of this clarification, we understand the term ''track'' to refer to a distinct arrangement through which an APM Entity participates in the APM, and that such participation is mutually exclusive of the APM Entity's participation in another ''track'' within the same APM. For example, we consider the three risk arrangements under OCM to be three separate ''tracks.''

The following is a summary of the public comments received on this clarification and our responses:

Comment: Some commenters supported our clarification. One commenter noted that this clarification allows for maximum flexibility, and allows APM the ability to offer different risk levels, which would, in turn, expand the pool of participants able to join APMs.

Response: We appreciate the support, and agree with the commenter that identifying MIPS APMs by considering each distinct track of an APM against our criteria to be a MIPS APM would be likely to increase the potential number of eligible participants to join MIPS APMs.

We will continue to evaluate whether each distinct track of an APM meets our criteria to be a MIPS APM. We note that this may result in an APM having tracks that are MIPS APMs and tracks that are not MIPS APMs.

We also clarified our interpretation of the regulation at § 414.1370(b)(4)(i) for APMs that begin after the first day of the MIPS performance period for the year (currently January 1), but require participants to report quality data for quality measures tied to payment for the full MIPS performance period, beginning January 1. Under these circumstances where quality measures tied to payment must be reported for purposes of the APM from the first day of the MIPS performance period, we consider the first performance year for an APM to begin as of the first date for which eligible clinicians and APM entities participating in the model must report on quality measures under the terms of the APM.

The following is a summary of the public comments received on this clarification and our responses:

Comment: Commenters noted that this clarification will provide flexibility to those eligible clinicians and APM entities participating in an APM that begins after January 1. Commenters also stated that this clarification would prevent duplicative reporting of quality measures for both the APM and for MIPS, and would be consistent with CMS's efforts to reduce administrative burden.

Response: We appreciate the commenters' support of our clarification. We agree that our interpretation of § 414.1370(b)(4)(i) will prevent duplicative reporting of quality measures and is consistent with our other efforts to reduce administrative burden.

We are clarifying our interpretation of the regulation at § 414.1370(b)(4)(i). Therefore, we consider the first performance year for an APM to begin as of the first date for which eligible clinicians and APM entities participating in the model must report on quality measures under the terms of the APM. We believe that this interpretation will eliminate possibly conflicting incentives between the quality scoring requirements and payment incentive structures under the APM and MIPS and will reduce the likelihood of duplicative reporting of quality information.

Based on the MIPS APM criteria we expect that the following 10 APMs likely will satisfy the requirements to be MIPS APMs for the 2019 performance year:

- Comprehensive ESRD Care Model (all Tracks).
- Comprehensive Primary Care Plus Model (all Tracks).
- Next Generation ACO Model.
- Oncology Care Model (all Tracks).
- Medicare Shared Savings Program (all Tracks).
- Medicare ACO Track 1+ Model.
- Bundled Payments for Care Improvement Advanced.
- Independence at Home Demonstration.
- Maryland Total Cost of Care Model (Maryland Primary Care Program).
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).

Final CMS determinations of MIPS APMs for the 2019 MIPS performance year will be announced via the Quality Payment Program website at *https://qpp.cms.gov/*. Further, we make these determinations based on the established MIPS APM criteria as specified in § 414.1370(b) of our regulation, taking into account the clarifications made in this final rule.

(d) Calculating MIPS APM Performance Category Scores

(i) Quality Performance Category

For the quality performance category, MIPS eligible clinicians in APM Entities will continue to be scored only on the quality measures that are required under the terms of their respective APMs, and available for scoring as specified in § 414.1370(g)(1) and explained in the CY 2017 Quality Payment Program final rule (82 FR 53698, 53692).

(A) Web Interface Reporters

In the CY 2018 Quality Payment Program final rule, we discussed the

requirements for MIPS eligible clinicians participating in a MIPS APM that requires use of the CMS Web Interface for quality reporting, subsequently referred to as ''Web Interface Reporters'' (82 FR 53954). In that rule we finalized a policy to use quality measure data that participating APM Entities submit using the CMS Web Interface and CAHPS surveys as required under the terms of the APM (82 FR 53568, 53692). We also codified at § 414.1370(f)(1) a policy under which, in the event a Shared Savings Program ACO does not report quality measures as required by the Shared Savings Program under § 425.508, each ACO participant TIN will be treated as a unique APM entity for purposes of the APM scoring standard, and may report data for the MIPS quality performance category according to the MIPS submission and reporting requirements.

For the 2019 MIPS performance year, we anticipate that there will be four Web Interface Reporter APMs: The Shared Savings Program; the Medicare ACO Track 1+ Model; Next Generation ACO Model; and the Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).

(aa) Complete Reporting Requirement

Under § 414.1370(f)(1), if a Shared Savings Program ACO does not report data on quality measures as required by the Shared Savings Program under § 425.508, each ACO participant TIN will be treated as a unique APM Entity for purposes of the APM scoring standard and the ACO participant TINs may report data for the MIPS quality performance category according to the MIPS submission and reporting requirements. In the CY 2019 PFS proposed rule (83 FR 35935), we stated that we would like to clarify that any ''partial'' reporting through the CMS Web Interface that does not satisfy the requirements of the Shared Savings Program will be considered a failure to report. Should a Shared Savings Program ACO fail to report, the exception under § 414.1370(f)(1) is triggered. In this scenario, each ACO participant TIN has the opportunity to report quality data to MIPS according to MIPS group reporting requirements to avoid a score of zero for the quality performance category (81 FR 77256).

We recognized that, under this policy, successfully reporting to MIPS according to group reporting requirements may be difficult for solo practitioners, for whom case thresholds and other requirements may make many group reporting measures unavailable. Therefore, we proposed to modify the exception such that beginning in 2019, in the case of a Shared Savings Program ACO's failure to report quality measures as required by the Shared Saving Program, we will also allow a solo practitioner (a MIPS eligible clinician who has only one NPI billing through their TIN), to report on any available MIPS measures, including individual measures, in the event that their ACO fails to complete reporting for all Web Interface measures.

The following is a summary of the public comments received on this clarification and our responses:

Comment: One commenter noted that this modification will increase Shared Savings Program ACO participants' flexibility in the unlikely event that the ACO does not submit quality measures.

Response: We agree with the commenter that allowing solo practitioners to report any available MIPS measures, including individual measures, will allow additional flexibility when reporting to MIPS in the event their ACO fails to complete the reporting of all Web Interface measures.

After consideration of all public comments, we are clarifying that beginning in 2019, in the case of a Shared Savings Program ACO's failure to completely report all Web Interface measures as required by the Shared Savings Program, we will allow a solo practitioner to report on any available MIPS measures, including individual measures.

We also proposed, beginning with the 2019 performance period, to modify the complete reporting requirement for Web Interface reporters to specify that if an APM Entity (in this case, an ACO) fails to complete reporting for Web Interface measures but successfully reports the CAHPS for ACOs survey, we will score the CAHPS for ACOs survey and apply it towards the APM Entity's quality performance category score. In this scenario the Shared Savings Program TIN-level reporting exception will not be triggered and all MIPS eligible clinicians within the ACO will receive the APM Entity score.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Some commenters supported our proposal. Other commenters expressed concern about applying the CAHPS score for ACOs to the APM Entity's quality performance score.

Response: Upon further consideration, we believe that the proposed change could unduly limit the ACO participant TINs' opportunity to achieve the highest possible quality performance category score: By scoring the ACO entity's CAHPS score in this scenario, the entity's total possible quality score would be capped at the total possible CAHPS score. Therefore, in the case where an ACO entity fails to successfully report Web Interface measures but does successfully report CAHPS, we will continue to treat ACO participant TINs as unique APM Entities under the APM scoring standard and will score each TIN only on the MIPS measures it has reported, up to a score of 100 percent for the performance category.

After taking all comments into account, we are not finalizing our proposal to modify the complete reporting requirement for Web Interface reporters to apply the CAHPS for ACOs survey score toward an APM Entity's quality performance category score if an ACO fails to complete reporting for Web Interface measures but successfully reports the CAHPS for ACOs survey.

(B) Other MIPS APMs

Under § 414.1370(g)(1)(ii), the MIPS quality performance category score for a MIPS performance period is calculated for the APM Entity using the data submitted by the APM Entity based on measures specified by us through notice and comment rulemaking and available for scoring for each Other MIPS APM from among those used under the terms of the Other MIPS APM.

In the 2019 MIPS performance year, we anticipate that there will be up to six Other MIPS APMs for which we will use this scoring methodology, based on their respective measure sets and reporting requirements:

- The Oncology Care Model.
- Comprehensive ESRD Care Model.
- Comprehensive Primary Care Plus Model.
- Bundled Payments for Care Improvement Advanced.
- Maryland Total Cost of Care Model (Maryland Primary Care Program).
- Independence at Home Demonstration.

(ii) Promoting Interoperability Performance Category

In the CY 2017 Quality Payment Program final rule (81 FR 77262 through 77264; 81 FR 77266 through 77269), we established a policy at § 414.1370(g)(4)(ii) for MIPS APMs other than the Shared Savings Program, under which we attribute one Promoting Interoperability performance category score to each MIPS eligible clinician in an APM Entity group based on the higher of either individual or group-level data submitted for the MIPS

eligible. We will then use these scores to create an APM Entity group score equal to the average of the highest scores available for each MIPS eligible clinician in the APM Entity group.

For the Shared Savings Program, we also finalized at § 414.1370(g)(4)(i) that ACO participant TINs are required to report on the Promoting Interoperability performance category, and we will weight and aggregate the ACO participant TIN scores to determine an APM Entity group score (81 FR 77258 through 77260). This policy was meant to align requirements between the MIPS Promoting Interoperability measures and the Shared Savings Program ACO–11 measure, which is used to assess Shared Savings Program ACOs based on the MIPS Promoting Interoperability measures. However, we have found that limiting reporting to the ACO participant TIN creates unnecessary confusion, and restricts Promoting Interoperability reporting options for MIPS eligible clinicians who participate in the Shared Savings Program. Therefore, beginning in the 2019 MIPS performance period, we proposed (83 FR 35935) to no longer apply the requirement as finalized at § 414.1370(g)(4)(i) and instead to apply the existing policy at § 414.1370(g)(4)(ii) to MIPS eligible clinicians who participate in the Shared Savings Program so that they may report on the Promoting Interoperability performance category at either the individual or group level like all other MIPS eligible clinicians under the APM scoring standard.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Several commenters supported our proposed policy. One commenter recommended that CMS allow reporting at the individual level only when group-level information is not reported.

Response: We believe that by aligning Shared Savings Program Promoting Interoperability scoring rules with those for the rest of MIPS and MIPS APMs we will reduce confusion while creating opportunities for individual MIPS eligible clinicians to contribute positively to the total ACO Entity score in the event that a participant TIN fails to report on this performance category.

Comment: One commenter requested that CMS maintain the current requirement for ACO participant TIN-level reporting for Promoting Interoperability performance category measures. The commenter noted that although the proposed change increases flexibility, larger ACOs may encounter difficulty managing the Promoting Interoperability reporting for all of the individual MIPS eligible clinicians that bill through TINs of ACO participants, risking a payment consequences for failing to report.

Response: The Promoting Interoperability performance category may be reported at either the individual or group level, not the APM Entity (ACO) level; therefore, this policy change will increase MIPS eligible clinicians' opportunities to report in the event that an ACO participant TIN does not, but should not give rise to a scenario where an ACO's performance category score would be negatively impacted. If the participant TIN reports for the PI performance category, there would be no need for the ACO to manage reporting for individual MIPS eligible clinicians; if the TIN fails to report, the individual MIPS eligible clincians within that TIN would have an opportunity to reduce the negative impact of that failure by reporting individually.

After consideration of the comments received, we are finalizing the proposal to allow MIPS eligible clinicians participating in the Shared Savings Program to report on the Promoting Interoperability performance category at either the individual or group level.

(e) MIPS APM Performance Feedback

As we discussed in the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77270, and 82 FR 53704 through 53705, respectively), MIPS eligible clinicians who are scored under the APM scoring standard will receive performance feedback under section 1848(q)(12) of the Act.

Regarding access to performance feedback, we should note that whereas split-TIN APM Entities and their participants can only access their performance feedback at the APM Entity or individual MIPS eligible clinician level, MIPS eligible clinicians participating in the Shared Savings Program, which is a full-TIN APM, will be able to access their performance feedback at the ACO participant TIN level.

(f) Summary of Finalized Policies

In this section, we are finalizing the following policies:

MIPS APM Criteria:

- We are modifying the MIPS APM criterion at § 414.1370(b)(3) to state that the APM bases payment on performance (either at the APM entity or eligible clinician level) on quality measures and cost/utilization.
- We are finalizing our clarification that we separately evaluate to each distinct track of an APM to determine whether it meets our criteria to be a MIPS APM. We note that this may result in an APM having some tracks that are MIPS APMs and other tracks that are not MIPS APMs.
- We are finalizing our clarification of our interpretation of the regulation at § 414.1370(b)(4)(i). Therefore, we consider the first performance year for an APM to begin as of the first date for which eligible clinicians and APM entities participating in the model must report on quality measures under the terms of the APM. We believe that this will eliminate possibly conflicting incentives between the quality scoring requirements and payment incentive structures under the APM and MIPS and will reduce the likelihood of duplicative reporting of quality information.
- Final determinations of MIPS APMs for the 2019 MIPS performance year will be made by CMS and announced on the QPP website at *https://qpp.cms.gov/*. Further, in making these final determinations for 2019, we will use the MIPS APM criteria established in § 414.1370(b), taking into account the clarifications we are finalizing in this final rule.

Complete Reporting Requirements:

- We are finalizing our policy as proposed so that beginning in 2019, if a Shared Savings Program ACO fails to report quality measures as required by the Shared Savings Program we would also allow a solo practitioner (a MIPS eligible clinician who has only one NPI billing through their TIN), to report on any available MIPS measures, including individual measures.
- We are not finalizing our proposal to modify the complete reporting requirement for Web Interface reporters so that, in the case where a Shared Savings Program ACO fails to complete reporting for Web Interface measures but successfully reports the CAHPS for ACOs survey, we would apply the CAHPS for ACOs survey toward and APM Entity's quality performance category score. Therefore, in the case where a Shared Savings Program ACO fails to successfully report Web Interface measures but does successfully report the CAHPS for ACOs survey, we will continue to treat the ACO participant TINs as unique APM Entities under the APM scoring standard and will score each TIN only on the MIPS measures it has reported.

Promoting Interoperability Performance Category:

- We are finalizing the proposal to allow MIPS eligible clinicians participating in the Shared Savings

Program to report on the Promoting Interoperability performance category at either the individual or group level.

(g) Measure Sets

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TABLE 44: MIPS APM Measure List-- Comprehensive ESRD Care Model

Measure Name	NQF/ Quality ID #	National Quality Strategy Domain	Measure Description	Primary Measure Steward
Diabetes Care: Eye Exam	0055	Effective Clinical Care	Percentage of patients 18–75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	NCQA
Diabetes Care: Foot Exam	0056	Effective Clinical Care	Percentage of patients 18–75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the previous measurement year.	NCQA
Advance Care Plan	0326	Communication and Care Coordination	Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	NCQA
Medication Reconciliation Post-Discharge	0554	Communication and Care Coordination	The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following the discharge in the office by the physicians, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. National Committee for Quality Assurance. This measure is reported as three rates stratified by age group: • Reporting Criteria 1: 18–64 years of age. • Reporting Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and Older.	NCQA
Influenza Immunization for the ESRD Population	Not Endorsed	N/A	Percentage of patients aged 6 months and older seen for a visit between July 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	KCQA
Pneumococcal Vaccination Status	0043	Community/Population Health	Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	NCQA
Screening for Clinical Depression and Follow-Up Plan	0418	Community/Population Health	Percentage of patients aged 12 and older screened for depression on the date of the encounter and using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	CMS
Tobacco Use: Screening and Cessation	0028	Community/Population Health	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received	PCPI Foundation

Measure Name	NQF/ Quality ID #	National Quality Strategy Domain	Measure Description	Primary Measure Steward
Intervention			cessation counseling intervention if identified as a tobacco user.	
Falls: Screening, Risk Assessment, and Plan of Care to Prevent Future Falls	0101	Patient Safety	(A) Screening for Future Fall Risk: Patients who were screened for future fall risk at last once within 12 months. (B) Multifactorial Falls Risk Assessment: Patients at risk of future fall who had a multifactorial risk assessment for falls completed within 12 months. (C) Plan of Care to Prevent Future Falls: Patients at risk of future fall with a plan of care or falls prevention documented within 12 months.	NCQA
ICH CAHPS: Nephrologists' Communication and Caring	0258	N/A	Summary/Survey Measures may include: ● Getting timely care, appointments, and information. ● How well providers communicate. ● Patients' rating of provider. ● Access to specialists. ● Health promotion and education. ● Shared Decision-making. ● Health status and functional status. ● Courteous and helpful office staff. ● Care coordination. ● Between visit communication. ● Helping you to take medications as directed, and ● Stewardship of patient resources.	CMS
ICH CAHPS: Quality of Dialysis Center Care and Operations	0258	N/A	Comparison of services and quality of care that dialysis facilities provide from the perspective of ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease.	CMS
ICH CAHPS: Providing Information to Patients	0258	N/A	Comparison of services and quality of care that dialysis facilities provide from the perspective of ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease.	CMS
ICH CAHPS: Rating of the Nephrologist	0258	N/A	Comparison of services and quality of care that dialysis facilities provide from the perspective of ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease.	CMS
ICH CAHPS: Rating of Dialysis	0258	N/A	Comparison of services and quality of care that dialysis facilities provide from the perspective of	CMS

Measure Name	NQF/ Quality ID #	National Quality Strategy Domain	Measure Description	Primary Measure Steward
Center Staff			ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease.	
ICH CAHPS: Rating of the Dialysis Facility	0258	N/A	Comparison of services and quality of care that dialysis facilities provide from the perspective of ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease.	CMS
Standardized Mortality Ratio	0369	N/A	This measure is calculated as a ratio but expressed as a rate.	CMS
Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR)	Not Endorsed	N/A	The standardized ratio of the observed to expected number of incident patients under age 75 listed on the kidney or kidney-pancreas transplant waitlist or who received a living donor transplant within the first year of initiating dialysis based on the national rate.	CMS
Percentage of Prevalent Patients Waitlisted (PPPW)	Not Endorsed	N/A	The percentage of patients who were on the kidney or kidney-pancreas transplant waitlist.	CMS

TABLE 45: MIPS APM Measure List-- Comprehensive Primary Care Plus (CPC+) Model

Measure Name	NQF/ Quality ID #	National Quality Strategy Domain	Measure Description	Primary Measures Steward
Controlling High Blood Pressure	0018	Effective Treatment/ Clinical Care	Percentage of patients 18–85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9 percent)	0059	Effective Treatment/ Clinical Care	Percentage of patients 18–75 years of age with diabetes who had hemoglobin A1c >9.0 percent during the measurement period.	National Committee for Quality Assurance
Dementia: Cognitive Assessment	2872	Effective Treatment/ Clinical Care	Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	PCPI Foundation
Falls: Screening for Future Fall Risk	0101	Patient Safety	Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
Initiation and Engagement of Alcohol and Other Drug Dependence Treatment	0004	Effective Treatment/ Clinical Care	Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported: a. Percentage of patients who initiated treatment within 14 days of the diagnosis. b. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance
Closing the Referral Loop: Receipt of Specialist Report	Not Endorsed	Communication and Care Coordination	Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	CMS
Cervical Cancer Screening	0032	Effective Treatment/ Clinical Care	Percentage of women 21–64 years of age, who were screened for cervical cancer using either of the following criteria: ● Women age 21–64 who had cervical cytology performed every 3 years. ● Women age 30–64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	National Committee for Quality Assurance
Colorectal Cancer Screening	0034	Effective Treatment/ Clinical Care	Percentage of patients, 50–75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
Diabetes: Eye Exam	0055	Effective Treatment/ Clinical Care	Percentage of patients 18–75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam	National Committee for Quality Assurance

Measure Name	NQF/ Quality ID #	National Quality Strategy Domain	Measure Description	Primary Measures Steward
			(no evidence of retinopathy) in the 12 months prior to the measurement period.	
Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	0028	Community/Population Health	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months and who received cessation counseling intervention if identified as a tobacco user.	PCPI Foundation
Breast Cancer Screening	2372	Effective Treatment/ Clinical Care	Percentage of women 50–74 years of age who had a mammogram to screen for breast cancer.	National Committee for Quality Assurance
CG–CAHPS® Survey 3.0 - modified for CPC+	Not Endorsed	Person and Caregiver-Centered Experience and Outcomes	CG–CAHPS® Survey 3.0	AHRQ
Inpatient Hospital Utilization	Not Endorsed	Communication and Care Coordination	For members 18 years of age and older, the risk-adjusted ratio of observed to expected acute inpatient discharges during the measurement year reported by Surgery, Medicine, and Total.	National Committee for Quality Assurance
Emergency Department Utilization	Not Endorsed	Communication and Care Coordination	For members 18 years of age and older, the risk-adjusted ratio of observed to expected emergency department (ED) visits during the measurement year.	National Committee for Quality Assurance
Diabetes: Medical Attention for Nephropathy	0062	Effective Treatment/ Clinical Care	The percentage of patients 18–75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
Preventive Care and Screening: Depression and Follow-Up Plan	0418	Community/Population Health	Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	PCPI Foundation
Depression Utilization of the PHQ-9 Tool	0712	Effective Treatment/ Clinical Care	The percentage of patients age 18 and older with the diagnosis of major depression or dysthymia who have a completed PHQ-9 during each applicable 4 month period in which there was a qualifying visit.	MN Community Measurement
Preventive Care and Screening: Influenza Immunization	0041	Community/Population Health	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	American Medical Association-convened Physician Consortium for Performance Improvement(R) (AMA-PCPI)
Pneumococcal Vaccination Status for Older	Not Endorsed	Community/Population Health	Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality

Measure Name	NQF/ Quality ID #	National Quality Strategy Domain	Measure Description	Primary Measures Steward
Adults				Assurance
Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet	0068	Effective Treatment/ Clinical Care	Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period.	National Committee for Quality Assurance
Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	Not Endorsed	Effective Treatment/ Clinical Care	Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: ● Adults aged >=21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR ● Adults aged >=21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL–C) level >=190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR ● Adults aged 40–75 years with a diagnosis of diabetes with a fasting or direct LDL–C level of 70–189 mg/dL.	CMS
Use of High-Risk Medications in the Elderly	0022	Patient Safety	Percentage of patients 65 years of age and older who were ordered high-risk medications.	National Committee for Quality Assurance
Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Not Endorsed	Community/Population Health	Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	CMS
Documentation of Current Medications in the Medical Record	0419	Patient Safety	Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	CMS
Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan	0421	Community/Population Health	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous	CMS

Measure Name	NQF/ Quality ID #	National Quality Strategy Domain	Measure Description	Primary Measures Steward
			twelve months of the current encounter.	
Diabetes: Foot Exam	0056	Effective Treatment/ Clinical Care	Percentage of patients 18–75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the previous measurement year.	National Committee for Quality Assurance
Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)	0081	Effective Treatment/ Clinical Care	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40 percent who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge.	PCPI Foundation
Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	0083	Effective Treatment/ Clinical Care	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40 percent who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	PCPI Foundation
Coronary Artery Disease (CAD): Beta-Blocker Therapy-Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40 percent)	0070	Effective Treatment/ Clinical Care	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF <40 percent who were prescribed beta-blocker therapy.	PCPI Foundation
Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture	Not Endorsed	Effective Treatment/ Clinical Care	Percentage of female patients aged 50 to 64 without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	CMS
HIV Screening	Not Endorsed	Community/Population Health	Percentage of patients 15-65 years of age who have ever been tested for human immunodeficiency virus (HIV).	Centers for Disease Control and Prevention (CDC)

Measure Name	NQF/ Quality ID #	National Quality Strategy Domain	Measure Description	Primary Measures Steward
Total Resource Use Population-based PMPM Index (RUI)	1598	N/A	This measure is used to assess the total resource use index population-based per member per month (PMPM). The Resource Use Index (RUI) is a risk adjusted measure of the frequency and intensity of services utilized to manage a provider group's patients. Resource use includes all resources associated with treating members including professional, facility inpatient and outpatient, pharmacy, lab, radiology, ancillary and behavioral health services.	Minneapolis (MN): Health Partners

TABLE 46: MIPS APM Measure List-- Oncology Care Model

Measure Name	NQF/ Quality ID	National Quality Strategy Domain	Measure Description	Primary Measure Steward
Adjuvant chemotherapy is recommended or administered within 4 months (120 days) of diagnosis to patients under the age of 80 with AJCC III (lymph node positive) colon cancer	0223	Communication and Care Coordination	Percentage of patients under the age of 80 with AJCC III (lymph node positive) colon cancer for whom adjuvant chemotherapy is recommended and not received or administered within 4 months (120 days) of diagnosis.	Commission on Cancer, American College of Surgeons
Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer	0387	Communication and Care Coordination	Percentage of female patients aged 18 years and older with Stage I (T1b) through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period.	AMA-convened Physician Consortium for Performance Improvement
Oncology: Medical and Radiation – Plan of Care for Pain	0384	Person and Caregiver-Centered Experience and Outcomes	Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology
Combination chemotherapy is recommended or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1cN0M0, or Stage IB - III hormone receptor negative breast cancer	0559	Communication and Care Coordination	Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage T1cN0M0 (tumor greater than 1 cm), or Stage IB–III, whose primary tumor is progesterone and estrogen receptor negative recommended for multiagent chemotherapy (recommended or administered) within 4 months (120 days) of diagnosis.	Commission on Cancer, American College of Surgeons
Documentation of Current Medications in the Medical Record	0419	Patient Safety	Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over the counters, herbals, and vitamin/mineral/ dietary AND must contain the medications' name, dosage, frequency and route of administration.	CMS
Oncology: Medical and Radiation -Pain Intensity Quantified	0383	Person and Caregiver Centered Experience	Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	Physician Consortium for Performance Improvement Foundation
Patient-Reported Experience of Care	N/A	Person and Caregiver-Centered Experience	Summary/Survey Measures may include:	CMS

Measure Name	NQF/ Quality ID	National Quality Strategy Domain	Measure Description	Primary Measure Steward
		and Outcomes	• Overall measure of patient experience. • Exchanging Information with Patients. • Access. • Shared Decision Making. • Enabling Self-Management. • Affective Communication.	
Preventive Care and Screening: Screening for Depression and Follow-Up Plan	0418	Community/Population Health	Percentage of patients aged 12 and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool and if positive, a follow-up plan is documented on the date of the positive screen.	CMS
Proportion of patients who died who were admitted to hospice for 3 days or more	N/A	N/A	Percentage of OCM-attributed FFS beneficiaries who died and spent at least 3 days in hospice during the measurement time period.	CMS
Risk-adjusted proportion of patients with all-cause ED visits that did not result in a hospital admission within the 6-month episode	N/A	N/A	Percentage of OCM-attributed FFS beneficiaries who had an ER visit that did not result in a hospital stay during the measurement period.	CMS
Risk-adjusted proportion of patients with all-cause hospital admissions within the 6-month episode	N/A	N/A	Percentage of OCM-attributed FFS beneficiaries who were had an acute-care hospital stay during the measurement period.	CMS
Trastuzumab administered to patients with AJCC stage I (T1c) - III and human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy	1858	Efficiency and Cost reduction	Proportion of female patients (aged 18 years and older) with AJCC stage I (Tlc)–Ill, human epidermal growth factor receptor 2 (HER2) positive breast cancer receiving adjuvant Chemotherapy.	American Society of Clinical Oncology

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Part II—Continued

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, et al.

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act; Final Rules and Interim Final Rule

TABLE 47: MIPS APM Measure List--Bundled Payments for Care Improvement Advanced Model

Measure Name	NQF/ Quality ID #	National Quality Strategy Domain	Measure Description	Primary Measure Steward
All-Cause Hospital Readmission	1789	Communication and Care Coordination	This measure estimates a hospital-level risk-standardized readmission rate (RSRR) of unplanned, all cause readmission after admission for any eligible condition within 30 days of hospital discharge.	CMS
Advanced Care Plan	0326 (adapted) [1]	Communication and Care Coordination	Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	NCQA
Perioperative Care: Selection of Prophylactic Antibiotic: First or Second Generation Cephalosporin	0268	Patient Safety	Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic who had an order for first OR second generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Elective Coronary Artery Bypass Graft (CABG) Surgery	2558	Patient Safety	The measure estimates a hospital-level, risk-standardized mortality rate (RSMR) for patients 18 years and older discharged from the hospital following a qualifying isolated CABG procedure. Mortality is defined as death from any cause within 30 days of the procedure date of an index CABG admission. The measure was developed using Medicare Fee-for-Service (FFS) patients 65 years and older and was tested in all-payer patients 18 years and older. An index admission is the hospitalization for a qualifying isolated CABG procedure considered for the mortality outcome.	CMS
Excess Days in Acute Care After Hospitalization for Acute Myocardial Infarction	2881	Patient Safety	This measure assesses days spent in acute care within 30 days of discharge from an inpatient hospitalization for acute myocardial infarction (AMI) to provide a patient-centered assessment of the post-discharge period. This measure is intended to capture the quality of care transitions provided to discharged patients hospitalized with AMI by collectively measuring a set of adverse acute care outcomes that can occur post-discharge: emergency department (ED) visits, observation stays, and unplanned readmissions at any time during the 30 days post-discharge. To aggregate all three events, we measure each in terms of days. In 2016, CMS will begin annual reporting of the measure for patients who are 65 years or older, are enrolled in fee-for-service (FFS) Medicare, and are hospitalized in	CMS

Measure Name	NQF/ Quality ID #	National Quality Strategy Domain	Measure Description	Primary Measure Steward
			non-federal hospitals.	
AHRQ Patient Safety Measures	0531	Patient Safety	The modified PSI-90 Composite measure (name changed to Patient Safety and Adverse Events Composite) consists of ten component indicators: PSI-3 Pressure ulcer rate; PSI-6 Iatrogenic pneumothorax rate; PSI-8 Postoperative hip fracture rate; PSI-09 Perioperative hemorrage or hematoma rate; PSI-10 hysiologic and metabolic derangement rate; PSI-11 postoperative respiratory failure rate; PSI-12 Perioperative pulmonary embolism or Deep vein thrombosis rate; PSI-13 Postoperative sepsis rate; PSI-14 Postoperative wound dehiscence rate; and PSI-15 Accidental puncture or laceration rate.	AHRQ
Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty	1550	Patient Safety	The measure estimates a hospital-level risk-standardized complication rate (RSCR) associated with elective primary THA and TKA in Medicare Fee-For-Service beneficiaries who are 65 years and older. The outcome (complication) is defined as any one of the specified complications occurring from the date of index admission to 90 days post date of the index admission (the admission included in the measure cohort).	CMS

1 The specifications used for the Advanced Care Plan quality measure in BPCI Advanced are not NQF endorsed, but have been created specifically for BPCI Advanced.

TABLE 48: MIPS APM Measure List—Maryland Total Cost of Care Model (Maryland Primary Care Program)

Measure Name	NQF/ Quality ID	National Quality Strategy Domain	Measure Description	Primary Measure Steward
Controlling High Blood Pressure	0018	Effective / Clinical Care	Percentage of patients 18–85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9 percent)	0059	Effective Clinical Care	Percentage of patients 18–75 years of age with diabetes who had hemoglobin A1c > 9.0 percent during the measurement period.	National Committee for Quality Assurance
Initiation and Engagement of Alcohol and Other Drug Dependence Treatment	0004	Effective / Clinical Care	Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported: a. Percentage of patients who initiated treatment within 14 days of the diagnosis. b. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance
CG -CAHPS Survey 3.0 - modified for CPC+	Not Endorsed	Person and Family Engagement/ Patient and Caregiver Experience	CG–CAHPS Survey 3.0	AHRQ
Inpatient Hospital Utilization	Not Endorsed	Communication and Care Coordination	For members 18 years of age and older, the risk-adjusted ratio of observed to expected acute inpatient discharges during the measurement year reported by Surgery, Medicine, and Total.	National Committee for Quality Assurance
Emergency Department Utilization	Not Endorsed	Communication and Care Coordination	For members 18 years of age and older, the risk-adjusted ratio of observed to expected emergency department (ED) visits during the measurement year.	National Committee for Quality Assurance

TABLE 49: MIPS APM Measure List-- Independence at Home Demonstration

Measure Name	NQF/ Quality ID	National Quality Strategy Domain	Measure Description	Primary Measure Steward
Number of inpatient admissions for ambulatory-care sensitive conditions per 100 patient enrollment months	Not Endorsed	N/A	Number of inpatient admissions for ambulatory-care sensitive conditions per 100 patient enrollment months.	CMS
Number of readmissions within 30 days per 100 inpatient discharges	Not Endorsed	N/A	Risk adjusted readmissions to a hospital within 30 days following discharge from the hospital for an index admission.	CMS
Emergency Department Visits for Ambulatory Care Sensitive Conditions	Not Endorsed	N/A	Risk adjusted emergency department visits for three ambulatory care sensitive conditions: diabetes, congestive heart failure (CHF), and chronic obstructive pulmonary disease (COPD).	CMS
Contact with beneficiaries within 48 hours upon admission to the hospital and discharge from the hospital and/or ED	Not Endorsed	N/A	Percent of hospital admissions, hospital discharges, and emergency department (ED) visits for beneficiaries enrolled in IAH with a follow-up contact within 48 hours.	CMS
Medication reconciliation in the home	Not Endorsed	N/A	Percent of hospital discharges and emergency department (ED) visits for beneficiaries enrolled in IAH with medication reconciliation in the home within 48 hours.	CMS
Percentage with Documented Patient Preferences	Not Endorsed	N/A	Percent of beneficiaries enrolled in IAH with patient preferences documented in the medical record for a demonstration year.	CMS

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We proposed to update the MIPS APM measure sets that apply for purposes of the APM scoring standard (83 FR 35933 through 35934). The following is a summary of the public comments received on these measure sets and our responses:

Comment: Several commenters supported the measure sets set forth in the proposed rule. Other commenters recommended additional measures to be used in future years or suggested modifications to the measures themselves.

Response: We thank the commenters for their support and note that, consistent with § 414.1370(g)(1)(i)(A) and (ii)(A), we are using only measures that are included or that CMS intends to include in each APM measures set at the time of publication of this final rule. Should those measures be removed or revised from that measure set before the end of the performance year, we will not score APM Entities on their performance on those measures, but will include updated measures in future rulemaking.

Per our policy expressed in last year's final rule (82 FR 53695 and 53696), the measure sets on the MIPS APM measure list for the year will represent all possible measures which may contribute to an APM Entity's MIPS score for the MIPS quality performance category, and may include measures that are the same as or similar to those used by MIPS. However, a given measure ultimately might not be used for scoring, for example if its data becomes inappropriate or unavailable for scoring.

After consideration of the comments received, we are finalizing our proposal to update the MIPS APM measure sets that apply for purposes of the APM scoring standard and will score only measures that already have been included in the measure sets of their given APM, according to the terms of participation in that APM. We note that Table 48 has been updated to reflect the most current APM measure sets.

i. MIPS Final Score Methodology

(1) Converting Measures and Activities Into Performance Category Scores

(a) Background

For the 2021 MIPS payment year, we intend to build on the scoring methodology we finalized for the transition years, which allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians. The rationale for our scoring methodology continues to be grounded in the understanding that the MIPS scoring system has many components and various moving parts.

As we continue to move forward in implementing the MIPS program, we strive to balance the statutory requirements and programmatic goals with the ease of use, stability, and meaningfulness for MIPS eligible clinicians. We do so while also emphasizing simplicity and the continued development of a scoring methodology that is understandable for MIPS eligible clinicians.

In the CY 2017 Quality Payment Program final rule, we finalized a unified scoring system to determine a final score across the 4 performance categories (81 FR 77273 through 77276). For the 2019 MIPS performance period, we proposed to build on the scoring methodology we previously finalized, focusing on encouraging MIPS eligible clinicians to meet data completeness requirements (83 FR 35948 through 35949). For quality performance category scoring, we proposed to extend some of the transition year policies to the 2019 MIPS performance period, and we also proposed several modifications to existing policies (83 FR 35947 through 35949). In the CY 2018 Quality Payment Program final rule (82 FR 53712 through 53714), we established a methodology for scoring improvement in the cost performance category. However, as required by section 51003(a)(1)(B) of the Bipartisan Budget Act of 2018, we proposed that the cost performance category score would not take into account improvement until the 2024 MIPS payment year (83 FR 35956). In the CY 2018 Quality Payment Program final rule (82 FR 53753 through 53767), we finalized the availability of a facility-based measurement option for clinicians who met certain requirements, beginning with the 2019 MIPS performance period. As discussed in section III.I.3.i.(1)(d) of this final rule, we are finalizing our proposal to change the determination of facility-based measurement to include consideration of presence in the on-campus outpatient hospital. The policies for scoring the 4 performance categories are described in detail in section III.I.3.i.(1) of this final rule.

These policies will help eligible clinicians as they participate in the 2019 MIPS performance period/2021 MIPS payment year, and as we move beyond the transition years of the program. Section 51003 of the Bipartisan Budget Act of 2018 provides flexibility to continue the gradual ramp up of the Quality Payment Program and enables us to extend some of the transition year policies to the 2019 performance period.

Unless otherwise noted, for purposes of this section III.I.3.i. of this final rule, the term ''MIPS eligible clinician'' will refer to MIPS eligible clinicians who collect and submit data and are scored at either the individual or group level, including virtual groups; it will not refer to MIPS eligible clinicians who are scored by facility-based measurement, as discussed in section III.I.3.i.(1)(d) of this final rule. We also note that the APM scoring standard applies to MIPS eligible clinicians in APM Entities in MIPS APMs, and those policies take precedence where applicable. Where those policies do not apply, scoring for MIPS eligible clinicians as described in section III.I.3.h.(6) of this final rule will apply. We refer readers to section III.I.4. of this final rule for additional information about the APM scoring standard.

(b) Scoring the Quality Performance Category for the Following Collection Types: Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, CMS Web Interface Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

Although we did not propose changing the basic scoring system that we finalized in the CY 2018 Quality Payment Program final rule for the 2021 MIPS payment year (82 FR 53712 through 53748), we proposed several modifications to scoring the quality performance category, including removing high-priority measure bonus points for CMS Web Interface measures and extending the bonus point caps, and adding a small practice bonus to the quality performance category score. The following section describes these previously finalized policies and our proposals (83 FR 35950 through 35952).

We also proposed updates to § 414.1380(b)(1) in an effort to more clearly and concisely capture previously established policies (83 FR 35946 through 35955). These proposed updates are not intended to be substantive in nature, but rather to bring more clarity to the regulatory text. We will make note of the updated regulatory citations in their relevant sections below.

(i) Scoring Terminology

In the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77008 through 77831 and 82 FR 53568 through 54229, respectively), we used the term ''submission mechanisms'' in reference to the various ways in which a MIPS eligible clinician or group can submit data to CMS. As discussed in section III.I.3.h.(1)(b) of this final rule, it has come to our attention that the way we have described the various ways in which MIPS eligible clinicians, groups and third-party intermediaries can submit data to our systems does not accurately reflect the experience users have when submitting data to us. We refer readers to section III.I.3.h.(1)(b) of this final rule for further discussion on our finalized changes to the scoring terminology related to measure specification and data collection and submission. For additional discussion on the impact of the proposed terminology change on our benchmarking methodology, validation process, and end-to-end reporting bonus, we refer readers to sections III.I.3.i.(1)(b)(ii), (v), and (x) of this final rule.

(ii) Quality Measure Benchmarks

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77282 and 82 FR 53718, respectively) for our previously established benchmarking policies. As part of our proposed technical updates to § 414.1380(b)(1) discussed in section III.I.3.i.(1)(a)(i) of this final rule, our previously established benchmarking policies at § 414.1380(b)(1)(i) through (iii) would now be referenced at § 414.1380(b)(1)(i) through (ii).

When we developed the quality measure benchmarks, we sought to develop a system that enables MIPS eligible clinicians, beneficiaries, and other stakeholders to understand what is required for a strong performance in MIPS while being consistent with statutory requirements (81 FR 28249 through 28250). The feedback we have received thus far from stakeholders on our benchmarks is helping to inform our approach to the benchmarking methodology, especially as we look for possible ways of aligning with Physician Compare benchmarks. As described in section III.I.3.i.(1)(b)(xii) of this final rule, we solicited comment on potential future approaches to scoring the quality performance category to continue to promote value and improved outcomes.

We anticipate changes in scoring would be paired with potential modifications to measure selection and criteria discussed in section III.I.3.h.(2)(b) of this final rule. In the CY 2019 PFS proposed rule (83 FR 35947), we sought input on opportunities to further reduce confusion about our benchmarking methodology described in the CY 2017 Quality Payment Program final rule (81 FR 77277 through 77278), which includes further clarification of our benchmarking process and potential areas of alignment between the MIPS and Physician Compare benchmarking methodologies.

We thank commenters for their input and may take this input into consideration in future years.

(A) Revised Terminology for MIPS Benchmarks

We previously established at § 414.1380(b)(1)(iii) separate benchmarks for the following submission mechanisms: EHR; QCDR/registry, claims; CMS Web Interface; CMS-approved survey vendor; and administrative claims. In the CY 2019

PFS proposed rule, we did not propose to change our basic approach to our benchmarking methodology; however, we proposed to amend § 414.1380(b)(1)(ii) consistent with the proposed data submission terminology changes discussed in section III.I.3.h.(1)(b) of this final rule (83 FR 35947). Specifically, beginning with the 2021 MIPS payment year, we proposed to establish separate benchmarks for the following collection types: eCQMs; QCDR measures (as described at § 414.1400(e)); MIPS CQMs; Medicare Part B claims measures; CMS Web Interface measures; the CAHPS for MIPS survey; and administrative claims measures. We would apply benchmarks based on collection type rather than submission mechanism. For example, for an eCQM, we would apply the eCQM benchmark regardless of submitter type (MIPS eligible clinician, group, third party intermediary). In addition, we would establish separate benchmarks for QCDR measures and MIPS CQMs since these measures do not have comparable specifications. In addition, we note that our proposed benchmarking policy allows for the addition of future collection types as the universe of measures continues to evolve and as new technology is introduced. Specifically, we proposed to amend § 414.1380(b)(1)(ii) to remove the mention of each individual benchmark and instead state that benchmarks will be based on collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

The following is a summary of the public comments on these proposals and our responses:

Comment: A few commenters expressed support for our proposal to establish separate benchmarks by collection types, citing the difference in measure performance across collection types. One commenter stated this update would maintain consistency when migrating between current MIPS terminology to proposed MIPS terminology.

Response: We thank commenters for their support as we continue to clarify and improve our benchmarking policies.

Comment: One commenter expressed concern about the proposal to update our regulatory text to state that benchmarks are based on collection types from all available sources, including APMs. Specifically, the commenter noted that incorporating APM data into benchmark calculations will set the benchmarks too high since APM participants tend to be high performers.

Response: We recognize commenter's concern; however, this is not a new policy, and we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77279) for additional discussion on the inclusion of APMs in the MIPS benchmarks. As measures and technology evolve, we are constantly reviewing and evaluating what data sources are appropriate for benchmarks.

Comment: One commenter requested clarification on whether QCDR measures that have an e-specified collection type and a manual collection type will also be considered separate collection types with distinct benchmarks.

Response: We expect that a QCDR measure for which data is abstracted through EHRs or manually (that is, paper records) would have to be approved as two separate measures. As a result, each measure would only be compared to its own benchmark.

After consideration of public comments, we are finalizing our proposal, beginning with the 2021 MIPS payment year, to amend § 414.1380(b)(1)(ii) to establish separate benchmarks based on collection type and to remove the mention of each individual benchmark and state that benchmarks will be based on collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

(iii) Assigning Points Based on Achievement

In the CY 2017 Quality Payment Program final rule, we established the policies for scoring quality measures performance (81 FR 77286). We refer readers to § 414.1380(b)(1) for more on these policies.

(A) Floor for Scored Quality Measures

For the 2019 and 2020 MIPS payment years, we finalized at § 414.1380(b)(1)(i) a global 3-point floor for each scored quality measure, as well as for the hospital readmission measure (if applicable). In this way, MIPS eligible clinicians would receive between 3 and 10 measure achievement points for each submitted measure that can be reliably scored against a benchmark, which requires meeting the case minimum and data completeness requirements (81 FR 77286 through 77287; 82 FR 53719). For measures with a benchmark based on the performance period (rather than on the baseline period), we stated that we would continue to assign between 3 and 10 measure achievement points for performance periods after the first transition year (81 FR 77282, 77287; 82 FR 53719). For measures with benchmarks based on the baseline period, we stated that the 3-point floor was for the transition year and that we would revisit the 3-point floor in future years (81 FR 77286 through 77287; 82 FR 53719).

For the 2021 MIPS payment year, we proposed to again apply a 3-point floor for each measure that can be reliably scored against a benchmark based on the baseline period, and to amend § 414.1380(b)(1)(i) accordingly (83 FR 35947). We will revisit the 3-point floor for such measures again in future rulemaking.

We requested comments on the proposal above. These comments and our responses are discussed below.

Comment: Several commenters expressed support for the three-point floor for measures that can be reliably scored against a benchmark based on the baseline period because it would reduce confusion, help reduce burden, maintain stability, and encourage physicians to continue to participate in MIPS.

Response: We thank commenters for their support.

After consideration of public comments, we are finalizing our proposal, for the 2021 MIPS payment year, to apply a 3-point floor for each measure that can be reliably scored against a benchmark, and to amend § 414.1380(b)(1)(i) accordingly.

(B) Additional Policies for the CAHPS for MIPS Measure Score

Although participating in the CAHPS for MIPS survey is optional for all groups, some groups will be unable to participate in the CAHPS for MIPS survey because they do not meet the minimum beneficiary sampling requirements. CMS has sampling requirements for groups of 100 or more eligible clinicians, 25 to 99 eligible clinicians, and 2 to 24 eligible clinicians to ensure an adequate number of survey responses and the ability to reliably report data. Our sampling timeframes necessitate notifying groups of their inability to meet the sampling requirements late in the performance period (see 82 FR 53630 through 53632). As a result, we are concerned that some groups that expect and plan to meet the quality performance category requirements using the CAHPS for MIPS survey may find out late in the performance period that they are unable to meet the sampling requirements and, therefore, are unable to have their performance assessed on this measure. These groups may need to report on another measure to meet the

requirements of the quality performance category.

We want to encourage the reporting of the CAHPS for MIPS survey and do not want the uncertainty regarding sampling requirements to be a barrier to selecting the CAHPS for MIPS survey. To mitigate this concern, beginning with the 2021 MIPS payment year, we proposed to reduce the denominator (that is, the total available measure achievement points) for the quality performance category by 10 points for groups that register for the CAHPS for MIPS survey but do not meet the minimum beneficiary sampling requirements (83 FR 35948). By reducing the denominator instead of only assigning the group a score of zero measure achievement points (because the group would be unable to submit any CAHPS for MIPS survey data), we are effectively removing the impact of the group's inability to submit the CAHPS for MIPS survey. We believe this reduction in denominator would remove any need for groups to find another measure if they are unable to submit the CAHPS for MIPS survey. Therefore, we proposed to amend § 414.1380 to add paragraph (b)(1)(vii)(B) to state that we will reduce the total available measure achievement points for the quality performance category by 10 points for groups that registered for the CAHPS for MIPS survey but do not meet the minimum beneficiary sampling requirements.

We requested comments on the proposal above. These comments and our responses are discussed below.

Comment: Several commenters supported our proposed policy. One commenter believes this will encourage more groups to conduct the survey.

Response: We appreciate the commenters' support.

Comment: One commenter requested clarification on when groups would be notified that they did not meet the beneficiary sampling requirement. The commenter also requested clarification on what protections the agency will institute for groups who must cancel their contracts with survey vendors ''late in the performance period'' when they are notified that they did not meet the beneficiary sampling requirement. The commenter stated that CMS should not hold groups accountable for vendor costs that result from the agency's late notification process.

Response: We do not anticipate the notification process for minimum beneficiary sample requirements will change. CMS provides information on sample design and sample size requirements in the QPP Resource Library to aid groups in deciding whether or not to elect CAHPS for MIPS. CMS sends communication about sample size eligibility to the point of contact provided by each group during the registration process for CAHPS for MIPS. Providing more than one point of contact will help to promote timely delivery of the information on sample size eligibility to the group. Groups should coordinate with their vendors to address any questions regarding costs in the event the group does not meet the beneficiary sampling requirement. For any additional questions please visit the Quality Payment Program website at *qpp.cms.gov.*

Comment: One commenter sought clarification whether CMS would automatically apply the scoring policy or first provide groups with the option to report on an alternate quality measure or improvement activity.

Response: We will not automatically apply the scoring policy. Notifications will be sent twice to groups that have registered for the CAHPS for MIPS survey and who have an insufficient sample size, with the second notification usually occurring in September. These notifications also encourage groups to select other relevant measures that can be completed. We believe that this policy is necessary because the notification late in the performance period might not allow sufficient time for groups to collect and report a different quality measure, however, some practices may have other quality measures (beyond the 6 minimum) that they have been reporting on that could be submitted within the performance period. For groups that submitted 5 or fewer quality measures and do not meet the CAHPS for MIPS sampling requirements, the quality denominator will be reduced by 10 points. For groups that submitted 6 or more quality measures and do not meet the CAHPS for MIPS sampling requirements, we will score the 6 measures with the highest achievement points.

The notification will also encourage groups to select other relevant improvement activities that can be completed within the performance period. We refer readers to section III.I.3.h.(4)(b) of this final rule for further information on submission criteria for the improvement activities performance category.

After consideration of public comments, we are finalizing our proposal to amend § 414.1380 to add paragraph (b)(1)(vii)(B) to state that we will reduce the total available measure achievement points for the quality performance category by 10 points for groups that submit 5 or fewer quality measures and register for the CAHPS for MIPS survey, but do not meet the minimum beneficiary sampling requirements.

We do not want groups to register for the CAHPS for MIPS survey if they know in advance that they are unlikely to be able to meet the sampling requirement, so we solicited comments on whether we should limit this proposed policy to groups for only one MIPS performance period. For example, for the performance period following the application of this proposed policy, a notice could be provided to groups during registration indicating that if the sampling requirement is not met for a second consecutive performance period, the proposed policy will not be applied. This would provide notice to the group that they may not meet the sampling requirement needed for the CAHPS for MIPS survey and may need to look for alternate measures but does not preclude the group from registering for the CAHPS for MIPS survey if they expect to meet the minimum beneficiary sampling requirements in the second MIPS performance period.

We thank commenters for their suggestions and may consider them for future rulemaking.

(iv) Assigning Measure Achievement Points for Topped Out Measures

We refer readers to CY 2017 Quality Payment Program final rule (82 FR 53721 through 53727) for our established policies for scoring topped out measures.

Under § 414.1380(b)(1)(xiii)(A), for the 2020 MIPS payment year, 6 measures will receive a maximum of 7 measure achievement points, provided that the applicable measure benchmarks are identified as topped out again in the benchmarks published for the 2018 MIPS performance period. Under § 414.1380(b)(1)(xiii)(B), beginning with the 2021 MIPS payment year, measure benchmarks (except for measures in the CMS Web Interface) that are identified as topped out for 2 or more consecutive years will receive a maximum of 7 measure achievement points beginning in the second year the measure is identified as topped out (82 FR 53726 through 53727). As part of our technical updates to § 414.1380(b)(1) outlined in section III.I.3.i.(1)(b) of this final rule, our previously finalized topped out scoring policies are now referenced at § 414.1380(b)(1)(iv).

We refer readers to the 2018 MIPS Quality Benchmarks' file that is located on the Quality Payment Program resource library (*https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Resource-library.html*) to determine which measure

benchmarks are topped out for 2018 and would be subject to the cap if they are also topped out in the 2019 MIPS Quality Benchmarks' file. We note that the final determination of which measure benchmarks are subject to the topped out cap will not be available until the 2019 MIPS Quality Benchmarks' file is released in late 2018.

We did not propose to apply our previously finalized topped out scoring policy to the CAHPS for MIPS survey (82 FR 53726). Because the CAHPS for MIPS survey was revised in 2018 (82 FR 53632), we do not have historical benchmarks for the 2018 performance period, so the topped out policy would not be applied for the 2019 performance period. Last year, we received limited feedback when we sought comment on how the topped out scoring policy should be applied to CAHPS for MIPS survey. In CY 2019 PFS proposed rule, we sought feedback on potential ways we can score CAHPS for MIPS Summary Survey Measures (SSM) (83 FR 35948). For example, we could score all SSMs, which means there would effectively be no topped out scoring for CAHPS for MIPS SSMs, or we could cap the SSMs that are topped out and score all other SSMs. We sought comment on these approaches and additional approaches to the topped out scoring policy for CAHPS for MIPS SSMs. We noted that we encourage groups to report the CAHPS for MIPS survey as it incorporates beneficiary feedback.

We thank commenters for their suggestions and will consider them for future rulemaking.

(v) Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmarks Requirements

In the CY 2017 Quality Payment Program final rule (81 FR 77288 through 77289), we established scoring policies for a measure that is submitted but is unable to be scored because it does not meet the required case minimum, does not have a benchmark, or does not meet the data completeness requirement. As part of our technical updates to § 414.1380(b)(1) discussed in section III.I.3.i.(1)(b) of this final rule, our previously finalized scoring policies are now referenced at § 414.1380(b)(1)(i)(A) and (B).

A summary of the current and proposed policies is provided in Table 50. For more of the statutory background and details on current policies, we refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77288 through 77289 and 82 FR 53727 through 53730, respectively).

TABLE 50: Quality Performance Category: Scoring Measures

Measure type	Description	Scoring rules
Class 1	For the 2018 and 2019 MIPS performance period: Measures that can be scored based on performance. Measures that were submitted or calculated that met the following criteria: (1) Has a benchmark; (2) Has at least 20 cases; and (3) Meets the data completeness standard (generally 60 percent.)	For the 2018 and 2019 MIPS performance period: 3 to 10 points based on performance compared to the benchmark.
Class 2*	For the 2018 and 2019 MIPS performance period: Measures that were submitted and meet data completeness, but do not have both of the following: (1) a benchmark (2) at least 20 cases.	For the 2018 and 2019 MIPS performance period: 3 points * This Class 2 measure policy does not apply to CMS Web Interface measures and administrative claims based measures
Class 3**	For the 2018 and 2019 MIPS performance period: Measures that were submitted, but do not meet data completeness criteria, regardless of whether they have a benchmark or meet the case minimum.	For the 2018 and 2019 MIPS performance period: 1 point except for small practices, which would receive 3 measure achievement points. Beginning with the 2020 MIPS performance period: MIPS eligible clinicians other than small practices will receive zero measure achievement points. Small practices will continue to receive 3 points. **This Class 3 measure policy would not apply to CMS Web Interface measures and administrative claims based measures

As the MIPS program continues to mature, we are looking to find ways to improve our policies, including what to do with measures that do not meet the case minimum. Although many MIPS eligible clinicians can meet the 20-case minimum requirement, we recognize that small practices and individual MIPS eligible clinicians may have difficulty meeting this standard. Although we process data from the CY 2017 MIPS performance period to determine how often submitted measures do not meet case minimums, we invited public comment on ways we can improve our case-minimum policy. In determining future improvements to our case minimum policy, our goal is to

balance the concerns of MIPS eligible clinicians who are unable to meet the case minimum requirement and for whom we cannot capture enough data to reliably measure performance, while not creating incentives for MIPS eligible clinicians to choose measures that do not meet case minimum even though other more relevant measures are available.

We thank commenters for their suggestions and will consider them for future rulemaking.

In the CY 2019 PFS proposed rule (83 FR 35949), we proposed to maintain the policies finalized for the CY 2018 MIPS performance period regarding measures that do not meet the case-minimum requirement, do not have a benchmark, or do not meet the data-completeness criteria for the CY 2019 MIPS performance period, and to amend § 414.1380(b)(1)(i) accordingly.

We also proposed to assign zero points for measures that do not meet data completeness starting with the CY 2020 MIPS performance period and to amend § 414.1380(b)(1)(i)(B)(*1*) accordingly (83 FR 35949). This policy is part of our effort to move toward complete and accurate reporting that reflects meaningful effort to improve the quality of care that patients receive. Measures submitted by small practices would continue to receive 3 points for all future CY MIPS performance periods, although we may revisit this policy through future rulemaking.

We requested comments on the proposals above. These comments and our responses are discussed below.

Comment: Several commenters supported the proposal to maintain the policies finalized for the CY 2018 MIPS performance period regarding measures that do not meet the case minimum requirement, do not have a benchmark, or do not meet the data-completeness criteria for the CY 2019 MIPS performance period.

Response: We thank commenters for their support. However, we want to stress that these policies were not meant to be permanent and as clinicians continue to gain experience with the program we will revisit the appropriateness of these policies in future rulemaking.

Comment: A few commenters did not support our proposal to reduce points for measures that do not meet data completeness to zero starting with the CY 2020 MIPS performance period because of concerns that it would add complexity and burden as clinicians are continuing to learn the program. A few commenters suggested that CMS should return to assigning these measures 3 points or, at a minimum, continue to assign them 1 point or provide special scoring for MIPS eligible clinicians with significant administrative burdens. A few commenters recommended that clinicians should at least get some credit for attempting to report and, through no fault of their own, fail to meet the data completeness threshold, citing the difficulty of getting all the necessary data from hospitals and/or their billing companies to report on 60 percent of all applicable patients.

Response: We understand and recognize commenters' concerns. However, as the program is being fully implemented, we want to ensure that our policies align with our goal of improving quality. This scoring policy was intended to be temporary, and we believe that data completeness is something that is within the direct control of clinicians. Although we understand that many clinicians have administrative burdens and we continuously strive to reduce paperwork, we also believe that it is important to develop policies that align with the program's goal to improve quality of care. By the fourth year of implementation, we believe this policy is no longer needed and that removing this policy helps streamline our scoring policies.

After consideration of public comments, we are finalizing the proposal to maintain the policies finalized for the CY 2018 MIPS performance period regarding measures that do not meet the case-minimum requirement, do not have a benchmark, or do not meet the data-completeness criteria for the CY 2019 MIPS performance period, and the amending of § 414.1380(b)(1)(i) accordingly.

After consideration of public comments, we are finalizing our proposal to assign zero points for measures that do not meet data completeness starting with the CY 2020 MIPS performance period and to amend § 414.1380(b)(1)(i)(B)(1) accordingly. Measures submitted by small practices will continue to receive 3 points for all future MIPS performance periods.

(vi) Scoring Flexibility for Measures With Clinical Guideline Changes During the Performance Period

In the CY 2018 Quality Payment Program final rule (82 FR 53714 through 53716), we finalized that, beginning with the 2018 MIPS performance period, we will assess performance on measures considered significantly impacted by ICD–10 updates based only on the first 9 months of the 12-month performance period (for example, January 1, 2018, through September 30, 2018, for the 2018 MIPS performance period). We noted that performance on measures that are not significantly impacted by changes to ICD–10 codes would continue to be assessed on the full 12-month performance period (January 1 through December 31). Lastly, we finalized that we will publish the list of measures requiring a 9-month assessment process on the CMS website by October 1st of the performance period if technically feasible, but by no later than the beginning of the data submission period (for example, January 2, 2019, for the 2018 MIPS performance period). As part of our technical updates to § 414.1380(b)(1) outlined in section III.I.3.i.(1)(b) of this final rule, these previously finalized policies are now referenced at § 414.1380(b)(1)(viii).

We remain concerned about instances where clinical guideline changes or other changes to evidence supporting a measure occur during the performance period that may significantly impact a measure. Clinical guidelines and protocols developed by clinical experts and specialty medical societies often underpin quality measures. At times, measure stewards must amend quality measures to reflect new research and changed clinical guidelines, and sometimes, as a result of the change in these guidelines, adherence to guidelines in the existing measures could result in patient harm or otherwise provide misleading results as to good quality care. We sought comment in the CY 2018 Quality Payment Program final rule regarding whether we should apply scoring flexibility to measures significantly impacted by clinical guideline changes (82 FR 53716). We refer readers to the CY 2019 PFS proposed rule for a summary of the comments we received (83 FR 35949 through 35950).

We remain concerned that findings of evidence-based research, providing the basis for sound clinical practice guidelines and recommendations that are the foundation of a quality measure, may change outside of the rulemaking cycle. As the clinical evidence and guidelines change, approved measures may no longer reflect the most up-to-date clinical evidence and could be contrary to patient well-being. There may be instances in which changes to clinical guidelines are so significant, that an expedited review is needed outside of the rulemaking cycle because measures may result in a practice that is harmful to patients. To further align with policies adopted within other value based programs such as the Hospital VBP Program (83 FR 20409), we proposed to suppress a measure without rulemaking, if during the performance period a measure is

significantly impacted by clinical guideline changes or other changes that CMS believes may pose patient safety concerns (83 FR 35950). We would rely on measure stewards for notification in changes to clinical guidelines. We will publish on the CMS website suppressed measures whenever technically feasible, but by no later than the beginning of the data submission period.

In the CY 2019 PFS proposed rule (83 FR 35950), we proposed policies to provide scoring flexibility in the event that we need to suppress a measure during a performance period. Scoring for a suppressed measure would result in a zero achievement points for the measure and a reduction of the total available measure achievement points by 10 points. We believe that this approach effectively removes the impact of the eligible clinician's inability to receive measure achievement points for the measure, if a submitted measure is later suppressed.

We also proposed to add a new paragraph at § 414.1380(b)(1)(vii) that, beginning with the 2019 MIPS performance period, CMS will reduce the total available measure achievement points for the quality performance category by 10 points for MIPS eligible clinicians that submit a measure significantly impacted by clinical guideline changes or other changes that CMS believes may pose patient safety concerns (83 FR 35950).

We requested comments on the proposal above. These comments and our responses are discussed below.

Comment: A few commenters supported the proposal because it holds the clinician harmless from clinical guideline changes that impact quality measures. One commenter noted that it is important that clinicians are protected from any adverse impacts on their scoring when they are following updated clinical guidelines to ensure proper patient care and safety.

Response: We appreciate the support of the proposal.

Comment: Several commenters did not support the proposal. Commenters questioned whether there would be an expectation that the clinician would continue collecting data on the measure, or whether they would be allowed to submit the measure with less than 12 months' data for the suppressed measure. A few commenters stated the policy should only be applied if the clinical guideline change relates to patient harm or patient safety, in which case data collection on the quality measure should cease immediately. A few commenters indicated that clinicians invest significant time and resources to assess and improve their performance over the course of the performance period, and thus suppressing the scoring of a quality measure, unless patient harm is involved, does not appropriately recognize these efforts. One commenter suggested that CMS establish an attestation process through the EIDM system to allow clinicians the option to attest their intent to report the measure, and CMS should adjust their scoring accordingly.

Response: We appreciate the commenters' suggestions. There are rare instances in which changes to clinical knowledge and guidelines can significantly impact measure specifications and the intent of the measure, which we believe requires suppression of scoring so as to encourage the clinicians to follow the guidelines that are best for the patient, rather than tracking the guidelines that were finalized in the measure set, which may negatively impact patient care. Clinical guideline changes that occur between rulemaking cycles would need to be significant enough that the change in the most up-to-date clinical evidence could result in patient harm if the clinician does not follow these new guidelines or otherwise provide misleading results as to what is measured as good quality care. We believe there are rare instances in which we should not delay our support of the use of the most current clinical evidence by continuing to require the collection of data and scoring the measure until the next rulemaking cycle. For example, a guideline may be updated because clinical evidence indicates that a new medication should replace a medication specified in a quality measure. If this occurs between rulemaking cycles, we would not want the scoring policy to disadvantage the clinicians adopting the updated guideline and using the recommended medication. We envision that this policy would be applied in two circumstances. First, there is a newly issued or updated guideline where there is wide consensus that would result in a significant change to a quality measure. In these cases, it would be expected that clinicians would adopt clinical processes to support the new guideline which may not be compatible with the existing measures and could provide misleading results or patient harm. In this case, we anticipate the quality measure would be reviewed and updated during the next rulemaking process. Second, we envision using this policy in rare cases where there is a new or revised guideline, even if there is no broad consensus within the specialty, because some clinicians will begin to adopt the new guideline which would not be consistent with the quality measures and scoring the measure could cause misleading results for those clinicians. We believe it important to suppress the measure until guideline and quality measure are reviewed by the Measures Application Partnership (MAP) and other processes to support the Annual List of Measures, including rulemaking. We do not envision using this policy solely based on indications that guideline revisions are anticipated but not completed. Until the guideline is updated, clinicians would be expected to follow the existing guideline and it would not be prudent to use the scoring policy. Nor would we activate the policy if the guideline change does not significantly impact the measure results.

In the event of the need for the special scoring policy, we would communicate to clinicians through multiple channels regarding the changes. We appreciate that clinicians invest significant time and resources to select measures, we also believe it is critical that the measure results do not cause patient harm or otherwise harm clinician performance by scoring potentially misleading data. We believe suppressing the measure and reducing the total possible achievement points by 10 would recognize this effort by not forcing clinicians in the middle of a performance to select a new measure to report.

We appreciate the time and resources clinicians expend to collect data for a quality measure; however, we believe the policy will only be used in rare occasions, which will limit disruption to clinicians. We also believe that the policy will not disadvantage the clinician and will ''hold harmless'' any clinician submitting data on the measure. Scoring would be suppressed for any clinician that submitted data on the measure prior to the announcement. Similarly, given how rarely we anticipate we will need to use this policy, we do not believe we require a process for attestation regarding which measures will be selected prior to the performance period.

Comment: A few commenters recommended regular communication between CMS and measure stewards and supported the proposal that it would be the responsibility of the measure steward to notify CMS of changes to the clinical guidelines that may impact existing quality measures. One commenter requested that CMS allow multiple sources, rather than just measure stewards, to identify potential significant changes to clinical guidelines that may pose patient safety

risks. Another commenter stated that only measure stewards should notify CMS of significant changes to clinical guidelines.

Response: We regularly monitor changes to quality measures and work closely with clinical organizations that maintain clinical guidelines and measure stewards to identify quality measures impacted by significant changes to clinical guidelines during the performance period. We will mainly rely on measure stewards to identify significant changes, especially those relating to potential patient harm. We clarify that measure stewards are not necessarily the owner and/or developer of the clinical guidelines. In many instances measure stewards defer to the clinical organizations or stakeholders who own, maintain and update the clinical guideline when changes are warranted. We intend to continue to work collaboratively with measure stewards, clinical organizations, measure owners and other key stakeholders responsible for the maintenance of these guidelines prior to deciding to suppress the scoring of a measure. As noted above, if we decide to suppress these measures, we would notify clinicians through multiple means.

After consideration of public comments, we are finalizing a modification of our proposal and adding a new paragraph at § 414.1380(b)(1)(vii) stating that, beginning with the 2021 MIPS payment year, we will reduce the denominator of available measure achievement points for the quality performance category by 10 points for MIPS eligible clinicians for each measure submitted that is significantly impacted by clinical guideline changes or other changes when we believe adherence to the guidelines in the existing measures could result in patient harm or otherwise provide misleading results as to good quality care. To clarify, we regularly monitor changes to quality measures and clinical guidelines and we will rely mainly on measure stewards, who often defer to the clinical organizations or other stakeholders who own, maintain and update the clinical guideline when a guideline change is warranted, for notification in changes to clinical guidelines. We will publish on the CMS website suppressed measures whenever technically feasible, but by no later than the beginning of the data submission period.

(vii) Scoring for MIPS Eligible Clinicians That Do Not Meet Quality Performance Category Criteria

In the CY 2018 Quality Payment Program final rule (82 FR 53732), we finalized that, beginning with the 2021 MIPS payment year, we will validate the availability and applicability of quality measures only with respect to the collection type that a MIPS eligible clinician utilizes for the quality performance category for a performance period, and only if a MIPS eligible clinician collects via claims only, MIPS CQMs only, or a combination of MIPS CQMs and claims collection types. We will not apply the validation process to any data collection type that the MIPS eligible clinician does not utilize for the quality performance category for the performance period. We sought comment on how to modify the validation process for the 2021 MIPS payment year when clinicians may submit measures collected via multiple collection types.

As discussed in section III.I.3.h.(1)(b) of this final rule, we proposed to revise our terminology regarding data submission. This updated terminology will more accurately reflect our current submissions and validation policies. In the CY 2019 PFS proposed rule (83 FR 35950), we proposed to modify our validation process to provide that it only applies to MIPS CQMs and the claims collection type, regardless of the submitter type chosen. For example, this policy would not apply to eCQMs even if they are submitted by a registry.

We note that a MIPS eligible clinician may not have available and applicable quality measures. If we are unable to score the quality performance category, then we may reweight the clinician's score according to the reweighting policies described in sections III.I.3.i.(2)(b)(ii) and III.I.3.i.(2)(b)(iii) of this final rule.

We did not receive any comments on this proposal.

We are finalizing our proposal to modify our validation process to provide that it only applies to MIPS CQMs and the claims collection type, regardless of the submitter type chosen.

(viii) Small Practice Bonus

In the CY 2018 Quality Payment Program final rule (82 FR 53788), we finalized at § 414.1380(c)(4) to add a small practice bonus of 5 points to the final score for the 2020 MIPS payment year for MIPS eligible clinicians, groups, APM Entities, and virtual groups that meet the definition of a small practice as defined at § 414.1305 and submit data on at least one performance category in the 2018 MIPS performance period.

We continue to believe an adjustment for small practices is generally appropriate due to the unique challenges small practices experience related to financial and other resources, as well as the performance gap we have observed (based on historical PQRS data) for small practices in comparison to larger practices. We believe a small practice bonus specific to the quality performance category is preferable for the 2021 MIPS payment year and future years. We believe it is appropriate to apply a small practice bonus points to the quality performance category based on observations using historical data, which indicates that small practices are less likely to submit quality performance data, less likely to report as a group and use the CMS Web Interface, and more likely to have lower performance rates in the quality performance category than other practices. We want the final score to reflect performance, rather than the ability and infrastructure to support submitting quality performance category data.

We considered whether we should continue to apply the small practice bonus through bonus points in all 4 performance categories, but believe the need for doing so is less compelling. The improvement activities performance category already includes special scoring for small practices (please refer to § 414.1380(b)(3) and see section III.I.3.i.(1)(e) of this final rule for more information). In addition, for the Promoting Interoperability performance category, small practices can apply for a significant hardship exception if they have issues acquiring an EHR (see section III.I.3.h.(5) of this final rule). Finally, the cost performance category does not require submission of any data; therefore, there is less concern about a small practice being burdened by those requirements. For these reasons, we proposed to transition the small practice bonus to the quality performance category.

Starting with the 2021 MIPS payment year, we proposed at § 414.1380(b)(1)(v)(C) to add a small practice bonus of 3 points in the numerator of the quality performance category for MIPS eligible clinicians in small practices if the MIPS eligible clinician submits data to MIPS on at least 1 quality measure (83 FR 35950). Because MIPS eligible clinicians in small practices are not measured on the readmission measure and are not able to participate in the CMS Web Interface, they generally have a quality performance category denominator of 60 total possible measure achievement points. Thus, our proposal of 3 measure bonus points generally represents 5 percent of the quality performance category score. As described in section III.I.3.i.(2)(b)(iii) of this final rule, for clinicians in many small practices, the

quality performance category weight may be up to 85 percent of the final score. (For example, if a small practice applies for the Promoting Interoperability significant hardship application and does not meet the sufficient case minimum for cost measures, then the weights of Promoting Interoperability and cost performance categories are redistributed to quality and the quality performance category weight would be 85 percent.)

With a weight of 85 percent, a small practice bonus of 3 points added to the quality performance category will result in 4.25 bonus points added to the final score for clinicians in small practices.[29] We believe this is appropriate because it is similar to the impact of the small practice bonus we finalized for the 2020 MIPS payment year (5 points added to the final score). Although we recognize that the impact of the small practice bonus for MIPS eligible clinicians in small practices who do not receive reweighting for the cost and/or Promoting Interoperability performance categories will be less than 4.25 points added to the final score, we believe a consistent approach is preferable for simplicity, and we do not believe that a larger bonus is appropriate as that could potentially inflate the quality performance category score and the final score and mask poor performance.

We requested comments on the proposal above. These comments and our responses are discussed below.

Comment: Some commenters supported the proposal and recommended that CMS continue to evaluate the least complicated method to apply the small practice bonus in future years. One commenter indicated that a small practice bonus should be retained as long as possible to support small practices. A few commenters recommended stability over several performance periods for the small practice bonus, with incentives maintained over time with no changes from year-to-year. One commenter recommended that CMS codify the small practice bonus for at least 3 years.

Response: We will evaluate MIPS data to determine whether any future adjustment is still needed based on analysis of the performance of small group practices compared to larger practices. While we appreciate commenters' recommendations for stability in the bonus over time, we believe that we must be guided by the annual analysis of small practices' experience with the Quality Payment Program to determine if the adjustment is still warranted. Any extension to the small practice bonus would be proposed through future rulemaking.

Comment: One commenter recommended bonus points be applied evenly across the following performance categories: Quality; improvement activities; and Promoting Interoperability. Another commenter indicated that it did not support a bonus based on the size or location of the practice and recommended aligning the four performance categories and awarding bonuses for activities that apply across the performance categories. One commenter recommended that the clinician be allowed the option to have bonus points added to a performance category of his or her choice. A few commenters stated that small practices are consistently disadvantaged compared to large health systems for not only quality reporting, but also requirements of other performance categories including Promoting Interoperability and improvement activities.

Response: We considered dividing the small practice bonus between the performance categories; however, we believe that spreading the bonus across performance categories may not be appropriate, and the other performance categories already take small practices into account. As stated earlier, the improvement activities performance category already includes special scoring for small practices. The Promoting Interoperability performance category has a hardship exception for small practices. The cost performance category does not require submission of any data. For these reasons, we believe that it is appropriate for the small practice bonus to be in the quality performance category.

Comment: Many commenters did not support reducing the small practice bonus from 5 points in the final score to 3 measure bonus points in the quality performance category because of concerns that small practices will receive less points, which may not support small practices sufficiently. Several commenters stated that the bonus needs to be significant enough so that adjustments provide more equitable scoring to small practices. One commenter recommended that if the bonus is applied in the quality performance category, 5 points should be awarded.

Response: We understand commenters' concerns. We recently estimated quality performance category scores for the 2019 MIPS performance period using data from the 2017 MIPS performance period. This new data was not available before the publication of the proposed rule. In this new analysis, we found that the number of eligible clinicians whose quality performance category was reweighted to 85 percent of the final score was lower than we anticipated. We found that for approximately three-fourths of the clinicians in small practices (and those not subject to the APM scoring standard), quality was weighted between 45 and 60 percent when we applying our proposed CY 2019 performance period policies to MIPS year 1 data. Thus, the 3 bonus points proposed (which generally represents 5 percent of the quality performance category score for small practices) would represent a lower overall bonus when added to the final score than we had originally anticipated. While we still believe that the small practice bonus should be applied to the quality category performance score, it was not our intention to lower the overall impact on the final score.

With our updated impact analysis in this final rule, we discovered that trends identified when we originally established the small practice bonus still exist. For example, in the CY 2018 Quality Payment Program proposed rule (82 FR 30139 through 30140), we noted that clinicians in practices with more than 100 clinicians may perform better in the Quality Payment Program on average compared to clinicians in smaller practices. We believed this trend was due primarily to two factors: Participation rates and Web Interface reporting. While we estimate more clinicians in small practices are participating in MIPS in our updated model in this final rule compared to our estimates in the 2019 PFS proposed rule, we still see a gap in quality participation when comparing clinicians in small practices to clinicians in large practices (89.8 percent compared to 100.0 percent respectively). We also noticed a discrepancy in performance among those who submitted data for the quality performance category. Prior to applying a small practice bonus, the average quality score for submitters in small practices was 62 percent compared to 82 percent for clinicians in large groups. It is unclear whether the cause of the discrepancy is related to Web Interface reporting, to performance, or to factors related to data collection. While we continue to analyze the implications of these results, we believe increasing the small practice bonus from 3 to 6 measure bonus points for 1 year would be appropriate to ensure that we are correctly incentivizing participation

[29] We get 4.25 points using the following calculation: (3 measure bonus point/60 total measure points) * 85 percent * 100 = 4.25.

during the transition years without lowering the impact of the small practice bonus. The other bonuses in the quality performance category (for high-priority measures and end-to-end electronic reporting) are capped at 10 percent of the denominator of the quality performance category, which in almost all cases for small practices is 60 total possible measure achievement points. Setting the bonus at 6 points generally represents 10 percent of the quality performance category score. For those clinicians who have six measures and for whom the quality performance category weight is 45 percent, then the small practice bonus would equate to 4.5 final score points. For those with a quality performance category weight of 60 percent, the small practice bonus would equate to 6 final score points. We recognize that for some practices whose quality score is reweighted to 85 percent of their final score, this may account for a large part of the final score; however, based on the new CY 2017 MIPS performance period data, we do not believe this will be the case for a large proportion of small practices. On average, we estimate this change to the small practice bonus will add 4.4 points to the final score for clinicians in small practices who submit quality information to MIPS.

We want to remind readers that the small practice bonus was only meant to be temporary and as we further analyze CY 2017 MIPS performance period data we expect that the bonus will likely be reduced or removed in future rulemaking. While we currently believe that it is appropriate due to the unique challenges small practices experience related to financial and other resources, as well as the performance gap for small practices in comparison to larger practices, we believe that upon further analysis of CY 2017 MIPS performance period data the small practice bonus may not address the underlying reasons for the disparate performance between small practices and other clinicians. As a result, we intend to revisit this bonus during next year's rulemaking cycle.

Comment: Many commenters stated that the small practice bonus should not be embedded in the quality performance category and should be a standalone bonus at the final score level to reduce complication in scoring, provide greater flexibility, and reduce burden on small practices. Several commenters stated that the quality performance category is contributing less to the final score, since it is being reduced from 50 percent to 45 percent, and may be reduced in the future, which would continually reduce the small practice bonus. A few commenters noted that moving the bonus to the quality performance category provides additional scoring complexity and will not be equitable, since the bonus will be applied to small practices regardless of the number of measures submitted for the quality performance category. For example, the bonus of 3 points for a clinician being scored on one quality measure would translate to a higher contribution to the final score than applying a bonus of 3 points for a clinician being scored on 6 measures. One commenter was concerned that moving the small practices bonus to the quality performance category will remove the opportunity for a bonus from clinicians who do not, or cannot, report quality measures.

Response: We believe it is more appropriate for the small practice bonus to reside in the quality performance category because small practices have different reporting options than larger practices (for example, only small practices are able to submit data via Medicare Part B claims, but they cannot do so via the Web Interface), and burdens associated with submitting data could affect the quality performance category score. We also believe there is at least one quality measure that is relevant to the vast majority of clinicians in the Quality Payment Program. The small practice bonus is available to any small practice submitting at least one quality measure. We reiterate that we have special policies to assist small practices in the improvement activities and Promoting Interoperability performance categories, which limit the need for a small practice bonus in those performance categories. The cost performance category does not require additional burden to submit information and does not have the same reporting restrictions as the quality performance category. Over time, we will monitor the weight of the quality performance category and the small practice contribution to the final score to determine if the amount of the small practice bonus needs to be adjusted. We acknowledge that moving the small practice bonus may add to the complexity of scoring, but, on balance, we believe it is appropriate to encourage the submission of quality measures. Also, we note that previously the small practice bonus was added to the final score regardless of the number of quality measures that were submitted. Although the bonus is now in the quality category, the equity of the bonus does not change with this policy. In addition, we will continue to monitor data to evaluate the performance of small practices in the quality performance category to determine differences between small and large practices and propose any necessary changed in future rulemaking.

Comment: One commenter requested clarification on how CMS will extend the small practice bonus to MIPS APMs.

Response: The small practice bonus will be applied to the final quality performance category score for MIPS APMs at the MIPS APM entity-level. For further discussion on our MIPS APM scoring policies, we refer readers to section III.I.3.h.(6) of this final rule.

Comment: One commenter indicated that the bonus score changes based on the reweighting of certain performance categories for clinicians, which they believe gives an advantage to clinicians who have a higher percentage of the score weighed to the quality performance category. One commenter did not support moving the bonus to the quality performance category, because the potential to reweight performance categories results in a bonus that is not predictable during the performance period for clinicians, who do not know which performance categories will be reweighted.

Response: We appreciate that there might be differences in the reweighting of performance categories for small practices. As stated previously, we believe the quality performance category is an important component of the Quality Payment Program. While it was our intention to apply a bonus to the quality performance category with a cap approximately equal to the final score small practice bonus for the 2018 MIPS performance period/2020 MIPS payment year, we recognize that due to reweighting, the magnitude of the bonus will vary; however, in order to reduce complexity, we believe that a uniform bonus of 6 measure bonus points added to the numerator for quality is appropriate. As discussed in our response above, the policy is consistent with our other quality performance category bonuses because, for most clinicians, 6 measure bonus points is 10 percent of the 60-point denominator within the quality performance category. In addition, clinicians can predict whether their scores will be reweighted based on eligibility and special status information in the lookup tool. We will monitor the extent to which reweighting the quality performance category contribution to the final score affects quality measure bonus points awarded and so that we may keep the bonuses as equitable as possible.

Comment: A few commenters indicated that the small practice bonus should be extended to rural practices and different practice sizes. One

commenter recommended extending the bonus to all rural practices, regardless of practice size, because of the belief that all rural practices struggle with access to resources. One commenter indicated a belief that the program offers few bonus points and opportunities for high scores for small and rural practices, which may result in a skewed scoring system that rewards large groups with resources to support participation. One commenter recommended that the small practice bonus be available to groups with 10 or less participants, to align the definition with virtual group requirements. One commenter indicated that groups with more than 15 clinicians should be considered a small practice for purposes of the bonus.

Response: As discussed in the CY 2018 Quality Program final rule (82 FR 53778), we observed that performance for rural MIPS eligible clinicians is very similar to performance for non-rural MIPS clinicians once we account for practice size, so we do not believe a bonus for MIPS clinicians practicing in a rural setting is appropriate at this time. Additionally, we discussed in the CY 2018 Quality Payment Program final rule (82 FR 53777) that we believe it is important to maintain a consistent definition of small practices within the Quality Payment Program. In addition, we have not seen discrepancies between simulated MIPS final scores for practices of 16 to 24 clinicians and for practices of 15 or fewer clinicians. However, we will continue to monitor this issue and assess whether there are scoring differences between small rural and small urban practices and, if so, address it in future rulemaking.

Comment: One commenter requested that CMS articulate how the policies proposed align with other CMS efforts to support the long-term, sustainable transformation of small practices and those serving rural and underserved communities.

Response: We recognize the unique challenges that eligible clinicians in small practices face and have established a unique set of policies to reduce their participation burden and ease their transition into the program. The special policies include the provisions related to the assignment of 3 points for measures that do not meet data completeness criteria which are finalized in section III.I.3.i.(1)(b)(v) of this final rule; the significant hardship exception for Promoting Interoperability performance category and the associated reweighting policies available for small practices that do not have CEHRT (2018 Quality Payment Program final rule (82 FR 53683)); special scoring provisions available for the improvement activities performance category (82 FR 53656), and the provisions related to the low-volume threshold at section III.I.3.c. of this final rule. We are also continuing the Small, Underserved, and Rural Support initiative, which provides no-cost technical assistance to MIPS eligible clinicians in small practices. The initiative offers customized, one-on-one support to help MIPS eligible clinicians in small practices familiarize themselves with the program requirements, develop a strategy to successfully participate, and continue improving outcomes for beneficiaries. See: *https://qpp.cms.gov/about/small-underserved-rural-practices* for further information.

As discussed in the response above, we have estimated quality performance category scores using data from the 2017 MIPS performance period. As a result of this new data that was not available before the publication of the proposed rule we believe increasing the small practice bonus from 3 to 6 measure bonus points would be appropriate to ensure that we are correctly incentivizing participation without lowering the final score of small practices. The other bonuses in the quality performance category (for high-priority measures and end-to-end electronic reporting) are capped at 10 percent of the denominator of the quality performance category, which in almost all cases for small practices is 60 total possible measure achievement points. Setting the bonus at 6 points generally represents 10 percent of the quality performance category score.

After consideration of public comments, we are not finalizing as proposed the proposal to amend § 414.1380(b)(1)(v)(C) to add, beginning with the 2021 MIPS payment year, a small practice bonus of 3 measure bonus points in the numerator of the quality performance category for MIPS eligible clinicians in small practices if the MIPS eligible clinician submits data to MIPS on at least 1 quality measure. Instead, based on the rationale discussed previously, we are finalizing the amendment of § 414.1380(b)(1)(v)(C) to add, beginning with the 2021 MIPS payment year, a small practice bonus of 6 measure bonus points in the numerator of the quality performance category for MIPS eligible clinicians in small practices if the MIPS eligible clinician submits data to MIPS on at least 1 quality measure.

(ix) Incentives To Report High-Priority Measures

In the CY 2017 Quality Payment Program final rule, we established a cap on high-priority measure bonus points for the first 2 years of MIPS at 10 percent of the denominator (total possible measure achievement points the MIPS eligible clinician could receive in the quality performance category) of the quality performance category (81 FR 77294). As part of our proposed technical updates to § 414.1380(b)(1) discussed in section III.I.3.i.(1)(b) of this final rule, our previously established policy on incentives to report high-priority measures is now referenced at § 414.1380(b)(1)(v)(A). In the CY 2019 PFS proposed rule, we proposed to maintain the cap on measure bonus points for reporting high-priority measures for the 2021 MIPS payment year, and to amend § 414.1380(b)(1)(v)(A)(1)(ii), accordingly (83 FR 35951).

We requested comments on the proposal above. These comments and our responses are discussed below.

Comment: One commenter supported the proposal to maintain the cap on measure bonus points for reporting high-priority measures for the 2019 performance period/2021 MIPS payment year.

Response: We thank the commenter for its support of our proposal.

After consideration of public comments, we are finalizing our proposal to maintain the cap on measure bonus points for reporting high-priority measures for the 2021 MIPS payment year, and to amend § 414.1380(b)(1)(v)(A)(1)(ii), accordingly.

We established the scoring policies for high-priority measure bonus points in the CY 2017 Quality Payment Program final rule (81 FR 77293). We noted that, in addition to the required measures, CMS Web Interface reporters may also report the CAHPS for MIPS survey and receive measure bonus points for submitting that measure (81 FR 77293). We refer readers to § 414.1380(b)(1)(v)(A) for more details on the high-priority measure bonus points scoring policies.

For the 2021 MIPS payment year, we proposed to modify the policies finalized in the CY 2017 Quality Payment Program final rule (and amend § 414.1380(b)(1)(v)(A) accordingly) to discontinue awarding measure bonus points to CMS Web Interface reporters for reporting high-priority measures (83 FR 35951). As we continue to move forward in implementing the MIPS program, we no longer believe that it is appropriate to award CMS Web Interface reporters measure bonus points to be consistent with other policies regarding selection of measures. Based on additional data analyses since the first-year policy was implemented,

we have found that practices that elect to report via CMS Web Interface generally perform better than other practices that select other collection types. Therefore, the benefit of the bonus points is limited and instead we believe will create higher than normal scores. Bonus points were created as transition policies which were not meant to continue through the life of the program. Measure bonus points are also used to encourage the selection of additional high-priority measures. As the program matures, we have established other policies related to measures selection, such as applying a cap of 7 measure achievement points if a clinician selects and submits a measure that has been topped out for 2 or more years; however, we have excluded CMS Web Interface reporters from the topped out policies because reporters have no choice in measures. By the same logic, since CMS Web Interface reporters have no choice in measures, we do not believe it is appropriate to continue to provide additional high-priority measure bonuses for reporting CMS Web Interface measures. We note the CMS Web Interface users may still elect to report the CAHPS for MIPS survey in addition to the CMS Web Interface, and if they do, they would receive the high priority bonus points for reporting the survey.

We requested comments on the proposal above. These comments and our responses are discussed below.

Comment: A few commenters supported the proposal to discontinue awarding high-priority measure bonus points to CMS Web Interface reporters because it strengthens the incentive to report high-priority measures for those who actively elect to report these measures and reduces the advantage for the large practices that are able to report through CMS Web Interface. One commenter expressed support for the proposal because groups who report via Web Interface perform better than groups who use alternative data collection types, have an increased probability of earning higher quality performance category and overall higher MIPS scores, and can still earn bonus points for reporting CAHPS for MIPS survey measures.

Response: We thank the commenters for their support as we look for ways to improve our scoring policy.

Comment: Several commenters did not support the proposal to remove high-priority bonus points for CMS Web Interface reporters. One commenter stated it would disincentivize clinicians and groups from participating in APMs and stated that ACOs do not have an alternative submission method. Another commenter suggested that the bonus points should continue for non-MIPS APM participants because these submitters voluntarily choose a larger and more difficult and complex set of measures than are required. A few commenters stated that there is not an option to submit additional high-priority measures to earn these bonus points and that this proposal disadvantages ACOs which have demonstrated a high commitment to quality as evidenced by recent MIPS performance feedback reports. One commenter recommended that CMS should not remove all bonus points until it proposes to do the same for the other collection types. A few commenters suggested delaying removal of the bonus points to allow clinicians sufficient notice and until further information and insight is gained about performance in these measures. One commenter stated that the policy penalizes Web Interface reporters for their commitment to measures that truly reflects their practices.

Response: The high priority measure bonus points were intended to encourage the selection of certain measures. As we work towards improving our scoring policy to align with our goals of improving quality of care, we no longer believe we should award bonus points to CMS Web Interface reporters because they do not select individual measures to report, rather the Web Interface is a measurement set. This bonus policy was meant to be temporary, and we believe that as the MIPS program goes into its third year it is an appropriate time to begin to limit the assignment of high priority bonus points. While we recognize the commenters' concerns, the removal of the bonus was not intended to penalize Web Interface reporters and we still have several special policies available for Web Interface reporters. We have excluded CMS Web Interface reporters from the topped out measure cap (82 FR 53576), so although they are no longer able to receive this bonus, they are still able to receive maximum achievement points for all measures, even though some of the CMS Web Interface measures may be considered topped out. Additionally, CMS Web Interface reporters are still able to receive measure bonus points for reporting the CAHPS for MIPS survey and for end-to-end reporting.

We will consider commenters' concerns in future rulemaking.

After consideration of public comments, we are finalizing our proposal, beginning with the 2021 MIPS payment year, to discontinue awarding measure bonus points to CMS Web Interface reporters for reporting high-priority measures and to amend § 414.1380(b)(1)(v)(A) accordingly.

As part of our move towards fully implementing the high value measures as discussed in section III.I.3.h.(2)(b)(iv) of this final rule, we believe that bonus points for high priority measures for all collection types may no longer be needed, and as a result, we intend to consider in future rulemaking whether to modify our scoring policy to no longer offer high priority bonus points after the 2021 MIPS payment year (83 FR 35951).

We thank commenters for suggestions and may consider them for future rulemaking.

(x) Incentives To Use CEHRT To Support Quality Performance Category Submissions

Section 1848(q)(5)(B)(ii) of the Act requires the Secretary to encourage MIPS eligible clinicians to report on applicable quality measures through the use of CEHRT. Under § 414.1380(b)(1)(xv), 1 bonus point is available for each quality measure submitted with end-to-end electronic reporting, under certain criteria. In order to receive the bonus for end-to-end reporting, eligible clinicians must use the 2015 Edition CEHRT. We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77297) and section III.I.3.h.(2)(b)(i) of this final rule for further discussion on our certification requirements for the end-to-end reporting bonus. As part of our proposed technical updates to § 414.1380(b)(1) discussed in section III.I.3.i.(1)(b) of this final rule, our previously established electronic end-to-end reporting bonus point scoring policy is now referenced at § 414.1380(b)(1)(v)(B).

In the CY 2019 PFS proposed rule, we proposed to maintain the cap on measure bonus points for end-to-end electronic reporting for the 2021 MIPS payment year (83 FR 35951). We also proposed to continue to assign bonus points for end-to-end electronic reporting for the 2021 MIPS payment year, as we have seen that this policy encourages electronic reporting. We proposed to amend § 414.1380(b)(1)(v)(B) accordingly.

We requested comments on the proposal above. These comments and our responses are discussed below.

Comment: Several commenters supported maintaining the bonus points for end-to-end electronic reporting for the 2021 MIPS payment year and requested that CMS continue to assign them in future years. One commenter

noted that continuing the bonus points beyond the 2021 MIPS payment year will allow clinicians in smaller practices who are not yet capable of end-to-end electronic reporting an opportunity to do so. Another commenter supported the bonus only if those that are not able to submit using end-to-end electronic reporting have access to CEHRT at no cost to the clinician. One commenter suggested that CMS continue the bonus points until the program is more mature and additional data on performance and reporting is gathered. A few commenters who supported maintaining the bonus points beyond the 2021 MIPS payment year, stated that the removal of the bonus points would result in increased administrative burden to CMS and clinicians, and would adversely affect the ability for clinicians with limited quality measures available to earn bonus points.

Response: While we signaled our intent to discontinue bonus points for end-to-end electronic reporting in the future (83 FR 35951), we are taking into consideration the suggestions we received on additional ways we can incentivize and encourage these reporting methods for future rulemaking.

After consideration of public comments, we are finalizing our proposals to continue to assign and maintain the cap on measure bonus points for end-to-end electronic reporting for the 2021 MIPS payment year and to amend § 414.1380(b)(1)(v)(B) accordingly.

We also proposed to modify our end-to-end reporting bonus point scoring policy based on the changes to the submission terminology discussed in section III.I.3.h.(1)(b) of this final rule (83 FR 35951). We proposed that the end-to-end reporting bonus can only apply to the subset of data submitted by direct, log in and upload, and CMS Web Interface that meet the criteria finalized in the CY 2017 Quality Payment Program final rule (81 FR 77297 through 77298). However, the end-to-end reporting bonus would not be applied to the claims submission type because it does not meet the criteria discussed above. This is not a policy change but rather a clarification of our current process in light of the proposed terminology changes.

We did not receive any comments on this proposal.

After consideration of public comments, we are finalizing our proposals to modify our end-to-end reporting bonus point scoring policy based on the changes to the submission terminology and only apply the bonus to the subset of data submitted by direct, log in and upload, and CMS Web Interface that meet the criteria finalized in the CY 2017 Quality Payment Program final rule (81 FR 77297 through 77298).

As discussed in section III.I.3.i.(1)(b)(x) of this final rule, we believe that in the future, bonus points for end-to-end reporting for all submission types will no longer be needed as we move towards fully implementing the program, and as a result we intend to consider in future rulemaking modifying our scoring policy to no longer offer end-to-end reporting bonus points after the 2021 MIPS payment year (83 FR 35951). Consistent with the section 1848(q)(5)(B)(ii) of the Act, which requires the Secretary to encourage the use of CEHRT for quality reporting, we will continue to be committed to ways that we can incentivize and encourage these reporting methods. We invited comment on other ways that we can encourage the use of CEHRT for quality reporting.

We thank commenters for suggestions and will consider them for future rulemaking.

(xi) Calculating Total Measure Achievement and Measure Bonus Points

(A) Calculating Total Measure Achievement and Measure Bonus Points for Non-CMS Web Interface Reporters

In the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77300, and 82 FR 53733 through 53736, respectively), we established the policy for calculating total measure achievement and measure bonus points for Non-CMS Web Interface reporters. We refer readers to § 414.1380(b)(1) for more details on these policies.

We did not propose any changes to the policy for scoring submitted measures collected across multiple collection types; however, we provided a summary of how this policy will be scored using our new terminology (83 FR 35952). We noted that CMS Web Interface and facility-based measurement each have a comprehensive set of measures that meet the proposed MIPS category requirements. As a result, we did not combine CMS Web Interface measures or facility-based measurement with other ways groups can be scored for data submitted for MIPS (other than CAHPS for MIPS, which can be submitted in conjunction with the CMS Web Interface). We refer readers to section III.I.3.i.(1)(d) of this final rule for a description of our policies on facility-based measurement (83 FR 35956 through 35963).

Although we have established a policy to account for scoring in circumstances when the same measure is collected via multiple collection types, we anticipate that this will be a rare circumstance and do not encourage clinicians to submit the same measure collected via multiple collection types. Table 51 is included in this final rule for illustrative purposes and clarity due to the changes in terminology discussed in section III.I.3.h.(1)(b) of this final rule (83 FR 35893 through 35895). For further discussion of this example, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53734).

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TABLE 51: Example Assigning Total Measure Achievement and Bonus Points for an Individual MIPS Eligible Clinician Who Submits Measures Collected Across Multiple Collection Types

	Measure Achievement Points	Six Scored Measures	High-Priority Measure Bonus Points	Incentive for CEHRT Measure Bonus Points
MIPS CQMs				
Measure A (Outcome)	7.1	7.1 (Outcome measure with highest achievement points)	(required outcome measure does not receive bonus points)	
Measure B	6.2 (points not considered because it is lower than the 8.2 points for the same claims measure)			
Measure C (high priority patient safety measure that meets requirements for additional bonus points)	5.1 (points not considered because it is lower than the 6.0 points for the same claims measure)		1	
Claims				
Measure A (Outcome)	4.1 (points not considered because it is lower than the 7.1 points for the same MIPS CQM)		No bonus points because the MIPS CQM of the same measure satisfies requirement for outcome measure.	
Measure B	8.2	8.2		
Measure C (High priority patient safety measure that meets requirements for additional bonus points)	6.0	6.0	No bonus (Bonus applied to the MIPS CQMs)	
Measure D (outcome measure <50% of data submitted)	1.0		(no high priority bonus points because below data completeness)	
EHR (direct submission using end-to-end)				***Reporting that meets CEHRT /bonus point criteria***
Measure E	5.1	5.1		1
Measure F	5.0	5.0		1
Measure G	4.1			1
Measure H	4.2	4.2		1
Measure I (high priority patient safety measure that is below case minimum)	3.0		(no high priority bonus points because below	1

	Measure Achievement Points	Six Scored Measures	High-Priority Measure Bonus Points	Incentive for CEHRT Measure Bonus Points
			case minimum)	
		35.6	1 (below 10% cap[1])	5 (below 10% cap)
Quality Performance Category Percent Score Prior to Improvement Scoring		(35.6 + 1 + 5) / 60 = 69.33%		

[1] In this example, the cap would be 6 points, which is 10 percent of the total available measure achievement points of 60.

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We did not propose any changes to our policy regarding scoring measure achievement points and bonus points when using multiple collection types for non-Web Interface MIPS eligible clinicians in the quality performance category for the 2019 MIPS performance period.

(B) Calculating Total Measure Achievement and Measure Bonus Points for CMS Web Interface Reporters

In the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77302 through 77306, and 82 FR 53736 through 82 FR 53737, respectively), we finalized the scoring policies for CMS Web Interface reporters. As part of our technical updates to § 414.1380(b)(1) discussed in section III.I.3.i.(1)(b) of this final rule, our previously established policies for CMS Web Interface reporters are now referenced at § 414.1380(b)(1)(i)(A)(*2*)(*i*) and (b)(1)(v)(A).

(xii) Future Approaches To Scoring the Quality Performance Category

As we discuss in section III.I.3.h.(2)(b)(iv) of this final rule, we anticipate making changes to the quality performance category to reduce burden and increase the value of the measures we are collecting. We discussed that existing measures have differing levels of value and our approaches for implementing a system where points are awarded based on the value of the measure. Should we adopt these approaches, we anticipate needing to modify our scoring approaches accordingly. In addition, we have received stakeholder feedback requesting that we simplify scoring for the quality performance category. Therefore, we solicited comment on the following approaches to scoring that we may consider in future rulemaking and whether these approaches move the clinicians towards reporting high value measures and more accurate performance measurement (83 FR 35954 through 35955).

One option for simplification is restructuring the quality requirements with a pre-determined denominator, for example, 50 points, but no specific requirements regarding the number of measures that must be submitted. Further, we would categorize MIPS and QCDR measures by value, because we recognize that not all measures are created equal. We seek to ensure that the collection and submission of data is valuable to clinicians and worth the cost and burden of collection of information. A system to classify measures as a particular value (for example, gold, silver, or bronze) is discussed in section III.I.3.h.(2)(b)(iv) of this final rule. In this approach, the highest tier would include measures that are considered ''gold'' standard, such as outcome measures, composite measure, or measures that address agency priorities (such as opioids). The CAHPS for MIPS survey, which collects patient experience data, may also be considered a high-value measure. Measures considered in the second tier, or at a ''silver'' standard, would be process measures that are directly related to outcomes and have a good gap in performance (there is no high, unwavering performance) and demonstrate room for improvement, or topped out outcome measures. Lower value measures, such as standard of care process measures or topped out process measures, would have scoring caps in place that would reflect the measure's status as a ''bronze measure.'' In this scenario, we could envision awarding points for achievement as follows: Up to 15 to 20 points in the top tier; up to 10 points in the next tier; and up to 5 points in the lowest tier. Similar to the structure of the improvement activities performance category, a clinician that chooses a top-tier measure would not have to submit as many measures to MIPS. We would still want to ensure the submission of high value measures and might include requirements that restrict the number of lower tier measures that could be submitted; alternatively, we could add a requirement that a certain number of higher tier measures would need to be submitted. With this approach, we could still incentivize reporting on high-priority measures by classifying them as ''gold'' standard measures which would be eligible for up to 15 to 20 achievement points.

Alternatively, we could keep our current approach for the quality performance category requiring 6 measures including one outcome measure, with every measure worth up to 10 measure achievement points in the denominator but change the minimum number of measure achievement points available to vary by the measure tier. For example, high-tier measures could qualify for high priority bonus and/or have a higher potential floor (for example, 5 measure achievement points instead of the floor of 3 measure achievement points for ''gold'' standard measures, which would be eligible for up to 10 measure achievement points.); whereas low-tier measures could have a lower floor (for example, 1 measure achievement point instead of the floor of 3 measure achievement points for ''bronze standard' measures).

Taking into consideration the potential future quality performance category change, we also believe that removing the validation process to determine whether the eligible clinician has measures that are available and applicable would simplify the quality performance category significantly. Several stakeholders have expressed their confusion with the validation process. A move to sets of measures in the quality performance category, potentially with some criteria to define the clinicians for whom these measures are applicable, would eliminate the need for a validation process for measures that are available and

applicable. Moving to sets of measures would also enable us to develop more robust benchmarks. We also believe that in the next few years, we could remove the validation process for measures that are available and applicable if we set the denominator at a pre-determined level (as outlined in the example above at 50 points) and let clinicians determine the best method to achieve 50 points. For the 2019 and 2020 MIPS payment years, MIPS eligible clinicians and groups who report on QCDR measures that do not have an available benchmark based on the baseline or performance period but meet data completeness are assigned a score of 3 measure achievement points (small practices receive 3 points regardless of whether they meet data completeness). Through stakeholder engagement, particularly feedback provided by QCDRs who have developed their own measures, we have heard that MIPS eligible clinicians are hesitant to report QCDR measures without established benchmarks. Eligible clinicians have voiced concern on reporting on QCDR measures without benchmarks because they are not certain that a benchmark could be calculated and established for the MIPS performance period, and they would therefore be limited to a 3-point score for that QCDR measure. In addition, QCDRs have inquired about the possibility of creating QCDR benchmarks. To encourage reporting of QCDR measures, we sought comment on an approach to develop QCDR measure benchmarks based off historical measure data. This may require QDCRs to submit historical data in a form and manner that meets benchmarking needs as required by CMS. We anticipate that the historical QCDR measure data would need to be submitted at the time of self-nomination of the QCDR measure, during the self-nomination period. Detailed discussion of the self-nomination period timeline and requirements can be found in section III.I.3.k of this final rule. Our concern with utilizing historical data provided by QCDRs to develop benchmarks is whether QCDRs have the capability to filter through their historical measure data to extract only data from MIPS eligible clinicians and groups prior to submitting the historical data to CMS for QCDR measure benchmarking consideration. Furthermore, once the historical data is submitted by the QCDR, CMS would analyze the data to ensure that it met benchmarking standards prior to it being accepted to form a benchmark. However, to perform this analysis CMS may need additional data elements such as the sources of the data, data completeness, and the collection period. In addition to seeking comment on developing QCDR measure benchmarks from historical data, we also solicited comment as to how our aforementioned concerns may be addressed in future rulemaking.

We also recognize that improving the electronic capture, calculation, and reporting of quality measures is also an important component of reducing provider burden. We invited comment on how we can incorporate incentives for the use of electronic clinical quality measurement into the future approaches described under this section, as well as other ways to encourage more efficient technology-enabled measurement approaches.

We solicited comment on these approaches and other approaches to simplify scoring, provide incentives to submit more impactful measures that assess outcomes rather than processes, and develop data that can show differences in performance and determine clinicians that provide high value care (83 FR 35954 through 35955).

We thank commenters for suggestions and will consider them for future rulemaking.

(xiii) Improvement Scoring for the MIPS Quality Performance Category Percent Score

Section 1848(q)(5)(D)(i) of the Act stipulates that, beginning with the second year to which the MIPS applies, if data sufficient to measure improvement is available, the improvement of the quality performance category score for eligible clinicians should be measured. To measure improvement, we require a direct comparison of data from one Quality Payment Program year to another (82 FR 52740). For more descriptions of our current policies, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53737 to 53747). As part of our technical updates to § 414.1380(b)(1) discussed in section III.I.3.i.(1)(b) of this final rule, our previously established improvement scoring policies are now referenced at § 414.1380(b)(1)(vi).

In the CY 2018 Quality Payment Program final rule, we adopted a policy that MIPS eligible clinicians must fully participate to receive a quality performance category improvement percent score greater than zero (82 FR 53743 through 53745). In § 414.1380(b)(1)(vi)(F), we determined ''participation'' to mean compliance with § 414.1330 and § 414.1340 in the current performance period. We issued a technical correction for the CY 2018 Quality Payment Year final rule, replacing § 414.1330 with § 414.1335 since § 414.1335 is more specific because it discusses the quality performance category requirements.

We finalized at § 414.1380(b)(1)(vi)(C)(4) that we would compare the 2018 performance to an assumed 2017 quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year (82 FR 53744 through 53745). In the CY 2019 PFS proposed rule, we proposed to continue this policy for the 2019 MIPS performance period and amend § 414.1380(b)(1)(vi)(C)(4), accordingly (83 FR 35955). We proposed to compare the 2019 performance to an assumed 2018 quality performance category achievement percent score of 30 percent.

The following is a summary of the public comments on the proposal and our responses:

Comment: One commenter supported the proposal.

Response: We thank the commenter for its support.

After consideration of public comments, we are finalizing the proposal to continue our previously established policy for the 2019 MIPS performance period and amend § 414.1380(b)(1)(vi)(C)(4), accordingly. Specifically, we will compare the 2019 performance to an assumed 2018 quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year.

(xiv) Calculating the Quality Performance Category Percent Score Including Achievement and Improvement Points

In the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77300 and 82 FR 53747 through 53748, respectively), we finalized the policies on incorporating the improvement percent score into the quality performance category percent score. As part of our technical updates to § 414.1380(b)(1) discussed in section III.I.3.i.(1)(b) of this final rule, our previously established policies are now referenced at § 414.1380(b)(1)(vii).

(c) Scoring the Cost Performance Category

(i) Scoring Achievement in the Cost Performance Category

For a description of the statutory basis and our existing policies for scoring achievement in the cost performance

category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77308 through 77311) and the CY 2018 Quality Payment Program final rule (82 FR 53748 through 53749). In the CY 2017 Quality Payment Program final rule (81 FR 77308 through 77309), we established that we will determine cost measure benchmarks based on cost measure performance during the performance period. We also established that at least 20 MIPS eligible clinicians or groups must meet the minimum case volume that we specify for a cost measure in order for a benchmark to be determined for the measure, and that if a benchmark is not determined for a cost measure, the measure will not be scored. We proposed to codify these final policies at § 414.1380(b)(2)(i) (83 FR 35955 through 35956).

While we did not receive any public comments for this proposal, we are finalizing our proposal to codify these final policies at § 414.1380(b)(2)(i).

(ii) Scoring Improvement in the Cost Performance Category

For a description of the statutory basis and our existing policies for scoring improvement in the cost performance category, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53749 through 53752). Section 51003(a)(1)(B) of the Bipartisan Budget Act of 2018 modified section 1848(q)(5)(D) of the Act such that the cost performance category score shall not take into account the improvement of the MIPS eligible clinician for each of the second, third, fourth, and fifth years for which the MIPS applies to payments. We do not believe this change requires us to remove our existing methodology for scoring improvement in the cost performance category (see 82 FR 53749 through 53752), but it does prohibit us from including an improvement component in the cost performance category percent score for each of the 2020 through 2023 MIPS payment years. Therefore, we proposed to revise § 414.1380(b)(2)(iv)(E) to provide that the maximum cost improvement score for the 2020, 2021, 2022, and 2023 MIPS payment years is zero percentage points (83 FR 35955). Under our existing policy (82 FR 53751 through 53752), the maximum cost improvement score for the 2020 MIPS payment year is 1 percentage point, but due to the statutory changes and under our proposal, the maximum cost improvement score for the 2020 MIPS payment year would be zero percentage points. We also proposed at § 414.1380(a)(1)(ii) to modify the performance standards to reflect that the cost performance category percent score will not take into account improvement until the 2024 MIPS payment year (83 FR 35956). The following is a summary of the public comments received on these proposals and our responses:

Comment: A few commenters supported the proposals to set the maximum cost improvement score for the 2020, 2021, 2022, and 2023 MIPS payment years at zero percentage points.

Response: We thank the commenter for their support.

Comment: Several commenters requested that the cost performance category score be determined in a different manner because of the proposed inclusion of episode-based measures. A few commenters recommended that the new measures have a lower weight in determining the cost performance category score than the previously-established MSPB and total per capita cost measures. A few commenters recommend that similar to the quality performance category, only the 6 measures with the highest scores among those for which the clinician or group met the case minimum should be included in calculating the cost performance category score. Likewise, a few commenters recommended that similar to the quality performance category, scores for cost measures should not be below 3 out of 10 points. One commenter recommended that a cost performance category score not be calculated if a clinician or group only meets the case minimum for a single cost measure.

Response: We do not believe that the inclusion of new measures in the cost performance category necessitates a change in the determination of the cost performance category score. Measures in the cost performance category differ from quality measures because they do not require reporting on the part of the clinicians outside of the usual claims submission process. Therefore, there is no choice of measures for clinicians nor burden of reporting. We believe that this is an important consideration in maintaining a simpler scoring mechanism in the cost performance category and scoring all measures for which an individual or group meets the case minimum. Some groups due to their size and comprehensiveness will meet the case minimum for all cost measures. Other individuals and groups will meet the case minimum for fewer measures. A scoring policy that would only score the top 6 measures in the cost performance category would provide an advantage for those groups with more than 6 measures because it would disregard those measures on which performance was poorest. For example, a group that met the case minimum for 10 measures and scored in the lowest decile for the total per capita cost score and the highest decile for all other measures, would have the score for the total per capita measure dropped and would receive the highest possible score in the cost performance category. A group that met the case minimum for only 6 measures, and also performed in the lowest decile for the total per capita cost score and the highest decile for the other 5 cost measures for which it met the case minimum, would not have performance on this measure disregarded and receive a lower score.

We believe that not scoring clinicians and groups that meet the case minimum for only a single measure would fail to recognize that a single measure, such as total per capita cost, could reflect care provided to a large number of patients.

After consideration of the public comments, we are finalizing as proposed our proposal to revise § 414.1380(b)(2)(iv)(E) to provide that the maximum cost improvement score for the 2020, 2021, 2022, and 2023 MIPS payment years is zero percentage points. We are also finalizing as proposed our proposal at § 414.1380(a)(1)(ii) to modify the performance standards to reflect that the cost performance category percent score will not take into account improvement until the 2024 MIPS payment year.

(d) Facility-Based Measures Scoring Option for the 2021 MIPS Payment Year for the Quality and Cost Performance Categories

(i) Background

In the CY 2018 Quality Payment Program final rule, we established a facility-based measurement scoring option for clinicians that meet certain criteria beginning with the 2019 MIPS performance period/2021 MIPS payment year (82 FR 53752 through 53767). We originally proposed a facility-based measurement scoring option for the 2018 MIPS performance period. We did not finalize the policy because we were concerned that we would not have the operational ability to inform clinicians early enough in the 2018 MIPS performance period to allow them to consider the consequences and benefits of participation (82 FR 53755).

(ii) Facility-Based Measurement Applicability

(A) General

In the CY 2018 Quality Payment Program final rule, we limited facility-based reporting to the inpatient hospital in the first year for several reasons,

including because a more diverse group of clinicians (and specialty types) provide services in an inpatient setting than in other settings, and because the Hospital Value-Based Purchasing (VBP) Program adjusts payment to hospitals for inpatient services in connection with their performance under that program (82 FR 53753 through 53755). We also limited measures applicable for facility-based measurement to those used in the Hospital VBP Program because the Hospital VBP Program compares hospital performance on a series of different measures intended to capture the breadth of inpatient care in the facility (82 FR 53753). We noted that we were open to the consideration of additional facility types in the future but recognized that adding a facility type would be dependent upon whether CMS has established a value-based purchasing program for that facility type, the applicability of measures, and our ability to appropriately attribute a clinician to a facility (82 FR 53754). Please note that when we use the term value-based purchasing, we are referring in general to value-based purchasing programs or scores, and not specifically the Hospital VBP Program, unless specifically stated.

We did not propose to add additional facility types for facility-based measurement, but we are interested in potentially expanding to other settings in future rulemaking. Therefore, in section III.I.3.i.(1)(d)(vii) of this final rule, we outline several issues on which we requested feedback and would need to be resolved in order to expand this option to a wider group of facility-based clinicians in future years.

(B) Facility-Based Measurement by Individual Clinicians

In the CY 2018 Quality Payment Program final rule, we established individual eligibility criteria for facility-based measurement at § 414.1380(e)(2)(i). We established that a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital or emergency room based on claims for a period prior to the performance period as specified by CMS (82 FR 53756 through 53757) is eligible as an individual for facility-based measurement. We had noted, as a part of our proposal summary, that we would use the definition of professional services in section 1848(k)(3)(A) of the Act in applying this standard (82 FR 53756). For purposes of determining eligibility for facility-based measurement, we discussed CMS using data from the period between September 1 of the calendar year, 2 years preceding the MIPS performance period, through August 31 of the calendar year preceding the MIPS performance period, with a 30-day claims run out but did not finalize that as part of the applicable regulation (82 FR 53756 through 53757). Because we are using the quality measures associated with the inpatient hospital to determine the MIPS quality and cost performance category score, we wanted to ensure that eligible clinicians contributed to care in that setting during that time period.

We indicated that CMS will use POS code 21 (inpatient) and POS code 23 (emergency department) for this purpose (82 FR 53756). Commenters on our proposal (as summarized in the CY 2018 Quality Payment Program final rule (82 FR 53756 through 53757)) expressed concern that adopting the definition that we did for facility-based clinicians would limit the number of clinicians who would be eligible.

In the CY 2019 PFS proposed rule, we proposed to modify our determination of a facility-based individual at § 414.1380(e)(2)(i) in four ways (83 FR 35957). First, we proposed to add on-campus outpatient hospital (as identified in the POS code in the HIPAA standard transaction, that is, POS code 22) to the settings that determine whether a clinician is facility-based. Second, we proposed that a clinician must have at least a single service billed with the POS code used for the inpatient hospital or emergency room. Third, we proposed that, if we are unable to identify a facility with a value-based purchasing score to attribute as a clinician's performance, that clinician is not eligible for facility-based measurement. Fourth, we proposed to align the time period for determining eligibility for facility-based measurement with changes to the dates used to determine MIPS eligibility and special status detailed in section III.I.3.b. of this final rule. We explain these four proposals from the proposed rule in this section. In the CY 2019 PFS proposed rule, we stated our belief that these proposals will further expand the opportunity for facility-based measurement and eliminate issues associated with the provision of observation services while still restricting eligibility to those who work in an inpatient setting.

First, we proposed to add the on-campus outpatient hospital (POS code 22) to the list of sites of service used to determine eligibility for facility-based measurement (83 FR 35957). We agree with commenters that limiting the eligibility to our current definition may prevent some clinicians who are largely hospital-based from being eligible. However, expanding eligibility without taking into account the relationship between the clinician and the facility and facility's performance could result in unfairly attributing to a clinician performance for which the clinician is not responsible or has little to no role in improving. We do believe that a significant provision of services in the on-campus outpatient hospital are reflected in the quality captured by the Hospital VBP Program. For example, patients in observation status are typically treated by the same staff and clinicians as those who meet the requirements for inpatient status. Although there are some clinical differences that may result in a patient having observation status, we believe that the quality of care provided to these patients in this same setting would be comparable, reflecting the overall healthcare system at that particular location. In the CY 2019 PFS proposed rule, we stated our conviction, based on this that a sufficient nexus exists for attributing the hospital's VBP Total Performance Score to clinicians that provide services in on-campus outpatient hospital settings.

Second, we proposed to require that clinicians bill at least a single service with the POS codes for inpatient hospital or the emergency room in order to be eligible for facility-based measurement (83 FR 35957). Although we generally believe that clinicians who provide services in the outpatient hospital can affect the quality of care for inpatients, we noted in the CY 2019 PFS proposed rule our belief that a clinician who is measured according to the performance of a hospital should at least have a minimal presence in the inpatient or emergency room setting. We explained our concern about attributing inpatient facility performance to clinicians who provide at least 75 percent of their services at on-campus outpatient hospitals (with POS code 22) when such clinicians exclusively provide outpatient services that are unrelated to inpatient hospital service by describing an example: A dermatologist who provides office-based services in a hospital-owned clinic but who never admits or treats patients within the inpatient or emergency room setting does not meaningfully contribute to the quality of care for patients measured under the Hospital VBP Program.

We stated in the CY 2019 PFS proposed rule how we had considered different ways to best identify those who contribute to the quality of care in the inpatient setting while keeping the

facility-based scoring option as simple as possible. We provided one explanation of an alternative we had considered: Separately measuring the HCPCS codes for observation services; however, as also noted in the proposed rule, we believe that such a measurement may not fairly consider services provided by clinicians for whom observations services may be embedded in a global code for a procedure rather than billed as a separate observation service. We also considered requiring a clinician to provide a certain percentage of services with the inpatient hospital POS. We described how we had not identified a threshold (other the one claim threshold we proposed) that would more meaningfully differentiate clinicians who provide services with the outpatient hospital POS code versus those who do not contribute to the services that would be measured under the Hospital VBP Program. We identified our goal of ensuring that the program rules are clear and easily applied to clinicians, so as to both avoid confusion on program participation requirements and to meet overall agency goals to increase transparency in the agency's activities. Our proposal of using a single service as the threshold would provide a simple, bright-line to differentiate those who never provide inpatient services from clinicians that do provide inpatient services as well as outpatient services. We explained in the proposed rule that this would limit the chance of clinicians who exclusively practice in the outpatient setting being measured on the Hospital VBP Program's performance of an unrelated hospital. We recognized this requirement of one service with the inpatient or emergency department POS may not demonstrate a significant presence in a particular facility and solicited comment on whether a better threshold could be used to identify those who are contributing to the quality of care for patients in the inpatient setting without creating unnecessary or inappropriate barriers to eligibility for facility-based measurement.

We explained in the proposed rule our rationale and reasoning for these first two proposals as being based in large part on our analysis of the previously finalized policy for eligibility for the facility-based measurement scoring option. Using claims data, we had identified all clinicians that would be MIPS eligible as either an individual or group, and identified the POS codes submitted for PFS services provided by those clinicians. We then modeled the existing final policy based on inpatient and ER services. Although almost all ER physicians would be scored under facility-based measurement, a relatively small percentage of clinicians in other specialties, even those which we expected to have significant presence in the hospital, would be eligible for the facility-based measurement scoring option. For example, only 13.45 percent of anesthesiologists would be eligible for the facility-based measurement scoring option under the policy finalized in the CY 2018 Quality Payment Program final rule. Adding the on-campus outpatient hospital POS code substantially increased eligibility for the facility-based measurement scoring option in our modeling, even after we adjusted for requiring one service with the inpatient or emergency department POS. Under our proposal, our model illustrated that 72.55 percent of anesthesiologists would be eligible. However, the model did not show that the proposal would substantially increase the number of clinicians eligible for the facility-based measurement scoring option who, based on specialty identification, may not have a significant presence in the hospital. For example, the modeling of the proposed policy projected an increase in the percentage of family physicians eligible for the facility-based measurement scoring option from 11.34 percent to 13.86 percent, which is still a very small percentage of those clinicians.

Third, we proposed to add a new criterion (to be codified at § 414.1380(e)(2)(i)(C)) that stated to be eligible for facility-based measurement, we must be able to attribute a clinician to a particular facility that has a value-based purchasing score (83 FR 35957 through 35958). We explained in the proposed rule how, for facility-based measurement to be applicable, we must be able to attribute a clinician to a facility with a value-based purchasing score. Based on our definition of facility-based measurement, we stated that this means a clinician must be associated with a hospital with a Hospital VBP Program Total Performance Score. We explained our concern that the proposed expansion of eligibility for facility-based measurement would increase the number of clinicians eligible for facility-based measurement but to whom we would be unable to attribute the performance of a particular facility that has a value-based purchasing score. As we noted in the CY 2018 Quality Payment Program final rule (82 FR 53766), some hospitals do not have a Hospital VBP Program Total Performance Score that could be used to determine a MIPS quality and cost performance category score, such as hospitals in the state of Maryland. Hence, clinicians associated with those hospitals would not be able to use facility-based measurement but could report quality measures through another method and have cost measures calculated if applicable. We explained that, under our proposal, a similar result, although relatively rare, would happen if we could not attribute a clinician identified as facility-based to a specific facility; those clinicians who are identified as facility-based but whom we cannot attribute to a hospital would have to participate in MIPS quality reporting through another method, or they would receive a score of zero in the quality performance category. Therefore, we proposed to add the requirement to § 414.1380(e)(2)(i)(C) that a clinician must be able to be attributed to a particular facility with a value-based purchasing score under the methodology specified in § 414.1380(e)(5) to be eligible for facility-based measurement. The cross-reference to paragraph (e)(5) is to the methodology we also proposed for determining the applicable facility score to be used. Our proposed new regulatory text at § 414.1380(e)(2)(i)(C) addresses both attribution to a facility and the need for that facility to have a value-based purchasing score by conditioning eligibility for facility-based scoring for an individual clinician on the clinician being attributed under the methodology in paragraph (e)(5) to a facility with a value-based purchasing score.

Fourth, we proposed to change the dates of determining eligibility for facility-based measurement (83 FR 35958). In section III.M.3.b. of the proposed rule, we proposed to modify the dates of the MIPS determination period that would provide eligibility determination for small practice size, non-patient facing, low-volume threshold, ASC, hospital-based, and facility-based determination periods. To align this regulation controlling facility-based scoring with these other determination periods, we proposed that CMS would use data from the initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period, with a 30-day claims run out, in determining eligibility for facility-based measurement.

The following is a summary of the public comments received on these proposals and our responses:

Comment: Many commenters supported the four proposed changes to the determination of a facility-based individual.

Response: We appreciate the commenters' support.

Comment: One commenter recommended that CMS include the place of service code used for the off-campus outpatient hospital (POS code 19) in determining individual eligibility for facility-based measurement, noting that many clinicians work in both on-campus and off-campus outpatient hospital settings. The commenter further suggested the inclusion of the measures from the Hospital Outpatient Quality Reporting Program.

Response: While we are finalizing our proposal to add on the on-campus outpatient code (POS code 22), we disagree that the off-campus outpatient hospital setting (POS code 19) indicates that a clinician has a significant impact on the quality and cost within an inpatient hospital setting in the way that POS code 22 might. A clinician may work at an off-campus outpatient hospital setting that is miles from the hospital and not have any involvement with patients that are hospitalized. We do not believe the Hospital VBP Program measures, which reflect the quality of care furnished to patients in hospitals in inpatient settings, are applicable to (or relate to the performance of) those clinicians who primarily bill within the off-campus outpatient hospital setting; therefore, we do not believe such clinicians should be eligible for facility-based measurement.

While the measures used in the Hospital Outpatient Quality Reporting Program do reflect quality for the off-campus outpatient hospital, section 1848(q)(2)(C)(ii) of the Act provides that we may not use measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists. Our determination of facility-based measurement does not consider the specialty of clinicians, so we therefore do not believe it is appropriate or consistent with the statutory authority to add this setting or these measures at this time.

Comment: One commenter recommended that the threshold of services required to be provided in facilities to be eligible for facility-based measurement be reduced from 75 percent to more than 50 percent of services, because clinicians often work in multiple settings.

Response: As we stated in the CY 2018 Quality Payment Program final rule (82 FR 53757), we believe the 75 percent threshold is appropriate to use because it is similar to our determination of hospital-based eligible clinicians in the Promoting Interoperability performance category. In the context of our proposal to change the eligibility criteria for facility-based measurement, we still believe that a 75 percent threshold indicates that a clinician is spending much of their clinical time working in a hospital and the quality of their work is reflected in that setting. Clinicians who work in more varied settings may be better measured through another method of participating in MIPS.

Comment: One commenter recommended that CMS not include the requirement to bill at least a single service with the POS code used for the inpatient hospital or emergency room as this requirement could easily be gamed.

Response: We continue to believe that that using a single service as the threshold provides a simple, bright line to differentiate those who never provide inpatient services from clinicians that do provide inpatient services, as well as outpatient services. We will monitor this requirement and may consider changing it in future rulemaking if we find evidence or examples of gaming, such as that clinicians are providing services in the inpatient setting primarily so they may meet the requirements of facility-based measurement.

Comment: Several commenters supported the facility-based measurement and the proposed policies because this option would reduce burden and recognize the joint accountability for measures in the hospital environment.

Response: We appreciate the commenters' support as we begin to implement facility-based measurement in the 2019 MIPS performance period/2021 MIPS payment year.

Comment: Several commenters requested that CMS provide more data analysis on the implementation of facility-based measurement. A few commenters noted concerns with how the facility-based scoring option could contribute to an uneven playing field. Commenters' concerns highlighted that automatically applying a quality and cost score eliminates incentives to coordinate care which may place these clinicians at an unfair advantage over those who must report on measures and take steps to perform well on those measures. Hence, commenters encouraged CMS to closely monitor the impact of the facility-based scoring option policy. One commenter suggested that CMS provide more data on how MIPS eligible clinicians might score in the facility-based scoring option. Another commenter suggested that CMS provide data on the percentage of certain specialists who would be eligible. A few commenters suggested that CMS should closely monitor how facility-based measurement impacts total MIPS scores between specialties and groups working within the same hospital, as well as the effect of facility-based measurement on those who are not eligible. One commenter suggested that CMS provide more information via educational resources; another commenter requested that CMS explain how the Hospital VBP Program Total Performance Score is converted into MIPS scoring and requirements for group reporting options.

Response: We recognize the value of data analysis when developing additional scoring options for MIPS eligible clinicians. We continue to believe that the facility-based scoring option will reduce administrative burden by streamlining reporting and allowing clinicians to focus on quality improvement. We disagree that clinicians have an advantage under facility-based scoring option given that we have established an eligibility threshold to identify those clinicians that have a significant impact on the care delivered within the facility and the facility's performance under the Hospital VBP Program. The scoring methodology developed for facility-based measurement translates scores in the Hospital VBP Program to scores in the Quality and Cost performance category. Because that translation takes into account the distribution of scores in the Hospital VBP program, which is analogous to the distribution of scores in MIPS, clinicians who are scored using facility-based measurement will have a similar range of scores as those who are not eligible for facility-based measurement. We will continue to monitor the impact of the finalized facility-based scoring policies in efforts to avoid unfair advantages within the MIPS program.

Comment: Several commenters expressed concern about the availability of facility-based measurement beginning in the 2019 MIPS performance period/2021 MIPS payment year. The commenters expressed concern that the measures included in the Hospital VBP Program were not representative of the care provided by clinicians and would distract from efforts to focus on measures on which these clinicians could have an effect. A few commenters

supported facility-based measurement as a short-term solution to reducing administrative burden for clinicians who primarily work within an inpatient setting but encouraged movement towards measures that are more meaningful for certain specialists who also predominantly work within an inpatient setting.

Response: We recognize that the Hospital VBP Program was not designed to measure clinicians' performance but rather hospitals' performance. However, we believe that by using the established 75 percent threshold to identify clinicians as eligible for facility-based scoring, we are distinguishing between those clinicians who ultimately have a significant impact on the hospital's performance score for the care and cost rendered within that facility versus those who do not. We therefore believe that the Hospital VBP Program measures do reflect the performance of the clinicians in a team-based environment. We note that there may be more opportunities for clinicians, particularly specialists who wish to report on more clinically meaningful measures, to participate in MIPS using qualified registries or QCDRs that may be related to care provided to those specific patients in a facility setting, and we encourage clinicians who find the MIPS measures more meaningful in the context of their patient population to report in that manner.

After consideration of the public comments, we are finalizing our proposals to add the on-campus outpatient hospital (POS code 22) to the list of sites of service used to determine eligibility for facility-based measurement and to require that clinicians bill at least a single service with the POS codes for inpatient hospital or the emergency room in order to be eligible for facility-based measurement as reflected in the regulation text at § 414.1380(e)(2)(i)(A) and (B). We are also finalizing our proposal that we must be able to attribute a clinician to a particular facility that has a value-based purchasing score under the methodology specified in § 414.1380(e)(5) to meet eligibility for facility-based measurement as codified at § 414.1380(e)(2)(i)(C). We are also finalizing our proposed policy that CMS would use data from the initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period, with a 30-day claims run out to determine eligibility for facility-based measurement.

(C) Facility-Based Measurement by Group

In the CY 2018 Quality Payment Program final rule (82 FR 53757), we finalized at § 414.1380(e)(2)(ii) that a MIPS eligible clinician is eligible for facility-based measurement under MIPS if they are determined to be facility-based as part of a group. We established at § 414.1380(e)(2)(ii) that a facility-based group is a group in which 75 percent or more of its eligible clinician NPIs billing under the group's TIN meet the requirements at § 414.1380(e)(2)(i) (82 FR 53758). We did not propose any changes to the determination of a facility-based group but acknowledged that our proposal to change how individual clinicians are determined to be eligible for facility-based measurement will necessarily have a practical impact for practice groups. For more of the statutory background and descriptions of our current policies on determining a facility-based group, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53757 through 53758).

(iii) Facility Attribution for Facility-Based Measurement

In the CY 2018 Quality Payment Program final rule (82 FR 53759), we finalized at § 414.1380(e)(5) a method to identify the hospital whose scores would be associated with a MIPS eligible clinician or group for purposes of facility-based measurement scoring. However, because of a discrepancy in the preamble and the proposed regulation text in the CY 2018 Quality Payment Program proposed rule (82 FR 53759), we indicated we would address this issue as part of the next Quality Payment Program rulemaking cycle. Under the current regulation text § 414.1380(e)(5), a facility-based clinician or group receives a score under the facility-based measurement scoring standard derived from the value-based purchasing score for the facility at which the clinician or group provided services to the most Medicare beneficiaries during the year claims are drawn (that is, the 12-month period described in paragraph (e)(2)). Although we did not propose any changes, we are revising this section to replace the word ''segment'' with ''period'' for clarity purposes.

If an equal number of Medicare beneficiaries are treated at more than one facility, then we will use the value-based purchasing score for the highest-scoring facility (82 FR 53759 through 53760). For more of the statutory background and descriptions of our current policies for attributing a facility to a MIPS eligible clinician, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53759 through 53760).

In considering the issue of facility attribution for a facility-based group, we stated in the CY 2019 PFS proposed rule that we believe that a change to facility-based attribution is appropriate to better align the policy with the determination of a facility-based group at § 414.1380(e)(2)(ii). A facility-based group is one in which 75 percent or more of the eligible clinician NPIs billing under the group's TIN are eligible for facility-based measurement as individuals. Additionally, under the current regulation, the value-based purchasing score for the highest scoring facility would be used in the case of a tie among the number of facilities at which the group provided services to Medicare beneficiaries. We proposed to revise § 414.1380(e)(5) to differentiate how a facility-based clinician or group receives a score based on whether they participate as a clinician or a group (83 FR 35958).

We proposed to remove ''or group'' from § 414.1380(e)(5) and redesignate that paragraph as (e)(5)(i) so that it only applies to individual MIPS eligible clinicians (83 FR 35958). Under our proposal, newly redesignated paragraph (e)(5)(i) would retain the rule for facility attribution for an individual MIPS eligible clinician as finalized in the CY 2018 Quality Payment Program final rule; we also proposed a few minor edits to the paragraph for grammar and to improve the sentence flow. We also proposed to add a new paragraph (e)(5)(ii) to provide that a facility-based group receives a score under the facility-based measurement scoring standard derived from the value-based purchasing score for the facility at which the plurality of clinicians identified as facility-based would have had their score determined under the methodology described in § 414.1380(e)(5)(i) if the clinicians had been scored under facility-based measurement as individuals (83 FR 35958). We made this proposal because of our wish to emphasize the connection between an individual clinician and a facility. We explained in the CY 2019 PFS proposed rule that using the plurality of clinicians reinforces the connection between an individual clinician and facility and is more easily understandable for larger groups.

The following is a summary of the public comments received on these proposals and our responses:

Comment: A few commenters suggested that CMS consider additional rules or standards for attribution of a

clinician or group to a facility for purposes of using that facility's Total Performance Score. One commenter requested that CMS consider using an eligible clinician's/group's second most utilized facility in cases where the top utilized facility does not have a Hospital VBP Program Total Performance Score. Another commenter encouraged CMS develop a group level attribution methodology to account for groups that practice in multiple sites and the commenter believed that an accountability model will be more meaningful and actionable for these groups.

Response: We are finalizing our proposal that if we are unable to identify a particular facility with a value-based purchasing score under the methodology specified in § 414.1380(e)(5), such as those facilities in the state of Maryland, to attribute for use as an individual clinician's performance, then that clinician is not eligible for facility-based measurement. We are concerned that using a hospital other than the most utilized could result in assigning a score based on a hospital at which the clinician rarely works. For example, in the case of using the second most utilized facility, an individual clinician may have primarily worked in the facility without a Hospital VBP Program Total Performance Score and then only have seen a single patient at the second most utilized hospital with a Hospital VBP Total Performance Score. However, we will consider looking into this issue in future rulemaking, including whether it may be appropriate to allow for the score to be based upon a facility other than the one at which a clinician provides services to the most patients.

We understand that some groups that may be facility-based include clinicians that practice in a number of different facilities. However, we believe this issue is similar to that experienced in other clinician groups that may have a diversity of clinicians and settings. In section III.I.3.e of the proposed rule (83 FR 35891), we requested comments on developing an opportunity for clinicians to participate in MIPS as subgroups. We believe that our consideration of that issue could inform the determination of members of a group that practice in a single TIN but who serve patients in many different facilities.

After consideration of the public comments, we are finalizing our proposals to remove ''or group'' from § 414.1380(e)(5); redesignate that paragraph as (e)(5)(i) so that it only applies to individual MIPS eligible clinicians; and add a new paragraph (e)(5)(ii) to § 414.1380(e)(5) regarding group scoring methodologies in which a facility-based group receives a score under the facility-based measurement scoring standard derived from the value-based purchasing score for the facility at which the plurality of clinicians identified as facility-based would have had their score determined under the methodology described in § 414.1380(e)(5)(i) if the clinicians had been scored under facility-based measurement as individuals.

(iv) No Election of Facility-Based Measurement

In the CY 2018 Quality Payment Program final rule (82 FR 53760), we did not finalize our proposal for how individual MIPS eligible clinicians or groups who wish to have their quality and cost performance category scores determined based on a facility's performance would elect to do so through an attestation. We did finalize, and reflect in the introductory text at § 414.1380(e), that an individual clinician or group would elect to use a facility-based score. In the CY 2019 PFS proposed rule (82 FR 53760), we specified that such clinicians or groups would be required to submit their election during the data submission period through the attestation submission mechanism established for the improvement activities and the Promoting Interoperability performance categories. An alternative approach, which likewise was not finalized, did not require an election process, but instead would have automatically applied a facility-based measurement to MIPS eligible clinicians and groups who met the eligibility criteria for facility-based measurement, if such an application were technically feasible (82 FR 53760). We noted in the CY 2018 Quality Payment Program final rule (82 FR 53760) that we would examine both the attestation process and the opt-out process, and work with stakeholders to identify a new proposal in future rulemaking. We explained in the CY2018 Quality Payment Program final rule (82 FR 53760) our interest in a process that would impose less burden on clinicians than an attestation requirement and requested comment on automatically assigning a clinician or group a facility-based score, but with a notice and opportunity to opt-out of facility-based measurement. We summarized those comments in the CY 2019 PFS proposed rule (83 FR 35958).

After further considering the advantages and disadvantages of an opt-in or an opt-out process, we proposed a modified policy that would not require an election process. We proposed to automatically apply facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based measurement and who would benefit by having a higher combined quality and cost performance category score (83 FR 35959). Under our proposal, if the MIPS eligible clinician or group is eligible for facility-based measurement, we would calculate a combined quality and cost performance category score. We proposed to use the facility-based score to determine the MIPS quality and cost performance category scores, unless we received another submission of quality data for or on behalf of that clinician or group and the combined quality and cost performance category score for the other submission results in a higher combined quality and cost performance score. If the other submission has a higher combined quality and cost performance score, then we would not apply the facility-based performance scores for either the quality or cost performance categories (83 FR 35959). Under our proposal, the combined score for the quality and cost performance categories would determine the scores to be used for both the quality and cost performance categories, for both individual clinicians and for groups that meet the requirements of paragraph (e)(2). We did not propose to adopt a formal opt-out process because, under our proposal, the higher of the combined quality and cost performance scores for the clinician or clinician group would be used, which would only benefit the clinician or group. We explained in the proposed rule our strong commitment to reducing burden as part of the Quality Payment Program and that we believe that requiring a clinician or group to elect a measurement process (or to opt-out of a measurement process) based on facility performance would add unnecessary burden.

In MIPS, we score clinicians as individuals unless they submit data as a group. We stated in the proposed rule that the same policy should apply to facility-based measurement, even though there are no submission requirements for the quality performance category for individuals under facility-based measurement. We proposed to revise § 414.1380(e)(4) to state that there are no submission requirements for individual clinicians in facility-based measurement, but a group must submit data in the improvement activities or Promoting Interoperability performance categories in order to be measured as a group under facility-based measurement. We explained how, if a group does not

submit improvement activities or Promoting Interoperability measures, we would apply facility-based measurement to the individual clinicians and such clinicians would not be scored as a group under our proposal. In the case of virtual groups, MIPS eligible clinicians will have formed virtual groups prior to the MIPS performance period; as a result, virtual groups eligible for facility-based measurement will always be measured as a virtual group (83 FR 35959). Although we can calculate a score for a TIN without the submission of data by the TIN, we would not be certain if the clinicians in that group actually wanted to be measured as a group without an active submission (in other words, if the group did not submit data as a group). As we explained in the proposed rule, we view submission of data on the improvement activities or Promoting Interoperability measures as an indication by the clinicians in that group that they want to be scored as a group; using the choice to submit data as a group to identify a group in the context of facility-based scoring would preserve and respect choices made by clinicians and groups while avoiding the burden of an election process to be scored as a group solely for the purpose of facility-based scoring. We solicited comment specifically on this proposal and other means to achieve the same ends.

In the CY 2018 Quality Payment Program final rule, we established that if a clinician or group elects facility-based measurement but also submits MIPS quality data, then the clinician or group would be measured on the method that results in the higher quality score (82 FR 53767). We proposed to adopt this same scoring principle in conjunction with our proposal not to use (or require) an election process. Therefore, we proposed at § 414.1380(e)(6)(vi) that the MIPS quality and cost score for clinicians and groups eligible for facility-based measurement would be based on the facility-based measurement scoring methodology described in § 414.1380(e)(6) unless the clinician or group receives a higher combined score for the MIPS quality and cost performance categories through data submitted to CMS for MIPS (83 FR 35959). We stated in the proposed rule that this policy is not applicable to any MIPS eligible clinicians scored under the APM scoring standard described at § 414.1370; we further clarify here that this includes Shared Savings Program participant TINs in ACOs that have failed to complete web interface reporting, unless these measures are specifically required under the terms of the applicable APM.

We also proposed conforming changes in two other sections of regulatory text. We proposed to revise the introductory text at § 414.1380(e) to remove ''elect to,'' and therefore, reflect that clinicians and groups who are determined to be facility-based will receive MIPS quality and cost performance categories under the methodology in paragraph (e) (83 FR 35959 through 35960). Because of our proposal to not require clinicians to opt-in into facility-based measurement, we acknowledged that there may be clinicians that will continue to submit data via other methods. We explained that these clinicians and groups are not prohibited from submitting quality measures to CMS for purposes of MIPS. However, under our proposal, if a higher combined quality and cost score is achieved using data submitted to CMS for purposes of MIPS, then we will use the MIPS scores based on the submission. We also proposed to revise § 414.1380(e)(4) and (e)(6)(v)(A) to reflect that facility-based measurement does not require election and to replace the phrase ''clinicians that elect facility-based measurement'' with ''clinicians and groups scored under facility-based measurement'' (83 FR 35960) as part of this policy.

The following is a summary of the public comments received on these proposals and our responses:

Comment: Many commenters supported our proposal to automatically apply facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based measurement and who would benefit by having a higher combined quality and cost performance category score.

Response: We thank the commenters for their support.

Comment: A few commenters opposed our proposal to require a group to submit information in the improvement activities or Promoting Interoperability performance categories to be measured as a facility-based group. A few of these commenters requested that rather than requiring the submission of information in these categories, CMS offer an election process. One commenter questioned how a group that was excluded from both the improvement activities and Promoting Interoperability performance categories could participate as a facility-based group. One commenter suggested that it would be difficult to complete an improvement activity if members of the group practice at more than one facility.

Response: We continue to believe that our proposal of a clinician receiving the higher of the quality and cost performance score available would only benefit the individual MIPS eligible clinician or group. If we do not require groups to submit data in the improvement activity or Promoting Interoperability performance categories, then we will be unable to tell whether the clinician should be measured as part of a group. We will consider whether there would be an opportunity for a facility-based group to elect to participate without submitting data on another performance category in the future as feasible. We do not believe that we would need to establish additional policies for groups that would have their improvement activities performance score re-weighted specifically because we generally expect reweighting to occur for the improvement activities performance category only in rare cases of extreme and uncontrollable events. We do note that the clinicians in a facility-based group who meet the requirements for facility-based measurement as individuals will have scores in the quality and cost performance categories determined for them as individuals if there is no data submission from the group in the improvement activity or Promoting Interoperability performance categories.

Comment: Commenters encouraged CMS to provide as much information as possible to eligible clinicians including information on eligibility for facility-based measurement, clinician type, potential performance score under facility-based scoring, and to which facility the eligible clinician will be attributed. Several commenters noted that more information would give clinicians the opportunity to assess the advantages and disadvantages of various reporting options under MIPS. One commenter stated that more information will avoid confusion as to how the facility-based scoring option will work during the performance period. A few commenters noted concerns with the timing of receiving information about facility-based measurement. Some commenters noted the risk of a clinician assuming that he or she will meet the criteria for facility-based measurement when that may not be the case. Another commenter noted that the timing is important in making decisions as to whether to report as a group or an individual under the facility-based scoring option.

Response: We intend to provide as much information as possible as early as possible to clinicians about their eligibility and the hospital performance upon which a MIPS eligible clinician's score would be based. We acknowledge

that clinicians may want to consider this information to make financial and operational decisions, regardless of not having to be required to opt-in to facility-based scoring. We intend to provide additional information to clinicians regarding their status with facility-based measurement eligibility, facility attribution, and a preview score based on data from the previous performance period. We anticipate that this information will be released during the first quarter of the performance period, if technically feasible, beginning with the 2019 performance period, and we aim to notify clinicians as soon as this information is available.

Comment: Many commenters expressed concern with our proposal to not require an opt-in or offer an opt-out for facility-based measurement. A few commenters noted that performing this calculation automatically would reduce the control that clinicians have over their participation in MIPS. A few commenters suggested that automatically calculating a score for facility-based clinicians would reduce the incentive to participate in clinical data registries. A few commenters suggested that not requiring an opt-in would provide a performance advantage to facility-based clinicians over those who are not eligible for facility-based measurement. One commenter expressed concern that clinicians could have measures displayed on Physician Compare from facility-based measurement.

Response: Receiving the higher of the combined quality and cost performance scores available would only benefit the applicable individual MIPS eligible clinician or group; however, we are uncertain that facility-based clinicians would necessarily perform better than those who submit MIPS data, because the opportunity to submit data via other methods provides individual clinicians or groups the opportunity to select quality measures. We continue to believe that adding a formal opt-in or opt-out process would add unnecessary burden for both individual clinicians and groups. Additionally, we believe that those MIPS eligible clinicians who will not be required to submit MIPS data will benefit from a reduction in administrative burden while being measured in a facility in which their care has a significant impact on the facility's performance. We note that clinicians who wish to better control their performance in MIPS may submit measures through another method. Hence, we are finalizing our proposal to not require an opt-in or opt-out for facility-based measurement. Additionally, we did not propose any policies for how facility-based measures, other than the scores derived from those measures and included as quality and cost performance category scores, will be displayed on Physician Compare, but we thank commenters for their input and will take this input into consideration in future years.

Comment: One commenter requested clarification on how CMS would score a facility-based clinician who submits data on the quality performance category but does not have a cost performance category score, and thus, the cost performance category weight would need to be redistributed to the quality performance category.

Response: The cost performance category can be reweighted to 0 percent if there are not sufficient cost measures applicable and available (for example, if the clinician does not meet the minimum case requirements for the cost measures). In cases in which a clinician or group does not have a score in the cost performance category, in general, the weight of the cost performance category would be redistributed to the quality performance category. In that case, the points assigned under § 414.1380(b) for purposes of calculating/assigning the MIPS final score in the cost and quality categories will be compared to the points that contribute to the final score from the quality and cost scores established under facility-based measurement. For example, a clinician whose data was submitted on their behalf by a third-party intermediary and received a MIPS quality performance category percent score of 50 percent but did not meet the case minimum for cost measures, would have a total of 30 points as the combined score for the quality and cost performance categories. If that same clinician were eligible for facility-based measurement, the score based on that third party intermediary submission would be used unless the combination of the quality and cost scores established under facility-based measurement (as calculated under § 414.1380(e)(6)) resulted in more than 30 points towards the final score.

Comment: One commenter requested guidance and language as to how to account for MIPS eligible clinicians who wish to use their facility's Hospital VBP Program Total Performance Score for the quality and cost performance categories, yet still use a QCDR to report.

Response: Our proposed policy to not require an opt-in or offer an opt-out for facility-based measurement anticipates that there may be some clinicians and groups who will both receive a score based upon facility-based measurement and submit quality measures via various collection types. These clinicians may believe these quality measures better represent their performance or that they will perform better submitting these measures. In all cases, under the policy we are finalizing here, we will compare combined performance in these two categories and assign the clinician or group the higher combined score, whether based on the facility-based measurement or through another submission type. We note that facility-based measurement only applies to the quality and cost performance categories; the Promoting Interoperability and improvement activity performance categories would still require reporting on the part of the clinicians or group.

After consideration of the public comments, we are finalizing our proposal to automatically apply facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based measurement and those who have a higher combined quality and cost performance category score. Additionally, we are finalizing our proposal to revise § 414.1380(e)(4) to state that there are no submission requirements for individual clinicians in facility-based measurement and that a group must submit data in the improvement activities or Promoting Interoperability performance categories to be measured as a group under facility-based measurement. Additionally, we are also revising the proposed regulation text for § 414.1380(e)(4) by adding ''to be'' between ''clinicians'' and ''scored'' to clarify that this paragraph is establishing the data submissions necessary for facility-based scoring to be possible as opposed to a provision governing MIPS reporting as a whole for all categories. We are also finalizing the conforming changes at § 414.1380(e)(4) and (e)(6) to revise text that referred to an election by the clinician or group to use facility-based scoring. Additionally, while we did not propose any changes, we are revising § 414.1380(e) to state, for the payment in 2021 MIPS payment year and subsequent years and subject to paragraph (e)(6)(vi) of this section, a MIPS eligible clinician or group will be scored under the quality and cost performance categories under the methodology described in this paragraph (e). These technical changes are made to conform to our policy in this section to not require or offer an election and to improve readability.

(v) Facility-Based Measures

(A) Background

Section 1848(q)(2)(C)(ii) of the Act provides that the Secretary may use

measures used for payment systems other than for physicians, such as measures for inpatient hospitals, for purposes of the quality and cost performance categories. However, the Secretary may not use measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists. In the CY 2018 Quality Payment Program proposed rule, we proposed to include for the 2020 MIPS payment year all the measures adopted for the FY 2019 Hospital VBP Program on the MIPS list of quality measures and cost measures for purposes of facility-based measurement (82 FR 30125). We noted how these measures meet the definition of additional system-based measures provided in section 1848(q)(2)(C)(ii) of the Act (82 FR 30125). In the CY 2018 Quality Payment Program final rule, we did not finalize our proposal that the facility-based measures available for the 2018 MIPS performance period would be the measures adopted for the FY 2019 Hospital VBP Program; nor did we finalize our proposal that, for the 2020 MIPS payment year, facility-based individual MIPS eligible clinicians or groups that were attributed to a facility would be scored on all measures on which the facility is scored via the Hospital VBP Program's Total Performance Score methodology (82 FR 53762).

We did finalize a facility-based measurement scoring standard but not the specific instance of using the FY 2019 Hospital VBP Program Total Performance Score methodology (82 FR 53755). We expressed our belief that using all measures from the Hospital VBP Program is appropriate; nevertheless, because we did not finalize the facility-based measurement scoring option for the 2018 MIPS performance period/2020 MIPS payment year, it was not appropriate to adopt these policies at that time (82 FR 53762 through 53763). We noted that we intended to propose measures that would be available for facility-based measurement for the 2019 MIPS performance period/2021 MIPS payment year in future rulemaking (82 FR 53763).

(B) Measures in Facility-Based Scoring

As we noted in the proposed CY 2019 PFS rule, we continue to believe it is appropriate to adopt all the measures for the Hospital VBP Program into MIPS for purposes of facility-based scoring; these Hospital VBP Program measures meet the definition of additional system-based measures provided in section 1848(q)(2)(C)(ii) of the Act. We also stated how it is appropriate to adopt the performance periods for the measures, which generally are consistent with the dates that we use to determine eligibility for facility-based measurement.

Beginning with the 2019 MIPS performance period, we proposed at § 414.1380(e)(1)(i) to adopt for facility-based measurement, the measure set that we finalize for the fiscal year Hospital VBP Program for which payment begins during the applicable MIPS performance period. For the 2019 MIPS performance period (which runs on the 2019 calendar year), we proposed to adopt the FY 2020 Hospital VBP Program measure set, for which payment begins on October 1, 2019. The performance period for these measures varies but performance ends in 2018 for all measures.

We also proposed at § 414.1380(e)(1)(ii) that, starting with the 2021 MIPS payment year, the scoring methodology applicable for MIPS eligible clinicians scored with facility-based measurement is the Total Performance Score methodology adopted for the Hospital VBP Program, for the fiscal year for which payment begins during the applicable MIPS performance period. Additionally, we note a typographical error in the CY 2019 PFS proposed rule (83 FR 35960) in which we state FY 2019 instead of FY 2020, which we believe commenters have likely understood given the comments we have received on FY 2020 measures. However, we provide additional clarification in this final rule.

We noted in the proposed rule that this approach of adopting all the measures in the Hospital VBP Program can be applied to other value-based purchasing programs in the future, should we decide to expand facility-based measurement to settings other than hospitals.

In the CY 2018 Quality Payment Program final rule we also established at § 414.1380(e)(6)(i) that the available quality and cost measures for facility-based measurement are those adopted under the value-based purchasing program of the facility for the year specified. We established at § 414.1380(e)(6)(ii) that we will use the benchmarks adopted under the value-based purchasing program of the facility program for the year specified (82 FR 53763 through 53764). We noted that we would determine the particular value-based purchasing program to be used for facility-based measurement in future rulemaking but would routinely use the benchmarks associated with that program (82 FR 53764). Likewise, at § 414.1380(e)(6)(iii), we established that the performance period for facility-based measurement is the performance period for the measures adopted under the value-based purchasing program of the facility program for the year specified (82 FR 53755). We noted that these provisions referred to the general parameters of our method of facility-based measurement and that we would address specific programs and years in future rulemaking (82 FR 53763). For the CY 2019 performance period, we proposed regulation text for these three provisions to specify that the measures, performance period, and benchmark period for facility-based measurement are the measures, performance period, and benchmark period established for the value-based purchasing program used to determine the score as described in § 414.1380(e)(1) (83 FR 35960). We provided an example in the proposed rule to illustrate this policy: For the 2019 MIPS performance period and 2021 MIPS payment year, the measures used would be those for the FY 2019 Hospital VBP Program along with the associated benchmarks and performance periods. As explained earlier, we intended this to mean that for the 2019 MIPS performance period and 2021 MIPS payment year, the measures used would be those for the FY 2020 Hospital VBP Program along with the associated benchmarks and performance periods.

The following is a summary of the public comments received on these proposals and our responses:

Comment: Several commenters noted their appreciation of the facility-based scoring option but requested that CMS consider additional measures that are more relevant to specific specialties as that would capture clinically meaningful information. One commenter suggested CMS develop episode-based risk adjusted measures even if they are not used in the Hospital VBP Program. Another commenter suggested that CMS consider additional avenues to collect more meaningful information.

Response: Section 1848(q)(2)(C)(ii) of the Act provides that the Secretary may use measures used for payment systems other than for physicians, such as measures for inpatient hospitals, for purposes of the quality and cost performance categories. Based on this statutory requirement and because we want to align incentives between clinicians and hospitals, we proposed to use measures that are developed and implemented in other programs, as opposed to new measures that reflect a facility's performance. Due to this limitation, we note that there may be additional avenues for clinicians to participate in MIPS using qualified

registries or QCDRs that measure quality for services that may be provided in a facility setting, such as inpatient surgeries, without being measured in facility-based measurement.

After consideration of the public comments, we are finalizing the proposed regulation text at § 414.1380(e)(1)(i) that the measures for facility-based measurement will be the measure set finalized for the fiscal year value-based purchasing program for which payment begins during the applicable MIPS performance period. We are also finalizing the proposed regulation text at § 414.1380(e)(1)(ii) that, beginning with the 2021 MIPS payment year, the scoring methodology applicable for MIPS eligible clinicians scored with facility-based measurement is the Total Performance Score methodology adopted for the Hospital VBP Program for the fiscal year for which payment begins during the applicable MIPS performance period. This means that for the 2021 MIPS payment year, the Total Performance Score for FY 2020 will be applied for the MIPS performance year 2019. Additionally, while we did not propose any changes, we are revising the regulation text at § 414.1380(e)(1)(i) to stated that the measures used for facility-based measurement are the measure set finalized for the fiscal year VBP program for which payment begins during the applicable MIPS performance period. This update is not intended to be substantive in nature, but rather to bring more clarity to the regulatory text. We have also made a technical revision in which we revise § 414.1380(e)(6)(ii), (iv), and (v) to reference only (e)(1) rather than (e)(1)(i) for improvements in readability and clarity of the regulation.

(C) Measures for MIPS 2019 Performance Period/2021 MIPS Payment Year

For informational purposes, we provided a list of measures included in the FY 2020 Hospital VBP Program that would be used in determining the quality and cost performance category scores for the 2019 MIPS performance period/2021 MIPS payment year. The FY 2020 Hospital VBP Program has adopted 12 measures covering 4 domains (83 FR 20412 through 20413). The performance period for measures in the Hospital VBP Program varies depending on the measure, and some measures include multi-year performance periods. We noted in the proposed rule that these measures are determined through separate rulemaking (83 FR 38244); the applicable rulemaking is usually the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System rule. We are using these measures, benchmarks, and performance periods for the purposes of facility-based measurement based on § 414.1380(e)(1) as finalized here. We repeat the list of measures finalized for the FY 2020 Hospital VBP measure set and Total Performance Score in Table 52.

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TABLE 52: FY 2020 Hospital VBP Program Measures

Short Name	Domain/Measure Name	NQF #	Performance Period
Person and Community Engagement Domain			
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure)	0166 (0228)	January 1, 2018 – December 31, 2018
Clinical Outcomes Domain			
MORT-30-AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization	0230	July 1, 2015 – June 30, 2018
MORT-30-HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization	0229	July 1, 2015 – June 30, 2018
MORT-30-PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0468	July 1, 2015 – June 30, 2018
THA/TKA	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550	July 1, 2015 – June 30, 2018
Safety Domain			
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138	January 1, 2018 – December 31, 2018
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139	January 1, 2018 – December 31, 2018
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753	January 1, 2018 – December 31, 2018
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716	January 1, 2018 – December 31, 2018
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure	1717	January 1, 2018 – December 31, 2018
PC-01	Elective Delivery	0469	January 1, 2018 – December 31, 2018
Efficiency and Cost Reduction Domain			
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	2158	January 1, 2018 – December 31, 2018

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(vi) Scoring Facility-Based Measurement

(A) Scoring Achievement in Facility-Based Measurement

In the CY 2018 Quality Payment Program final rule, we adopted certain scoring policies for clinicians and groups in facility-based measurement. We established at § 414.1380(e)(6)(iv) and (v) that the quality and cost performance category percent scores would be established by determining the percentile performance of the facility in the value-based purchasing program for the specified year, then awarding scores associated with that same percentile performance in the MIPS quality and cost performance categories for those MIPS eligible clinicians who are not scored using facility-based measurement for the MIPS payment year (82 FR 53764). We also finalized at § 414.1380(e)(6)(v)(A) that clinicians scored under facility-based measurement would not be scored on other cost measures (82 FR 53767).

For detailed descriptions of the current policies related to scoring achievement in facility-based measurement, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53763). Because we proposed to not require or allow an opt-in process for facility-based measurement, we proposed a change to the determination of the quality and cost performance category scores. We proposed that the quality and cost performance category percent scores would be established by determining the percentile performance of the facility in the Hospital VBP Program for the specified year, then awarding a score associated with that same percentile performance in the MIPS quality and cost performance categories for those MIPS eligible clinicians who are not eligible to be scored under facility-based measurement for the MIPS payment year (83 FR 35961). Under our proposal, the determination of percentile performance would be independent of those clinicians who would not have their quality or cost scores determined until we make the determination of their status under facility-based measurement.

The following is a summary of the public comments received on these proposals and our responses:

Comment: A few commenters supported our proposal that the quality and cost performance category percent scores for clinicians in facility-based measurement would be established by

determining the percentile performance of the facility in the Hospital VBP Program for the specified year, then awarding a score associated with that same percentile performance in the MIPS quality and cost performance categories for those MIPS eligible clinicians who are not eligible to be scored under facility-based measurement for the MIPS payment year.

Response: We thank the commenters for their support.

After consideration of the public comments, we are finalizing our proposal to change the determination of the quality and cost performance category scores at § 414.1380(e)(6)(iv) and (v) to establish both scores by determining the percentile performance of the facility in value-based purchasing program for the specified year, then awarding a score associated with that same percentile performance in the MIPS quality and cost performance categories for those MIPS eligible clinicians who are not eligible to be scored under facility-based measurement for the MIPS payment year. Also, we have revised the last sentence in paragraphs (e)(6)(iv) and (v) to more clearly state that a clinician or group receiving a facility-based performance score will not earn improvement points based on prior performance in the MIPS quality or cost categories.

(B) Scoring Improvement in Facility-Based Measurement

In the CY 2018 Quality Payment Program final rule, we finalized that we would not give a clinician or group participating in facility-based measurement the opportunity to earn improvement points based on prior performance in the MIPS quality and cost performance categories; we noted that the Hospital VBP Program already takes improvement into account in determining the Total Performance Score (82 FR 53764 through 53765). We proposed to add this previously finalized policy to regulatory text at § 414.1380(e)(6)(iv) and (v) (83 FR 35961).

We did not address in the CY 2018 Quality Payment Program final rule a policy for a clinician or group who participates in facility-based measurement for one performance period, and then does not participate in facility-based measurement in a subsequent performance period (for example, a clinician who is scored using facility-based measurement in the 2019 MIPS performance period and is not eligible for facility-based measurement in the 2020 MIPS performance period). After further considering the issue, we stated in the CY 2019 PFS proposed rule our position that it is not possible to assess improvement in the quality performance category for those who are measured under facility-based measurement in 1 year and then through another method in the following year. Our method of assessing and rewarding improvement in the MIPS quality performance category separates points awarded for measure performance from those received for bonus points (82 FR 53745). Our method of determining the quality performance category score using facility-based measurement does not allow for the separation of achievement from bonus points. For this reason, we proposed at § 414.1380(b)(1)(vi)(A)(4) [30] to not assess improvement for MIPS-eligible clinicians who are scored in MIPS through facility-based measurement in 1 year but through another method in the following year (83 FR 39561).

We did not receive any public comments on this proposal, so we will finalize our proposal to add regulatory text at § 414.1380(e)(6)(iv) and (v) and our proposal at § 414.1380(b)(1)(vi)(A)(4) to not assess improvement for MIPS-eligible clinicians who are scored in MIPS through facility-based measurement in 1 year but through another method in the following year.

(vii) Expansion of Facility-Based Measurement To Use in Other Settings

We initiated the process of facility-based measurement focusing on the inpatient hospital setting, but have noted in the past our policy goal of expanding the concept into other facilities and programs and future, in particular to use the post-acute care (PAC) and the end-stage renal disease (ESRD) settings as the basis for facility-based measurement and scoring. In the proposed rule, we summarized a number of issues and topics related to the use of PAC and ESRD facilities (83 FR 35962 through 35963). We solicited comment on these topics, including:

- How to attribute the quality and cost of care for patients in PAC settings to clinicians;
- Whether using a value-based purchasing program, that is, a similar approach to § 414.1380(e)(1), could work for PAC given the number and variation of PAC settings and clinicians;
- The level of influence MIPS-eligible clinicians have in determining performance on quality measures for individual settings and programs in the PAC setting;
- Which PAC QRP measures may be best utilized to measure clinician performance;
- Methods to identify the appropriate measures for scoring, and what measures would be most influenced by clinicians;
- Whether all measures that are reported as part of the PAC QRPs should be included or whether we should identify a subset of measures;
- Whether we should limit facility-based measurement to specific PAC settings and programs such as the IRF QRP or LTCH QRP, or whether we should consider all PAC settings in the facility-based measurement discussion;
- The extent to which the quality measures of dialysis centers reflect clinician performance; and
- Practical and policy considerations related to whether we could to attribute the performance of a specific ESRD facility to an individual clinician.

We appreciate the comments received in response to these considerations and may consider these suggestions in policies that will be proposed as part of future rulemaking.

(e) Scoring the Improvement Activities Performance Category

For our previously established policies regarding scoring the improvement activities performance category, we refer readers to § 414.1380(b)(3) and the CY 2018 Quality Payment Program final rule (82 FR 53767 through 53769). We also refer readers to § 414.1355 and the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53662) and CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199) for previously established policies regarding the improvement activities performance category generally.

(i) Regulatory Text Updates

In the CY 2019 PFS proposed rule, we proposed updates to both §§ 414.1380(b)(3) and 414.1355 to more clearly and concisely capture previously established policies (83 FR 35963). We also proposed one substantive change with respect to patient-centered medical homes and comparable specialty practices (83 FR 35963). These are discussed in more detail in this section.

[30] The codification was misidentified in the preamble of the proposed rule as § 414.1380(b)(1)(xi)(A)(4) but the regulation text was proposed, at 83 FR 36081, to be codified at § 414.1380(b)(1)(vi)(A)(4), where we are finalizing it.

(A) Improvement Activities Performance Category Score and Total Required Points

In an effort to more clearly and concisely capture previously established policies, we proposed updates to § 414.1380(b)(3) and refer readers to the CY 2019 PFS proposed rule for more details (83 FR 35963). We also clarified that the improvement activities performance category score cannot exceed 100 percent (83 FR 35963).

We solicited comments on the above proposal. We did not receive any comments on this proposal. We are finalizing our changes to regulation text at § 414.1380(b)(3) as proposed.

(B) Weighting of Improvement Activities

In an effort to more clearly and concisely capture previously established policies, we proposed updates to § 414.1380(b)(3) and refer readers to the CY 2019 PFS proposed rule for more details (83 FR 35963).

We solicited comments on the above proposal. We did not receive any comments on this proposal. We are finalizing our changes to regulation text at § 414.1380(b)(3) as proposed.

(C) APM Improvement Activities Performance Category Score

In an effort to more clearly and concisely capture previously established policies, we proposed updates to § 414.1380(b)(3)(i) and refer readers to the CY 2019 PFS proposed rule for more details (83 FR 35963).

We solicited comments on the above proposal. We did not receive any comments on this proposal. We are finalizing our changes to regulation text at § 414.1380(b)(3)(i) as proposed.

(D) Patient-Centered Medical Homes and Comparable Specialty Practices

In the CY 2019 PFS proposed rule (83 FR 35963), we proposed to modify our regulations at § 414.1380(b)(3)(ii) to more clearly and concisely capture our previously established policies for patient-centered medical homes and comparable specialty practices and refer readers to the CY 2019 PFS proposed rule for more details.

In addition, it had come to our attention that in the preamble of the CY 2017 Quality Payment Program final rule (81 FR 77186 and 77179), the terminology ''automatic'' was used in reference to patient-centered medical home or comparable specialty practice improvement activities scoring credit. In that rule (81 FR 77186), in response to one comment, we stated, ''. . . any MIPS eligible clinician or group that does not qualify by October 1st of the performance year as a certified patient-centered medical home or comparable specialty practice cannot receive automatic credit as such for the improvement activities performance category.'' In response to another comment in that rule (81 FR 77179), we stated, ''Other certifications that are not for patient-centered medical homes or comparable specialty practices would also not qualify automatically for the highest score.''

While we used the term ''automatic'' then, we have since come to realize it is inaccurate because an eligible clinician or group must attest to their status as a patient-centered medical home or comparable specialty practice in order to receive full credit for the improvement activities performance category. In the CY 2018 Quality Payment Program final rule (82 FR 53649), in response to comments we received regarding patient-centered medical homes or comparable specialty practices receiving full credit for the improvement activities performance category for MIPS, we stated that we would like to make clear that credit is not automatically granted; MIPS eligible clinicians and groups must attest in order to receive the credit.

Therefore, in the CY 2019 PFS proposed rule (83 FR 35963), we proposed codifying at § 414.1380(b)(3)(ii) to require that an eligible clinician or group must attest to their status as a patient-centered medical home or comparable specialty practice in order to receive this credit. Specifically, MIPS eligible clinicians who wish to claim this status for purposes of receiving full credit in the improvement activities performance category must attest to their status as a patient-centered medical home or comparable specialty practice for a continuous 90-day minimum during the performance period.

We solicited comments on the above proposal. We received the following comment on this proposal.

Comment: One commenter supported the proposal to modify current regulations to more clearly and concisely capture previously established policies for patient-centered Medical Homes and comparable specialty practices.

Response: We thank the commenter for your support.

After consideration of the comment we received, we are finalizing our changes to regulation text at § 414.1380(b)(3)(ii) as proposed.

(E) Improvement Activities Performance Category Weighting for Final Scoring

In the CY 2019 PFS proposed rule (83 FR 35963), in an effort to more clearly and concisely capture previously established policies, we proposed to make technical changes to § 414.1355(b) to state that unless a different scoring weight is assigned by CMS under section 1848(q)(5)(F) of the Act, performance in the improvement activities performance category comprises 15 percent of a MIPS eligible clinician's final score for the 2019 MIPS payment year and for each MIPS payment year thereafter). We stated that we believe these changes would better align the regulation text with the text of the statute.

We solicited comments on the above proposal. We did not receive any comments on this proposal. We are finalizing our changes to regulation text at § 414.1355(b) as proposed.

(ii) CEHRT Bonus

In the CY 2017 Quality Payment Program final rule (81 FR 77202 through 77209) and the CY 2018 Quality Payment Program final rule (82 FR 53664 through 53670), we established that certain activities in the improvement activities performance category will qualify for a bonus under the Promoting Interoperability performance category if they are completed using CEHRT. This bonus is applied under the Promoting Interoperability performance category and not under the improvement activities performance category. In the CY 2019 PFS proposed rule (83 FR 35932), we proposed a new approach for scoring the Promoting Interoperability performance category that is aligned with our MIPS program goals of flexibility and simplicity. We refer readers to section III.I.3.h.(5)(g) of this final rule for a summary of the comments we received regarding this proposal and our responses.

(f) Scoring the Promoting Interoperability Performance Category

We refer readers to section III.I.3.h.(5) of this final rule, where we discuss our proposals for scoring the Promoting Interoperability performance category.

(2) Calculating the Final Score

For a description of the statutory basis and our policies for calculating the final score for MIPS eligible clinicians, we refer readers to § 414.1380(c), the discussion in the CY 2017 Quality Payment Program final rule (81 FR 77319 through 77329), and the discussion in the CY 2018 Quality Payment Program final rule (82 FR 53769 through 53785). In this final rule, we discuss our proposal to continue the complex patient bonus for the 2021 MIPS payment year, as well as a

modification to the final score calculation for the 2021 MIPS payment year. Finally, we discuss refinements to reweighting policies.

(a) Accounting for Risk Factors

Section 1848(q)(1)(G) of the Act requires us to consider risk factors in our scoring methodology. Specifically, it provides that the Secretary, on an ongoing basis, shall, as the Secretary determines appropriate and based on individuals' health status and other risk factors, assess appropriate adjustments to quality measures, cost measures, and other measures used under MIPS and assess and implement appropriate adjustments to payment adjustments, final scores, scores for performance categories, or scores for measures or activities under MIPS. In doing so, the Secretary is required to take into account the relevant studies conducted under section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) and, as appropriate, other information, including information collected before completion of such studies and recommendations.

(i) Considerations for Social Risk

In the CY 2019 PFS proposed rule (83 FR 35964), we summarized our efforts related to social risk and the relevant studies conducted under section 2(d) of the IMPACT Act. We received several comments suggesting various approaches to adjust for social risk factors in the Quality Payment Program going forward. We thank commenters for their input and will take this input into consideration in future years. We also plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

(ii) Complex Patient Bonus for the 2021 MIPS Payment Year

In the CY 2018 Quality Payment Program final rule, under the authority in section 1848(q)(1)(G) of the Act, we finalized at § 414.1380(c)(3) a complex patient bonus of up to 5 points to be added to the final score for the 2020 MIPS payment year (82 FR 53771 through 53776). We intended for this bonus to serve as a short-term strategy to address the impact patient complexity may have on MIPS scoring while we continue to work with stakeholders on methods to account for patient risk factors. Our overall goal for the complex patient bonus was two-fold: (1) To protect access to care for complex patients and provide them with excellent care; and (2) to avoid placing MIPS eligible clinicians who care for complex patients at a potential disadvantage while we review the completed studies and research to address the underlying issues. We noted that we would assess on an annual basis whether to continue the bonus and how the bonus should be structured (82 FR 53771). For a detailed description of the complex patient bonus finalized for the 2020 MIPS payment year, please refer to the CY 2018 Quality Payment Program final rule (82 FR 53771 through 53776).

For the 2019 MIPS performance period/2021 MIPS payment year, we proposed in the CY 2019 PFS proposed rule to continue the complex patient bonus as finalized for the 2018 MIPS performance period/2020 MIPS payment year and to revise § 414.1380(c)(3) to reflect this policy (83 FR 35964 through 35965). Although we intended to maintain the complex patient bonus as a short-term solution, we did not believe we had sufficient information available at the time of the proposed rule to develop a long-term solution to account for patient risk factors in MIPS such that we would be able to propose a different approach for the 2019 MIPS performance period/2021 MIPS payment year. At the time of the proposed rule, we did not believe additional data sources were available that would be feasible to use as the basis for a different approach to account for patient risk factors in MIPS. In the CY 2019 PFS proposed rule, we noted our intention to analyze data when feasible from the 2017 MIPS performance period to identify differences in performance that are consistent across performance categories and that we may, in the future, shift the complex patient bonus to specific performance categories (83 FR 35965). In the absence of data analysis from the first year of MIPS, we did not believe that a change was appropriate at that time. Therefore, we stated that while we work with stakeholders to identify a long-term approach to account for patient risk factors in MIPS, we believed it was appropriate to continue the complex patient bonus for another year to support MIPS eligible clinicians who treat patients with risk factors, as well as to maintain consistency with the 2020 MIPS payment year and minimize confusion. We had received significant feedback from MIPS eligible clinicians that consistency in the MIPS program over time is valued when possible in order to minimize confusion and to help MIPS eligible clinicians predict how they will be scored under MIPS. Therefore, we stated our belief that it is appropriate to maintain consistent policies for the complex patient bonus in the 2021 MIPS payment year until we have sufficient evidence and new data sources that support an updated approach to account for patient risk factors.

Although we did not propose changes to the complex patient bonus for the 2021 MIPS payment year, we stated that the dates used in the calculation of the complex patient bonus may change as a result of other proposals we made in the CY 2019 PFS proposed rule (83 FR 35885 through 35886). For the 2020 MIPS payment year, we finalized that we will use the second 12-month segment of the eligibility determination period to calculate average HCC risk scores and the proportion of full benefit or partial benefit dual eligible beneficiaries for MIPS eligible clinicians (82 FR 53771 through 53772). We proposed to change the dates of the eligibility determination period (now referred to as the MIPS determination period) beginning with the 2021 MIPS payment year (83 FR 35885 through 35886). Specifically, the second 12-month segment would begin on October 1 of the calendar year preceding the applicable performance period and end on September 30 of the calendar year in which the applicable performance period occurs. We indicated that if this proposed change to the MIPS determination period is finalized, then beginning with the 2021 MIPS payment year, the second 12-month segment of the MIPS determination period (beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs) would be used when calculating average HCC risk scores and proportion of full benefit or partial benefit dual eligible beneficiaries for MIPS eligible clinicians.

We solicited comments on the above proposals. These comments and our responses are discussed below.

Comment: Several commenters supported our proposal to continue the complex patient bonus for the 2019 MIPS performance period/2021 MIPS payment year. Commenters stated that the bonus helps to create fairer scoring for MIPS eligible clinicians. Some commenters requested that we continue the bonus beyond the 2019 MIPS performance period/2021 MIPS payment year. A few commenters supported the complex patient bonus but requested that we increase the complex patient bonus above the proposed 5 points, stating that 5 points

will have a minimal impact on the final score.

Response: We thank commenters for their support of our proposal to maintain the complex patient bonus for the 2019 MIPS performance period/2021 MIPS payment year. We plan to review available information, including any updated data, in future years to determine if it is appropriate to modify our approach to adjusting for social risk factors. As we stated in the CY 2018 Quality Payment Program final rule (82 FR 53775), we believe a complex patient bonus of 5 points added to the final score is appropriate and is justified by information currently available at this time.

Comment: Several commenters did not support our approach for the complex patient bonus. Commenters pointed out limitations in the use of HCC and dual-eligibility to calculate the complex patient bonus. For instance, commenters stated that these indicators are not sufficient to adjust for differences in performance and suggested other indicators that might be more appropriate (such as income or education). Commenters urged us to continue to explore alternative methods to adjust for patient complexity in future years.

Response: We understand that both HCC risk scores and dual eligibility have some limitations as proxies for social risk factors. However, we are not aware of data sources for indicators such as income and education that are readily available for all Medicare beneficiaries that would be more complete indices of a patient's complexity. We have decided to pair the HCC risk score with the proportion of dual eligible patients to create a more complete complex patient indicator than can be captured using HCC risk scores alone. We will evaluate additional options in future years based on any updated data or additional information in order to better account for social risk factors while minimizing unintended consequences.

Comment: One commenter recommended that we use the 12-month performance period to determine the complex patient bonus, stating that it is the most accurate representation of the patient population of a MIPS eligible clinician.

Response: We believe that aligning the time period for assigning beneficiaries for purposes of calculating the complex patient bonus with the MIPS determination period is preferable for simplicity. In addition, when we designed our systems, we incorporated user feedback that requested eligibility information be connected to data submission. In order to be able to provide this information on the complex patient bonus at or near the time of data submission, it is necessary to use the second 12-month segment of the MIPS determination period as proposed to identify beneficiaries for purposes of assigning HCC risk scores and full benefit or partial benefit dual eligible beneficiaries to MIPS eligible clinicians, rather than the performance period. We note that this second 12-month segment begins 3 months before the year in which the performance period occurs and ends 9 months into the year in which the performance period occurs, creating a considerable overlap between the MIPS determination period and the year in which the performance period occurs (9 months).

After consideration of public comments, we are finalizing our proposal to continue the complex patient bonus for the 2019 MIPS performance period/2021 MIPS payment year as proposed. We are also finalizing the changes to the regulation text at § 414.1380(c)(3) as proposed. We are also modifying the timing used to calculate the complex patient bonus based on our changes to the MIPS determination period finalized in III.I.3.b. of this final rule. The second 12-month segment of the MIPS determination period will be used when calculating average HCC risk scores and the proportion of full benefit or partial benefit dual eligible beneficiaries for MIPS eligible clinicians.

(b) Final Score Performance Category Weights

(i) General Weights

Section 1848(q)(5)(E)(i) of the Act specifies weights for the performance categories included in the MIPS final score: In general, 30 percent for the quality performance category; 30 percent for the cost performance category; 25 percent for the Promoting Interoperability (formerly advancing care information) performance category; and 15 percent for the improvement activities performance category. For more of the statutory background and descriptions of our current policies, we refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77320 and 82 FR 53779, respectively). Under the proposals we are finalizing in sections III.I.3.h.(3)(a) and III.I.3.h.(2)(a)(ii) of this final rule, for the 2021 MIPS payment year, the cost performance category will make up 15 percent and the quality performance category will make up 45 percent of a MIPS eligible clinician's final score. Table 53 summarizes the weights specified for each performance category.

TABLE 53—FINALIZED WEIGHTS BY MIPS PERFORMANCE CATEGORY AND MIPS PAYMENT YEAR

Performance category	2019 MIPS payment year (previously finalized) (percent)	2020 MIPS payment year (previously finalized) (percent)	2021 MIPS payment year (finalized) (percent)
Quality	60	50	45
Cost	0	10	15
Improvement Activities	15	15	15
Promoting Interoperability	25	25	25

(ii) Flexibility for Weighting Performance Categories

Under section 1848(q)(5)(F) of the Act, if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician involved, the Secretary shall assign different scoring weights (including a weight of zero) for each performance category based on the extent to which the category is applicable to the type of MIPS eligible clinician involved and for each measure and activity with respect to each performance category based on the extent to which the measure or activity is applicable and available to the type of MIPS eligible clinician involved. Under section 1848(q)(5)(B)(i) of the Act, in the case of a MIPS eligible clinician who fails to report on an applicable measure or activity that is required to be reported by the clinician, the clinician must be treated as

achieving the lowest potential score applicable to such measure or activity. In this scenario of failing to report, the MIPS eligible clinician would receive a score of zero for the measure or activity, which would contribute to the final score for that MIPS eligible clinician. Assigning a scoring weight of zero percent and redistributing the weight to the other performance categories differs from the scenario of a MIPS eligible clinician failing to report on an applicable measure or activity that is required to be reported.

(A) Scenarios Where the Quality, Cost, Improvement Activities, and Promoting Interoperability Performance Categories Would Be Reweighted

In the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77322 through 77325 and 82 FR 53779 through 53780, respectively), we explained our interpretation of what it means for there to be sufficient measures applicable and available for the quality and cost performance categories, and we finalized policies for the 2019 and 2020 MIPS payment years under which we would assign a scoring weight of zero percent to the quality or cost performance category and redistribute its weight to the other performance categories in the event there are not sufficient measures applicable and available, as authorized by section 1848(q)(5)(F) of the Act. For the quality performance category, we stated that having sufficient measures applicable and available means that we can calculate a quality performance category percent score for the MIPS eligible clinician because at least one quality measure is applicable and available to the clinician (82 FR 53780). For the cost performance category, we stated that having sufficient measures applicable and available means that we can reliably calculate a score for the cost measures that adequately captures and reflects the performance of a MIPS eligible clinician (82 FR 53780). We established that if a MIPS eligible clinician is not attributed enough cases for a cost measure (in other words, has not met the required case minimum for the measure), or if a cost measure does not have a benchmark, then the measure will not be scored for that clinician (81 FR 77323). We stated that if we do not score any cost measures for a MIPS eligible clinician in accordance with this policy, then the clinician would not receive a cost performance category percent score (82 FR 53780).

In the CY 2019 PFS proposed rule, we proposed to codify these policies for the quality and cost performance categories at § 414.1380(c)(2)(i)(A)(1) and (2), respectively, and to continue them for the 2021 MIPS payment year and each subsequent MIPS payment year (83 FR 35966).

For the Promoting Interoperability performance category, in the CY 2017 Quality Payment Program final rule (81 FR 77238 through 77245) and the CY 2018 Quality Payment Program final rule (82 FR 53680 through 53687), we established policies for assigning a scoring weight of zero percent to the Promoting Interoperability performance category and redistributing its weight to the other performance categories in the final score. We proposed to codify those policies under § 414.1380(c)(2)(i) and (iii) (83 FR 35966).

For the improvement activities performance category, we stated in the CY 2019 proposed rule (83 FR 35967 through 35968) that we continue to believe that all MIPS eligible clinicians will have sufficient activities applicable and available, except for limited extreme and uncontrollable circumstances, such as natural disasters, where a clinician is unable to report improvement activities, and circumstances where a MIPS eligible clinician joins a practice in the final 3 months of the performance period as discussed in the CY 2019 PFS proposed rule (83 FR 35967 through 35968). We stated that, barring these circumstances, we believe that all MIPS eligible clinicians will have sufficient improvement activities applicable and available (82 FR 53780).

We solicited comments on the above proposals. These comments and our responses are discussed below.

Comment: One commenter supported our reweighting policies, stating that they provide flexibility for MIPS eligible clinicians who are unable to participate in specific performance categories.

Response: We thank this commenter for its support.

Comment: One commenter expressed concern with our reweighting policies, because the commenter believes MIPS eligible clinician may expend resources to submit data to us, and then receive reweighting based on our determination that there are not sufficient measures or activities applicable and available.

Response: Our reweighting policies would not lead us to reweight a MIPS eligible clinician after they submit data for a given performance category. Rather, we would consider whether these policies are applicable in the event that we do not receive any data for a MIPS eligible clinician for a particular performance category. If we determine that the clinician is eligible for reweighting under our policies, then we would redistribute the weight of the performance category, rather than awarding a score of zero to the clinician for that performance category.

After consideration of public comments, we are finalizing our proposal to codify the reweighting policies for the quality and cost performance categories at § 414.1380(c)(2)(i)(A)(1) and (2), respectively, and to continue them for the 2021 MIPS payment year and each subsequent MIPS payment year, as proposed. We are also finalizing our proposal to codify the Promoting Interoperability reweighting policies under § 414.1380(c)(2)(i) and (iii) as proposed.

(B) Reweighting the Quality, Cost, and Improvement Activities Performance Categories for Extreme and Uncontrollable Circumstances

For a summary of the final policy we adopted beginning with the 2018 MIPS performance period/2020 MIPS payment year to reweight the quality, cost, and improvement activities performance categories based on a request submitted by a MIPS eligible clinician, group, or virtual group that was subject to extreme and uncontrollable circumstances, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53780 through 53783). In the proposed rule (83 FR 35966), we proposed to codify this policy at § 414.1380(c)(2)(i)(A)(*5*), but we inadvertently referred to the wrong paragraph of the regulation text, and the citation should have read § 414.1380(c)(2)(i)(A)(6).

We proposed a few minor modifications to our extreme and uncontrollable circumstances policy (83 FR 35967). First, beginning with the 2019 MIPS performance period/2021 MIPS payment year, we proposed at § 414.1380(c)(2)(i)(A)(5) (which should have read § 414.1380(c)(2)(i)(A)(6)) that, if a MIPS eligible clinician submits an application for reweighting based on extreme and uncontrollable circumstances, but also submits data on the measures or activities specified for the quality or improvement activities performance categories in accordance with § 414.1325, he or she would be scored on the submitted data like all other MIPS eligible clinicians, and the categories would not be reweighted (83 FR 35967). We proposed this modification to align with a similar policy for the Promoting Interoperability performance category (82 FR 53680 through 53682). We stated that if a MIPS eligible clinician reports on measures or activities specified for the quality or improvement activities performance categories, then we assume the clinician

believes there are sufficient measures or activities applicable and available to the clinician.

For most quality measures and improvement activities, the data submission occurs after the end of the MIPS performance period, so clinicians would know about the extreme and uncontrollable circumstance prior to submission. However, for the quality performance category, measures submitted via the Medicare Part B claims collection type are submitted by adding quality data codes to a claim. As a result, it is possible that a MIPS eligible clinician could have submitted some Medicare Part B claims collection type data prior to the submission of a reweighting application for extreme and uncontrollable events. Under our proposal, we would score the quality performance category because we have received data. However, we previously finalized at § 414.1380(c) that if a MIPS eligible clinician is scored on fewer than two performance categories, he or she will receive a final score equal to the performance threshold (81 FR 77320 through 77321 and 82 FR 53778 through 53779). If a clinician experiences an extreme and uncontrollable event that affects all of the performance categories, then under our proposal, the clinician would only be scored on the quality performance category if they submit data for only that category. The clinician would also have to submit data for the improvement activities or the Promoting Interoperability performance categories in order to be scored on two or more performance categories and receive a final score different than the performance threshold.

This proposal did not include administrative claims data that we receive through the claims submission process and use to calculate the cost measures and certain quality measures. As finalized in the CY 2017 Quality Payment Program final rule (81 FR 77094 through 77095), and as we are codifying in this final rule at § 414.1325(a)(2), there are no data submission requirements for the cost performance category and for certain quality measures used to assess performance in the quality performance category. Please see section III.I.3.h.(1)(b) of this final rule for a description of collection types, submission types, and submitter types. We calculate performance on these measures using administrative claims data, and clinicians are not required to submit any additional data for these measures. Therefore, we stated that we did not believe that it would be appropriate to void a reweighting application based on administrative claims data we receive for measures that do not require data submission for purposes of MIPS.

We also proposed to apply the policy we finalized for virtual groups in the CY 2018 Quality Payment Program final rule (82 FR 53782 through 53783) to groups submitting reweighting applications for the quality, cost, or improvement activities performance categories based on extreme and uncontrollable circumstances (83 FR 35967). For groups, we would evaluate whether sufficient measures and activities are applicable and available to MIPS eligible clinicians in the group on a case-by-case basis and determine whether to reweight a performance category based on the information provided for the individual clinicians and practice location(s) affected by extreme and uncontrollable circumstances and the nature of those circumstances. In the CY 2019 PFS proposed rule (83 FR 35967), we stated that although we did not specifically propose to apply this policy to groups in the CY 2018 Quality Payment Program proposed rule, our intention was to apply the same policy for groups and virtual groups, and thus if we adopt this proposal, we would apply the policy to groups beginning with the 2018 performance period/2020 MIPS payment year.

We solicited comments on the above proposals. These comments and our responses are discussed below.

Comment: One commenter supported our proposal for groups, stating that all MIPS eligible clinicians in the group will likely be facing the same barriers and a group application will reduce administrative burden and redundancy.

Response: We thank the commenter for its support of our proposal to apply the same policy we established for virtual groups to groups. Under the proposed policy, we would evaluate whether sufficient measures and activities are applicable and available to MIPS eligible clinicians in the group on a case-by-case basis and determine whether to reweight a performance category based on the information provided for the individual clinicians and practice location(s) affected by extreme and uncontrollable circumstances and the nature of those circumstances.

Comment: One commenter expressed concern that MIPS eligible clinicians who submit an application for reweighting based on extreme and uncontrollable circumstances, but who also report via Medicare Part B claims collection type may be unfairly penalized if claims data is received prior to the extreme and uncontrollable event. Another commenter suggested that we should score data received from MIPS eligible clinicians who submit a reweighting application only if they would receive a score that would result in a payment adjustment no lower than a neutral adjustment.

Response: If a MIPS eligible clinician reports via Medicare Part B claims collection type for the quality performance category, and we receive an application for reweighting for the clinician based on extreme and uncontrollable circumstances, their Medicare Part B claims data would only contribute to their final score if they also submit data for either the Promoting Interoperability or the improvement activities performance categories. We previously finalized at § 414.1380(c) that if a MIPS eligible clinician is scored on fewer than two performance categories, he or she will receive a final score equal to the performance threshold (81 FR 77320 through 77321 and 82 FR 53778 through 53779). The clinician's cost performance category score would not contribute to their final score because as we discuss above, there are no data submission requirements for the cost performance category, and we do not believe that it would be appropriate to void a reweighting application based on administrative claims data we receive for measures that do not require data submission for purposes of MIPS.

We assume that if a MIPS eligible clinician submits data to us following the submission of an application for reweighting based on extreme and uncontrollable circumstances, the clinician believes there are sufficient measures or activities applicable and available to them and would like their data to contribute to their final score. However, once the data is submitted, it will be scored based on performance in accordance with our policies, and the clinician could receive a negative payment adjustment.

After consideration of public comments, we are finalizing our proposal to codify the final policy we adopted beginning with the 2018 MIPS performance period/2020 MIPS payment year to reweight the quality, cost, and improvement activities performance categories based on a request submitted by a MIPS eligible clinician, group, or virtual group that was subject to extreme and uncontrollable circumstances. We are finalizing our proposal that, beginning with the 2019 performance period/2021 MIPS payment year, if a MIPS eligible clinician submits an application for reweighting based on extreme and uncontrollable circumstances, but also

submits data on the measures or activities specified for the quality or improvement activities performance categories in accordance with § 414.1325, he or she will be scored on the submitted data like all other MIPS eligible clinicians, and the categories will not be reweighted. We are also finalizing our proposal, beginning with the 2018 performance period/2020 MIPS payment year, that, for groups, we will evaluate whether sufficient measures and activities are applicable and available to MIPS eligible clinicians in the group on a case-by-case basis and determine whether to reweight a performance category based on the information provided. We are finalizing the regulation text at § 414.1380(c)(2)(i)(A)(6) as proposed.

(C) Reweighting the Quality, Cost, Improvement Activities, and Promoting Interoperability Performance Categories for MIPS Eligible Clinicians Who Join a Practice in the Final 3 Months of the Performance Period Year

Beginning with the 2019 MIPS performance period, we proposed that a MIPS eligible clinician who joins an existing practice (existing TIN) during the final 3 months of the calendar year in which the MIPS performance period occurs (the performance period year) that is not participating in MIPS as a group would not have sufficient measures applicable and available (83 FR 35967 through 35968). We also proposed that a MIPS eligible clinician who joins a practice that is newly formed (new TIN) during the final 3 months of the performance period year would not have sufficient measures applicable and available, regardless of whether the clinicians in the practice report for purposes of MIPS as individuals or as a group (83 FR 35967 through 35968). In each of these scenarios, we proposed to reweight all four of the performance categories to zero percent for the MIPS eligible clinician and, because he or she would be scored on fewer than two performance categories, the MIPS eligible clinician would receive a final score equal to the performance threshold and a neutral MIPS payment adjustment under the policy at § 414.1380(c) (83 FR 35967 through 35968). We proposed to codify these policies at § 414.1380(c)(2)(i)(A)(3).

We proposed this policy because we are not currently able to identify these MIPS eligible clinicians (or groups if the group is formed in the final 3 months of the performance period year) at the start of the MIPS submission period. When we designed our systems, we incorporated user feedback that requested eligibility information be connected to the submission process. In order to submit data, an individual TIN/NPI or the group TIN must be in the files generated from the MIPS eligibility determination periods. As discussed in the CY 2019 PFS proposed rule (83 FR 35885 through 35886), we have two 12-month determination periods for eligibility. We proposed and are finalizing in section III.II.3.b. of this final rule that the second 12-month segment of the MIPS eligibility determination period will end on September 30 of the calendar year in which the applicable MIPS performance period occurs; therefore, we will have no eligibility information about clinicians who join a practice after September 30 of the performance period year. MIPS eligible clinicians who join an existing practice (existing TIN) in the final 3 months of the performance period year that is not participating in MIPS as a group will not be identified by our systems, and we will not have the ability to inform them that they are eligible or to receive MIPS data from them. Similarly, practices that form (new TIN) in the final 3 months of the performance period year will not be in the MIPS determination files. Accordingly, we stated that the measures and activities would not be available because any data from these MIPS eligible clinicians would not be accessible to us.

If a MIPS eligible clinician joins a practice (existing TIN) in the final 3 months of the performance period year, and the practice is not newly formed and is reporting as a group for the performance period, the MIPS eligible clinician will be able to report as part of that group. In this case, we are able to accept data for the group because the TIN would be in our MIPS eligibility determination files. Therefore, we stated that we believe the measures and activities would be available in this scenario, and reweighting would not be necessary for the MIPS eligible clinician. We noted that, if a MIPS eligible clinician's TIN/NPI combination was not part of the group practice during the MIPS determination period, the TIN/NPI combination will not be identified in our system at the start of the MIPS data submission period; however, if the MIPS eligible clinician qualifies to receive the group final score under our proposal, we would apply the group final score to the MIPS eligible clinician's TIN/NPI combination as soon as the information becomes available. Please see section III.I.3.j.(1) of this final rule for more information about assigning group scores to MIPS eligible clinicians.

We solicited comments on the above proposals. These comments and our responses are discussed below.

Comment: Several commenters supported our proposal to reweight MIPS eligible clinicians who form a new practice in the final 3 months of the performance period year or join an existing practice that does not participate in MIPS as a group.

Response: We thank commenters for their support of our proposal.

Comment: One commenter requested that we extend this policy to the 2018 performance period as well.

Response: We note that we did not propose to apply the policy to the 2018 performance period, and as such, we will not be extending it in this final rule.

Comment: One commenter did not support our proposal to treat MIPS eligible clinicians who join a new or existing practice in the final 3 months of the performance period year differently depending on whether the practice reports as a group. The commenter also requested that we reweight MIPS eligible clinicians who switch practices at any time during the performance period, because a MIPS eligible clinician's previous practice may not report on their behalf and because clinicians are impacted by training and other requirements associated with switching practices that may impact performance.

Response: A MIPS eligible clinician who joins an existing practice that is participating in MIPS as a group would have the opportunity to contribute to the group's performance and final score. We refer readers to section III.I.3.j.(1) of this final rule for a discussion of which MIPS eligible clinicians may receive a group final score. We do not believe it would be appropriate to reweight the performance categories for MIPS eligible clinicians who change practices at any time during the performance period year because, consistent with our discussion in the CY 2019 PFS proposed rule (83 FR 35967 through 35968), we would be able to identify these clinicians at the beginning of the MIPS submission period if they change practices prior to the final 3 months of the performance period year. We also believe MIPS eligible clinicians who change practices prior to the final 3 months of the performance period year generally should have sufficient time to prepare for MIPS reporting, in the event that their prior practice does not submit data for them.

After consideration of public comments, we are finalizing as

proposed our proposal to reweight the quality, cost, improvement activities, and Promoting Interoperability performance categories to zero percent for MIPS eligible clinicians who join an existing practice (existing TIN) during the final 3 months of the performance period year that is not participating in MIPS as a group, or a practice that is newly formed (new TIN) during the final 3 months of the performance period year regardless of whether the clinicians in the practice report for purposes of MIPS as individuals or as a group. We are finalizing the proposed regulation text at § 414.1380(c)(2)(i)(A)(3) as proposed.

(D) Automatic Extreme and Uncontrollable Circumstances Policy Beginning With the 2020 MIPS Payment Year

In conjunction with the CY 2018 Quality Payment Program final rule, and due to the impact of Hurricanes Harvey, Irma, and Maria, we issued an interim final rule with comment period (IFC) in which we adopted on an interim final basis a policy for automatically reweighting the quality, improvement activities, and advancing care information (now referred to as Promoting Interoperability) performance categories for the transition year of MIPS (the 2017 performance period/ 2019 MIPS payment year) for MIPS eligible clinicians who are affected by extreme and uncontrollable circumstances affecting entire regions or locales (82 FR 53895 through 53900).

In the CY 2019 PFS proposed rule (83 FR 35968), we stated that we believe that a similar automatic extreme and uncontrollable circumstances policy would be appropriate for any year of the MIPS program to account for natural disasters and other extreme and uncontrollable circumstances that impact an entire region or locale. As we discussed in the interim final rule (82 FR 53897), we believe such a policy would reduce burden on clinicians who have been affected by widespread catastrophes and would align with existing policies for other Medicare programs. We proposed at § 414.1380(c)(2)(i)(A)(7) and (c)(2)(i)(C)(3) to apply the automatic extreme and uncontrollable circumstances policy we adopted for the transition year to subsequent years of the MIPS program, beginning with the 2018 MIPS performance period and the 2020 MIPS payment year, with a few additions to address the cost performance category (83 FR 35968). We note that we inadvertently referred to the wrong paragraph of the regulation text in the proposed rule, and the citation should have read § 414.1380(c)(2)(i)(A)(8) instead of § 414.1380(c)(2)(i)(A)(7). For a description of the policy we adopted for the MIPS transition year, we refer readers to the discussion in the interim final rule (82 FR 53895 through 53900).

In the interim final rule (82 FR 53897), we stated that we were not including the cost performance category in the automatic extreme and uncontrollable circumstances policy for the transition year because the cost performance category is weighted at zero percent in the final score for the 2017 MIPS performance period/2019 MIPS payment year. We finalized a 10 percent weight for the cost performance category for the 2018 MIPS performance period/2020 MIPS payment year (82 FR 53643) and are finalizing a 15 percent weight for the 2019 performance period/ 2021 MIPS payment year (see section III.I.3.h.(3)(a) of this final rule). In the CY 2019 PFS proposed rule (83 FR 35968), we stated that for the reasons discussed in the CY 2018 Quality Payment Program final rule (82 FR 53781), we believe a MIPS eligible clinician's performance on measures calculated based on administrative claims data, such as the measures specified for the cost performance category, could be adversely affected by a natural disaster or other extreme and uncontrollable circumstance, and that the cost measures may not be applicable to that MIPS eligible clinician. Therefore, we proposed to include the cost performance category in the automatic extreme and uncontrollable circumstances policy beginning with the 2018 MIPS performance period/2020 MIPS payment year (83 FR 35968). Under our policy for the transition year, if a MIPS eligible clinician in an affected area submits data for any of the MIPS performance categories by the applicable submission deadline for the 2017 MIPS performance period, he or she will be scored on each performance category for which he or she submits data, and the performance category will not be reweighted to zero percent in the final score (82 FR 53898). Our policy for the transition year did not include measures that are calculated based on administrative claims data (82 FR 53898). As finalized in the CY 2017 Quality Payment Program final rule (81 FR 77094 through 77095), and as we are codifying in this final rule at § 414.1325(a)(2), there are no data submission requirements for the cost performance category, and we will calculate performance on the measures specified for the cost performance category using administrative claims data. We proposed for the cost performance category, if a MIPS eligible clinician is located in an affected area, we would assume the clinician does not have sufficient cost measures applicable to him or her and assign a weight of zero percent to that category in the final score, even if we receive administrative claims data that would enable us to calculate the cost measures for that clinician (83 FR 35968).

In the interim final rule (82 FR 53897), we did not include an automatic extreme and uncontrollable circumstances policy for groups or virtual groups, and we stated in the CY 2019 PFS proposed rule (83 FR 35968) that we continue to believe such a policy is not necessary. Unless we receive data from a TIN indicating that the TIN would like to be scored as a group for MIPS, performance by default is assessed at the individual MIPS eligible clinician level. Similarly, performance is not assessed at the virtual group level unless the member TINs submit an application in accordance with § 414.1315. We stated that if we receive data from a group or virtual group, we would score that data, even if individual MIPS eligible clinicians within the group or virtual group are impacted by an event that would be included in our automatic extreme and uncontrollable circumstances policy. Regardless of whether we receive data from a group or virtual group, we would have no mechanism to determine whether the group or virtual group did not submit data, or submitted data and performed poorly, because it had been affected by an extreme and uncontrollable event unless the group notifies us of its circumstances. Instead of establishing a threshold for groups or virtual groups to receive automatic reweighting based on the number of clinicians in the group or virtual group impacted by extreme and uncontrollable events, we stated that we believe it is preferable that these groups and virtual groups submit an application for reweighting based on extreme and uncontrollable circumstances under our existing policy (82 FR 53780 through 53783) where they may be eligible for reweighting if they establish that the group or virtual group was sufficiently impacted by the extreme and uncontrollable event.

We solicited comments on the above proposals. These comments and our responses are discussed below.

Comment: Several commenters supported our proposed application of the automatic extreme and uncontrollable policy starting with the 2018 MIPS performance period/2020 MIPS payment year to reduce burden on

impacted MIPS eligible clinicians. A few commenters supported our proposal to extend the automatic extreme and uncontrollable policy to include the cost performance category for the 2018 MIPS performance period/2020 MIPS payment year and future years.

Response: We thank commenters for their support of our proposals.

Comment: One commenter suggested that we only score performance categories (including the cost performance category) for MIPS eligible clinicians impacted by the automatic extreme and uncontrollable policy if they would receive a positive or neutral payment adjustment.

Response: If a MIPS eligible clinician reports via Medicare Part B claims collection type for the quality performance category, and we receive data for the clinician prior to a triggering event for the automatic extreme and uncontrollable circumstances policy, their Medicare Part B claims data would only contribute to their final score if they also submit data for either the Promoting Interoperability or the improvement activities performance categories. We previously finalized at § 414.1380(c) that if a MIPS eligible clinician is scored on fewer than two performance categories, he or she will receive a final score equal to the performance threshold (81 FR 77320 through 77321 and 82 FR 53778 through 53779). We assume that if a MIPS eligible clinician submits data to us following a triggering event, the clinician believes there are sufficient measures or activities applicable and available to them and would like their data to contribute to their final score. However, once the data is submitted, it will be scored based on performance in accordance with our policies, and the clinician could receive a negative payment adjustment.

Comment: One commenter disagreed with our decision to not propose an automatic extreme and uncontrollable circumstances policy for groups, because clinicians who choose to report as group for purposes of MIPS conduct all aspects of MIPS at a group level.

Response: We continue to believe that a group policy is not necessary and that there are barriers to implementing such a policy. For example, because group reporting is optional, we would have no mechanism to determine who would have been intending to report without receiving a data submission. Additionally, some groups may be split between areas that are impacted by the triggering event and areas that are not. We do not believe that it would be appropriate to make a decision about how the group is impacted without additional information. We believe our application-based extreme and uncontrollable circumstances policy provides the mechanism for such an assessment. Finally, we note that if all the MIPS eligible clinicians in a group are located in an area affected by the extreme and uncontrollable circumstance, and the group is not able to submit for MIPS as a group, then all the MIPS eligible clinicians in the group would be considered as individuals and covered by the automatic extreme and uncontrollable circumstances policy.

After consideration of public comments received, we are finalizing these proposals and the regulation text at § 414.1380(c)(2)(i)(A)(8) and (c)(2)(i)(C)(3) as proposed.

iii. Extreme and Uncontrollable Circumstance Policy for the 2017 Performance Period/2019 MIPS Payment Year

As discussed in the preceding section III.I.3.i.(2)(b)(ii)(D), in conjunction with the CY 2018 Quality Payment Program final rule, and due to the impact of Hurricanes Harvey, Irma, and Maria, we issued an interim final rule with comment period (IFC) in which we adopted on an interim final basis a policy for automatically reweighting the quality, improvement activities, and advancing care information (now referred to as Promoting Interoperability) performance categories for the transition year of MIPS (the 2017 performance period/2019 MIPS payment year) for MIPS eligible clinicians who are affected by extreme and uncontrollable circumstances affecting entire regions or locales (82 FR 53895 through 53900). In the CY 2019 PFS proposed rule (83 FR 35968), we proposed to codify this policy for the quality and improvement activities performance categories at § 414.1380(c)(2)(i)(A)(6) and for the advancing care information (now Promoting Interoperability) performance category at § 414.1380(c)(2)(i)(C)(3). We note that we inadvertently referred to the wrong paragraph of the regulation text in the proposed rule, and the citation should have read § 414.1380(c)(2)(i)(A)(7) instead of § 414.1380(c)(2)(i)(A)(6).

A summary of the comments we received on the IFC and our responses are included below.

Comment: Many commenters supported the automatic extreme and uncontrollable circumstance policy for the 2017 MIPS performance period. Several commenters stated that the policy is appropriate given the burden these events have had on impacted MIPS eligible clinicians. Several commenters supported the flexibility afforded by this policy and noted that the policy will allow impacted MIPS eligible clinicians to focus on providing patient care during natural disasters without having to focus on MIPS reporting. Several commenters supported our policy to allow clinicians impacted by extreme and uncontrollable events to report for MIPS if they choose because commenters believe some MIPS eligible clinicians may be less impacted by natural disasters and may have interest in reporting for MIPS. One commenter supported including events that have been designated by FEMA in the automatic extreme and uncontrollable circumstance policy. Another commenter supported using the practice location listed in PECOS to determine eligibility for the automatic extreme and uncontrollable policy.

Response: We believe that the automatic extreme and uncontrollable circumstance policy is appropriate to provide relief to MIPS eligible clinicians experiencing natural disasters and will help to ensure they are able to focus on providing patient care. In the CY 2018 Quality Payment Program final rule, we noted that we anticipate the types of events that could trigger this policy would be events designated as FEMA major disasters or a public health emergency declared by the Secretary, although we will review each situation on a case-by-case basis (82 FR 53897).

Comment: One commenter urged CMS to develop a clear communications plan for alerting MIPS eligible clinicians that they are eligible for the automatic extreme and uncontrollable circumstance policy.

Response: We agree that it will be important to effectively alert MIPS eligible clinicians who we determine are covered by the automatic extreme and uncontrollable circumstance policy. Similar to other CMS programs, we communicated applicability information through routine communication channels, including, but not limited to, issuing memos, emails, and notices on the QPP website, *qpp.cms.gov*.

Comment: One commenter stated that providing MIPS eligible clinicians who are impacted by extreme and uncontrollable events with a final score that is equal to the performance threshold if they report on only one performance category does not recognize their efforts for that performance category. Instead, commenter stated CMS should score the MIPS eligible clinician on that category.

Response: We continue to believe that the final score for MIPS should be a composite score. Therefore, for MIPS

eligible clinicians who are subject to the automatic extreme and uncontrollable circumstance policy, we will continue to apply our general MIPS policy codified at § 414.1380(c) that MIPS eligible clinicians who are scored on fewer than 2 performance categories receive a score equal to the performance threshold (82 FR 53958). MIPS eligible clinicians who are located in an area affected by extreme and uncontrollable circumstances who submit data for the quality performance category would also have to submit data for the Promoting Interoperability or improvement activities performance categories in order for the data submitted to contribute to their final score.

Comment: One commenter stated that scoring data that are submitted by impacted MIPS eligible clinicians is unfair because they are being assessed against MIPS eligible clinicians who were not impacted by natural disasters.

Response: Because the performance threshold is set very low (at 3 points) for the 2017 MIPS performance period, we believe that MIPS eligible clinicians who are eligible for the automatic extreme and uncontrollable circumstance policy but submit data will easily exceed the performance threshold and thus will not be negatively impacted. Furthermore, we assume that MIPS eligible clinicians who are located in an area affected by extreme and uncontrollable circumstances but then submit data for more than one performance category believe there are sufficient measures or activities applicable and available to them and would like their data to contribute to their final score.

Comment: One commenter suggested that CMS should not score Medicare Part B claims measures that are submitted by MIPS eligible clinicians impacted by extreme and uncontrollable events.

Response: If a MIPS eligible clinician reports via Medicare Part B claims for the quality performance category and we receive data prior to the extreme and uncontrollable event, their Medicare Part B claims data would only contribute to their final score if they also submit data for either the Promoting Interoperability or improvement activities performance categories. We previously finalized at § 414.1380(c) that if a MIPS eligible clinician is scored on fewer than two performance categories, he or she will receive a final score equal to the performance threshold (81 FR 77320 through 77321 and 82 FR 53778 through 53779).

Comment: One commenter suggested that CMS consider providing a positive payment adjustment for MIPS eligible clinicians who are eligible for the automatic extreme and uncontrollable circumstance policy instead of providing a neutral payment adjustment because this will help to incentivize MIPS eligible clinicians to return to affected areas.

Response: It is unclear to us how a positive payment adjustment would incentivize clinicians to return to affected areas, or how we would go about verifying whether and why they have returned, since many factors influence clinician choice in practice location.

After consideration of the public comments, we are adopting the IFC as a final rule without any modifications. We are finalizing the regulation text at § 414.1380(c)(2)(i)(A)(7) and § 414.1380(c)(2)(i)(C)(3) as proposed.

(iv) Redistributing Performance Category Weights

In the CY 2017 and CY 2018 Quality Payment Program final rules, we established policies for redistributing the weights of performance categories for the 2019 and 2020 MIPS payment years in the event that a scoring weight different from the generally applicable weight is assigned to a category or categories (81 FR 77325 through 77329; 82 FR 53783 through 53785, 53895 through 53900). We proposed to codify these policies under § 414.1380(c)(2)(ii) (83 FR 35969).

For the 2021 MIPS payment year, we proposed at § 414.1380(c)(2)(ii)(B) to apply similar reweighting policies as finalized for the 2020 MIPS payment year (83 FR 35969). We note that we inadvertently referred to the wrong paragraph of the regulation text in the proposed rule, and the citation should have read § 414.1380(c)(2)(ii)(C) instead of § 414.1380(c)(2)(ii)(B). In general, we would redistribute the weight of a performance category or categories to the quality performance category. We stated that redistributing weight to the quality performance category is appropriate because of the experience MIPS eligible clinicians have had reporting on quality measures under other CMS programs. We proposed to continue to redistribute the weight of the quality performance category to the improvement activities and Promoting Interoperability performance categories (83 FR 35969). However, for the 2021 MIPS payment year, based on our proposal to weight the cost performance category at 15 percent, we proposed to reweight the Promoting Interoperability performance category to 45 percent and the improvement activities performance category to 40 percent when the quality performance category is weighted at zero percent (83 FR 35969). We chose to weigh Promoting Interoperability higher in order to align with goals of interoperability and for simplicity because we generally have avoided assigning partial percentage points to performance category weights. Reweighting scenarios under the proposal are presented in Table 54.

TABLE 54: Performance Category Redistribution Policies Proposed for the 2021 MIPS Payment Year

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	45%	15%	15%	25%
Reweight One Performance Category				
-No Cost	60%	0%	15%	25%
-No Promoting Interoperability	70%	15%	15%	0%
-No Quality	0%	15%	40%	45%
-No Improvement Activities	60%	15%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	50%	50%
-No Cost and no Improvement Activities	75%	0%	0%	25%
-No Promoting Interoperability and no Quality	0%	15%	85%	0%
-No Promoting Interoperability and no Improvement Activities	85%	15%	0%	0%
-No Quality and no Improvement Activities	0%	15%	0%	85%

We stated that we have heard from stakeholders in previous years that our reweighting policies place undue weight on the quality performance category, and, although we continue to believe the policies are appropriate, we solicited comment on alternative redistribution policies in which we would also redistribute weight to the improvement activities performance category (see Table 55). Under the alternative redistribution policy we considered, we would redistribute the weight of the Promoting Interoperability performance category to the quality and improvement activities performance categories (83 FR 35969 through 35970). We would redistribute 15 percent of the Promoting Interoperability performance category weight to the quality performance category, and 10 percent to the improvement activities performance category. We stated that redistributing more of the weight of the Promoting Interoperability performance category to the quality performance category is appropriate because MIPS eligible clinicians have had more experience reporting on quality measures under other CMS programs than reporting on improvement activities. We would redistribute the cost performance category weight equally to the quality and improvement activities performance categories (5 percent to each) under this alternative policy.

TABLE 55: Alternative Performance Category Redistribution Policies Considered for the 2021 MIPS Payment Year

	Alternative Redistribution Policy: Reweight Promoting Interoperability and Cost to Quality and Improvement Activities			
Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	45%	15%	15%	25%
Reweight One Performance Category				
-No Promoting Interoperability	60%	15%	25%	0%
-No Cost	55%	0%	20%	25%
-No Quality	0%	15%	40%	45%
-No Improvement Activities	60%	15%	0%	25%
Reweight Two Performance Categories				
-No Cost and No Promoting Interoperability	70%	0%	30%	0%
-No Cost and no Quality	0%	0%	50%	50%
-No Cost and no Improvement Activities	75%	0%	0%	25%
-No Promoting Interoperability and no Quality	0%	15%	85%	0%
-No Promoting Interoperability and no Improvement Activities	85%	15%	0%	0%
-No Quality and no Improvement Activities	0%	15%	0%	85%

We solicited comments on the above proposals. These comments and our responses are discussed below.

Comment: A few commenters supported our proposed reweighting policies for the 2019 MIPS performance period/2021 MIPS payment year.

Response: We thank commenters for their support of our proposal.

Comment: Several commenters supported the alternative policy we considered to reweight to both quality and improvement activities, and stated our primary proposal which generally reweights to quality, places undue weight on the quality performance category. Some commenters stated that reweighting to the improvement activities performance category is appropriate given the importance of practice improvement. A few commenters stated that the quality performance category is particularly challenging, and therefore, placing additional weight on this performance category would not be fair to MIPS eligible clinicians who receive reweighting for the cost or Promoting Interoperability performance categories. A few commenters also mentioned that our reweighting policies place undue burden on small and rural practices who have particular difficulty performing well on the quality performance category. A few commenters requested that we redistribute all of the weight of the Promoting Interoperability or cost performance categories to the improvement activities performance category, in order to avoid placing undue focus on quality and due to the importance of quality improvement.

Response: We continue to believe reweighting to the quality performance category is appropriate as the quality performance category is a critical component of value-based care, and therefore, we believe performance on quality measures is important. While there is variation in performance for the quality performance category, for the improvement activities we are only assessing whether the MIPS eligible clinician completed activities. We believe that reweighting to the quality performance category will encourage MIPS eligible clinicians to report on the quality performance category due to the higher category weight (that is, a zero score for this performance category would have more significant impact), particularly those clinicians who may have only reported to the improvement activities performance category, and will minimize complexity. We believe it is important to encourage MIPS eligible clinicians to report on quality while the performance threshold is still relatively low. In regards to the concern on small and rural practice performance in the quality performance category, we note that small practices that report quality measures can receive the small practice bonus we are finalizing in section III.I.3.i.(1)(b)(viii) of this final rule and we have not seen differences in performance for rural practices. We plan to review available approaches to reweighting in future years including impact on small and rural practices and may revisit our policies to ensure they are fair and not overly complex.

Comment: One commenter disagreed with our proposal to reweight the quality performance category to the improvement activities and Promoting Interoperability performance categories, because the commenter noted concern with our discussion of available and applicable measures for the quality performance category and reweighting this category would place greater weight on other performance categories. Another commenter noted that reweighting the quality performance category may lead to MIPS eligible clinicians inaccurately receiving a positive, neutral, or negative payment adjustment.

Response: We believe reweighting to the improvement activities and Promoting Interoperability performance categories in the rare cases when the quality performance category is reweighted is appropriate because MIPS eligible clinicians have limited experience being scored on the cost performance category. We also expect the cases when a MIPS eligible clinician does not have any quality measures to be very rare.

After consideration of public comments, we are finalizing these proposals and the regulation text at § 414.1380(c)(2)(ii)(A) through (C) as proposed.

Because the cost performance category was zero percent of a MIPS eligible clinician's final score for the 2017 MIPS performance period, we stated in the CY 2019 PFS proposed rule (83 FR 35970) that it is not appropriate to redistribute weight to the cost performance category for the 2019 MIPS performance period because MIPS eligible clinicians have limited experience being scored on cost measures for purposes of MIPS. In addition, we were concerned that there would be limited measures in the cost performance category under our proposals for the 2019 MIPS performance period and stated that it may be appropriate to delay shifting additional weight to the cost performance category until additional measures are developed. However, we also noted that cost is a critical component of the Quality Payment Program and believe placing additional emphasis on the cost performance category in future years may be appropriate. Therefore, we solicited comment on redistributing weight to the cost performance category in future years.

We thank commenters for their input and will take this input into consideration in future years.

(c) Final Score Calculation

We proposed to revise the formula at § 414.1380(c) for calculating the final score (83 FR 35970). We did not propose to continue to add the small practice bonus to the final score for the 2021 MIPS payment year and proposed to add a small practice bonus to the quality performance category score instead starting with the 2021 MIPS payment year (83 FR 35950 through 35951). Therefore, we proposed to revise the formula to omit the small practice bonus from the final score calculation beginning with the 2021 MIPS payment year (83 FR 35970). We requested public comments on this proposal.

Although we received several comments on the small practice bonus, we did not receive any comments on our proposed revisions to the formula to calculate the final score. We discuss our policy for our revised small practice bonus in the quality performance category in section III.I.3.i.(1)(b)(viii) of this final rule.

After consideration of public comments, we are finalizing our proposed revisions to § 414.1380(c) as proposed.

In the CY 2019 PFS proposed rule, we solicited comments on approaches to simplify calculation of the final score (83 FR 35970). We thank commenters for their input and will take this input into consideration in future years.

j. MIPS Payment Adjustments

(1) Final Score Used in Payment Adjustment Calculation

For our previously established policies regarding the final score used in payment adjustment calculations, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77330 through 77332) and the CY 2018 Quality Payment Program final rule (82 FR 53785 through 53787). Under our policies, for groups submitting data using the TIN identifier, we will apply the group final score to all the TIN/NPI combinations that bill under that TIN during the performance period (82 FR 53785). We proposed to modify this policy for the application of the group final score, beginning with the 2019

performance period/2021 MIPS payment year (83 FR 35971). We proposed a 15-month window that starts with the second segment of the MIPS determination period (October 1 prior to the MIPS performance period through September of the MIPS performance period) and also includes the final 3 months of the calendar year of the performance period (October 1 through December 31 of the performance period year) (83 FR 35971). We proposed for groups submitting data using the TIN identifier, we would apply the group final score to all of the TIN/NPI combinations that bill under that TIN during the proposed 15-month window (83 FR 35971). We stated that we believe that partially aligning with the second segment of the MIPS determination period creates consistency with our eligibility policies that informs a group or eligible clinician of who is eligible. We refer readers to the CY 2019 PFS proposed rule (83 FR 35884 through 35886) where we discuss our proposals related to MIPS determination periods.

We noted that, if a MIPS eligible clinician's TIN/NPI combination was not part of the group practice during the MIPS determination period, the TIN/NPI combination would not be identified in our system at the start of the MIPS data submission period; however, if the MIPS eligible clinician qualifies to receive the group final score under our proposal, we would apply the group final score to the MIPS eligible clinician's TIN/NPI combination as soon as the information becomes available.

We solicited comments on the above proposal.

Comment: One commenter supported the concept of assigning a group score to clinicians who are in a group during the final 3 months of the calendar year of the performance period, stating that it is administratively burdensome for large organizations to track clinicians who join their practice during the last 3 months of the calendar year of the performance period and determine whether or not their previous practice intends to submit data on their behalf for the same calendar year of the performance period.

Response: We thank the commenter for their support.

Comment: One commenter expressed concern with the 15-month gap between the end of the first segment of the MIPS determination period and the end of the calendar year of the MIPS performance period for clinicians in groups who qualify for a group final score. The commenter stated that many clinicians move from one TIN to another and recommended we allow groups to report both on behalf of individual clinicians or as a group for all clinicians who have assigned their billing rights to the TIN during the calendar year of the performance period.

Response: We realize that the first segment of the MIPS determination period, as codified in this final rule at § 414.1305, ends 15 months before the end of the calendar year of the performance period; however, we believe the performance of a group should coincide, to the extent possible, with clinicians who are in the group during the performance period. Therefore, we believe it is appropriate to use the 15-month window which includes the second segment of the MIPS determination period and the last 3 months of the calendar year of the performance period. We note that group reporting is an option and practices may elect to submit for individual eligible clinicians, rather than as a group, as long as eligible clinicians are identified prior to end of the second segment of the MIPS determination period. As discussed in section III.I.3.i.(2)(b)(ii)(C) of this final rule, we do not have the ability to accept data for new group practices formed in the last 3 months of the calendar year of the performance period, or for individual MIPS eligible clinicians who switch practices in the last 3 months of the calendar year of the performance period if their new practice is not participating in MIPS as a group.

Comment: One commenter did not support the proposed 15-month window, citing the need for additional clarity and guidance to avoid complexity and confusion, and suggested that CMS provide examples of how this policy would apply in different scenarios. This commenter also recommended that CMS consider the implications of the proposal on clinician employment and how the proposal may negatively impact the ability of clinicians to switch practices.

Response: We do not agree that this proposal would cause confusion or add complexity. We believe the 15-month window aligns with our eligibility policies and better informs clinicians about their eligibility, streamlining the program. For example, for the 2019 MIPS performance period, if an eligible clinician joins a group practice in November of 2019 and that group practice existed prior to the last 3 months of the year (that is, prior to October 1, 2019) and submits MIPS data as a group, we would apply the group final score to that eligible clinician if the clinician bills under the group's TIN during the proposed 15-month window. Another example is a MIPS eligible clinician who joins a group practice in October of 2018 and that group practice submits MIPS data as a group for the 2019 MIPS performance period; for the 2019 performance period, we would apply the group final score to that eligible clinician if the clinician bills under the group's TIN during the proposed 15-month window. We appreciate the suggestion to consider the policy's implications on clinician employment and will take this into consideration in future rulemaking.

After consideration of the comments we received, we are finalizing our proposed 15-month window that starts with the second segment of the MIPS determination period (October 1 prior to the calendar year of the performance period through September 30 of the calendar year of the performance period) and also includes the final 3 months of the calendar year of the performance period (October 1 through December 31 of the calendar year of the performance period). We are also finalizing that for groups submitting data using the TIN identifier, we will apply the group final score to all of the TIN/NPI combinations that bill under that TIN during the 15-month window. We refer readers to section III.I.3.i.(2)(b)(ii)(C) of this final rule for a detailed discussion of the reweighting of the quality, cost, improvement activities and Promoting Interoperability performance categories for MIPS eligible clinicians who join a group practice in the final 3 months of the calendar year of the performance period.

(2) Establishing the Performance Threshold

Under section 1848(q)(6)(D)(i) of the Act, for each year of MIPS, the Secretary shall compute a performance threshold with respect to which the final scores of MIPS eligible clinicians are compared for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act for a year. The performance threshold for a year must be either the mean or median (as selected by the Secretary, and which may be reassessed every 3 years) of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary.

Section 1848(q)(6)(D)(iii) of the Act included a special rule for the initial 2 years of MIPS, which requires the Secretary, prior to the performance period for such years, to establish a performance threshold for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act and an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors under section 1848(q)(6)(C) of the Act, each of

which shall be based on a period prior to the performance period and take into account data available for performance on measures and activities that may be used under the performance categories and other factors determined appropriate by the Secretary. Section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 amended section 1848(q)(6)(D)(iii) of the Act to extend the special rule to apply for the initial 5 years of MIPS instead of only the initial 2 years of MIPS.

In addition, section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 added a new clause (iv) to section 1848(q)(6)(D) of the Act, which includes an additional special rule for the third, fourth, and fifth years of MIPS (the 2021 through 2023 MIPS payment years). This additional special rule provides, for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act, in addition to the requirements specified in section 1848(q)(6)(D)(iii) of the Act, the Secretary shall increase the performance threshold for each of the third, fourth, and fifth years to ensure a gradual and incremental transition to the performance threshold described in section 1848(q)(6)(D)(i) of the Act (as estimated by the Secretary) with respect to the sixth year (the 2024 MIPS payment year) to which the MIPS applies.

To determine a performance threshold to propose for the third year of MIPS (2019 MIPS performance period/2021 MIPS payment year), in the CY 2019 PFS proposed rule (83 FR 35971), we again relied upon the special rule in section 1848(q)(6)(D)(iii) of the Act, as amended by 51003(a)(1)(D) of the Bipartisan Budget Act of 2018. As required by section 1848(q)(6)(D)(iii) of the Act, we considered data available from a prior period with respect to performance on measures and activities that may be used under the MIPS performance categories. In accordance with newly added clause (iv) of section 1848(q)(6)(D) of the Act, we also considered which data could be used to estimate the performance threshold for the 2024 MIPS payment year to ensure a gradual and incremental transition from the performance threshold we would establish for the 2021 MIPS payment year. In the CY 2019 PFS proposed rule (83 FR 35971), we noted that we considered using the final scores for the 2017 MIPS performance period/2019 MIPS payment year; however, the data used to calculate the final scores was submitted through the first quarter of 2018, and final scores for MIPS eligible clinicians were not available in time for us to use in our analyses. We noted that if technically feasible, we would consider using the actual data used to determine the final scores for the 2019 MIPS payment year to estimate a performance threshold for the 2024 MIPS payment year in the final rule.

Because the final scores for MIPS eligible clinicians were not yet available at the time of the CY 2019 PFS proposed rule, we reviewed the data relied upon for the CY 2017 Quality Payment Program final rule regulatory impact analysis (81 FR 77514 through 77536) as we believed it was the best data available to us to estimate the actual data for the 2017 MIPS performance period/2019 MIPS payment year (83 FR 35971). Please refer to the CY 2019 PFS proposed rule (83 FR 35971 through 35973) for more details about the data we used.

In accordance with section 1848(q)(6)(D)(i) of the Act, the performance threshold for the 2024 MIPS payment year would be either the mean or median of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary. In the CY 2019 PFS proposed rule (83 FR 35972), we stated that when we analyzed the estimated final scores for the first year of the program (the 2019 MIPS payment year), the mean final score was between 63.50 and 68.98 points and the median was between 77.83 and 82.5 points based on the different participation assumptions. For purposes of estimating the performance threshold for the 2024 MIPS payment year, we used the mean final score based on data used for the CY 2017 Quality Payment Program final rule regulatory impact analysis (81 FR 77514 through 77536), which resulted in an estimated performance threshold between 63.50 and 68.98 points for the 2024 MIPS payment year. We noted that this is only an estimation we are providing in accordance with section 1848(q)(6)(D)(iv) of the Act, and we will propose the actual performance threshold for the 2024 MIPS payment year in future rulemaking.

We proposed a performance threshold of 30 points for the 2021 MIPS payment year to be codified at § 414.1405(b)(6) (83 FR 35972). A performance threshold of 30 points would be a modest increase over the performance threshold for the 2020 MIPS payment year (15 points), and we stated that we believe it would provide a gradual and incremental transition to the performance threshold we will establish for the 2024 MIPS payment year, which we have estimated would be between 63.50 and 68.98 points.

We stated that we want to encourage continued participation and the collection of meaningful data by MIPS eligible clinicians. A higher performance threshold would help MIPS eligible clinicians strive to achieve more complete reporting and better performance and prepare MIPS eligible clinicians for the 2024 MIPS payment year. However, a performance threshold set too high could also create a performance barrier, particularly for MIPS eligible clinicians who did not previously participate in PQRS or the EHR Incentive Programs. Additionally, we stated that we believe a modest increase from the performance threshold for the 2020 MIPS payment year would be particularly important to reduce the burden for MIPS eligible clinicians in small or solo practices. We stated that we believe that active participation of MIPS eligible clinicians in MIPS will improve the overall quality, cost, and care coordination of services provided to Medicare beneficiaries.

In the CY 2019 PFS proposed rule (83 FR 35972), we noted that we heard from stakeholders requesting that we continue a low performance threshold and from stakeholders that requested we ramp up the performance threshold to help MIPS eligible clinicians prepare for a future performance threshold of the mean or median of final scores and to meaningfully incentivize higher performance. We also noted that we heard from stakeholders who stated a higher performance threshold may incentivize higher performance by MIPS eligible clinicians through higher positive MIPS payment adjustments for those who exceed the performance threshold. We noted our belief that a performance threshold of 30 points for the 2021 MIPS payment year would provide a gradual and incremental increase from the performance threshold of 15 points for the 2020 MIPS payment year and could incentivize higher performance by MIPS eligible clinicians.

We also noted our belief that a performance threshold of 30 points represents a meaningful increase compared to 15 points, while maintaining flexibility for MIPS eligible clinicians in the pathways available to achieve this performance threshold, and we provided examples to support our belief in the CY 2019 PFS proposed rule (83 FR 35972). We invited public comment on the proposal to set the performance threshold for the 2021 MIPS payment year at 30 points (83 FR 35972). Alternatively, we considered whether the performance threshold should be set at a higher or lower number, for example, 25 points or 35 points, and also sought comment on

alternative numerical values for the performance threshold for the 2021 MIPS payment year (83 FR 35972).

We solicited comments on the above proposal.

Comment: Many commenters supported the proposed performance threshold of 30 points, indicating that the increase is reasonable; is aligned with what they believe to be Congress's intent to ensure that clinicians continue to be held accountable for quality and cost; is not a significant change from the prior year; encourages clinicians to increase their engagement and performance in MIPS; and is low enough to protect eligible clinicians who may not have experience reporting in MIPS from negative payment adjustments. One commenter stated that raising the performance threshold may help limit the flattening impact of the overall cost performance category score. One commenter stated the modest increase would not disadvantage small practices if the small practice bonus and other special scoring policies remain available to them and is reasonable considering that a fair portion of clinicians are excluded from MIPS under the low-volume threshold.

Response: We thank the commenters for their support.

Comment: Many commenters did not support the proposed performance threshold of 30 points and stated it is too high, is not gradual enough, would be unduly taxing, and many eligible clinicians are still adapting to the complexities of the MIPS program. Several commenters did not support the performance threshold citing the number of policy changes to the MIPS program and stated that group practices and clinicians, including newly eligible clinicians, should gain experience with MIPS policy changes, including changes to episode-based cost measures and the restructuring of the Promoting Interoperability performance category, before the performance threshold is raised. Several commenters recommended a performance threshold of 20 points given the number of changes being proposed. Commenters also indicated 20 points would help newly eligible clinicians adjust to program reporting requirements and that it could be met or exceeded by reporting on 6 quality measures that receive at least 3 points per measure and one high weighted improvement activity or 2 medium weighted improvement activities to avoid a negative MIPS payment adjustment. A few commenters indicated that clinicians need more time to be educated about the MIPS program.

Response: We acknowledge the concerns submitted by many commenters. We recognize that many requirements and scoring policies in the MIPS program have changed since the 2017 MIPS performance period/2019 MIPS payment year, but we believe the proposed performance threshold of 30 points is an appropriate increase that encourages increased participation and engagement in the MIPS program and that incentivizes clinicians to transition to value-based care with a focus on the delivery of high-value care.

We also do not believe that increasing the performance threshold to 30 points is unreasonable or too steep, but is rather a moderate step that encourages clinicians to gain experience with all MIPS performance categories. In the CY 2019 PFS proposed rule, we estimated the performance threshold we would establish for the 2024 MIPS payment year would be between 63.50 and 68.98 points. This information was based on year 1 estimates from the regulatory impact analysis (83 FR 35972; 81 FR 77514 through 77536). When we looked at the actual final scores for MIPS eligible clinicians for the 2017 MIPS performance period/2019 MIPS payment year, we found the mean final score was 74.01 points and the median final score was 88.97 points. As discussed in section VII.F.8.d. of the Regulatory Impact Analysis (RIA) of this final rule, we also estimated the potential final scores for the 2019 MIPS performance period/2021 MIPS payment year. In the RIA, we updated our estimates by using data submitted for the first year of MIPS (2017 MIPS performance period/2019 MIPS payment year) and applying the scoring and eligibility policies for the third year of MIPS (the 2019 MIPS performance period/2021 MIPS payment year). In the RIA, we estimated the mean final score for the 2019 performance period/2021 MIPS payment year at 69.53 points and the median final score at 78.72 points. Based on these numbers, we estimate the performance threshold that we would establish for the 2024 MIPS payment year would likely be over 65 points. We believe that if we set the performance threshold at 20 points (or another number lower than 30 points) for the 2021 MIPS payment year, then the increases in the performance threshold for each of the 2022 and 2023 MIPS payment years would have to be steeper to ensure a gradual and incremental transition to the performance threshold for the 2024 MIPS payment year, in accordance with 1848(q)(6)(D)(iv) of the Act.

Additionally, we recognize that some policy changes, such as those finalized in this final rule for the Promoting Interoperability performance category, the impact of topped out measures on the quality performance category, the increased weighting of the cost performance category, and the introduction of episode-based cost measures may dampen final scores because it will be more difficult to achieve a perfect performance category score of 100 percent. However, we believe there are also many options for a MIPS eligible clinician, including a newly eligible clinician, to earn a final score at or above a performance threshold of 30 points that do not require a perfect score in every performance category and that these policies do not preclude a MIPS eligible clinician from performing well. For example, a MIPS eligible clinician that submits the maximum number of improvement activities (achieving 40 points out of a possible 40 points) that is weighted at 15 percent of the final score (100 percent improvement activities performance category score × 15 percent × 100 equals 15 points toward the final score) and achieves a quality performance category score of 35 percent [31] that could be achieved through a minimum of complete reporting of quality measures at varying levels of performance (35 percent quality performance category score × 45 percent × 100 equals 15.75 points toward the final score) would qualify for 30.75 points and exceed the performance threshold. When we also consider the cost and Promoting Interoperability performance categories scores, clinicians have even more options to exceed a 30-point performance threshold. While the performance threshold could be met or exceeded without clinician participation in the quality performance category, we encourage clinicians to participate in multiple performance categories, including the quality performance category, to help facilitate successful participation in MIPS when the performance threshold will be increased in future years and to align with the MIPS program's focus on value-based care and the delivery of high quality care for Medicare beneficiaries.

We agree with commenters about the need to educate clinicians, including newly eligible clinicians, about MIPS program policies and policy changes from year to year and encourage

[31] The score for the quality performance category would be (6 measure achievement points × 1 measure plus 3 measure achievement points × 5 measures)/60 total possible achievement points or 35 percent. This assumes an outcome measure is submitted. That score could be higher if the clinician qualifies for bonuses in the quality performance category.

clinicians to utilize the resources available to educate clinicians about the MIPS program at the CMS Quality Payment Program Resource library at *https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Resource-library.html*.

Comment: Several commenters recommended a lower performance threshold specifically for eligible clinicians in their first year of MIPS eligibility, citing that this flexibility is more equitable and allows for a greater chance of successful participation, is a reasonable approach, and that 30 points creates an unlevel playing field. A few commenters recommended 25 points and other scoring accommodations for newly eligible clinicians, including occupational therapists and physical therapists. A few commenters suggested alternative performance thresholds for newly eligible clinicians including 3 points and a modified ''pick your pace'' threshold for these clinicians. One commenter recommended a performance threshold of 20 points and stated a 30-point performance threshold is a very high standard for eligible clinicians in their first year of eligibility.

Response: As described in section III.I.3.j.(2) of this final rule, the MIPS program is still ramping up, and we will continue to increase the performance threshold to ensure a gradual and incremental transition to the performance threshold for the 2024 MIPS payment year (year 6). Therefore, a clinician who is a MIPS eligible clinician beginning with the 2021 MIPS payment year would have 4 years in the program to ramp up to year 6. Conversely, a clinician who first becomes a MIPS eligible clinician in a later year would be afforded less time to ramp up the closer the program gets to year 6. We refer readers to section III.I.3.a. of this final rule for our discussion of new eligible clinician types.

Comment: Many commenters stated that CMS should not increase the performance threshold until there is actual MIPS participation data available to analyze and share with clinicians, indicating that there is insufficient historical MIPS data on which to set benchmarks and determine the feasibility of the current performance threshold, the program is still in its early stages, and that use of actual data would provide eligible clinicians a greater sense of how they performed in the program overall.

Response: We appreciate the commenters' concerns with the proposed performance threshold and their request for a delay in increasing the performance threshold until we have more information about how clinicians are actually performing under MIPS. As discussed earlier in this section, we estimate that we would likely set the performance threshold for the 2024 MIPS payment year at over 65 points. We did analyze the actual final scores for the 2019 MIPS payment year and found the mean final score was 74.01 points and the median final score was 88.97 points for MIPS eligible clinicians. We believe that setting the performance threshold at 30 points for the 2019 performance period/2021 MIPS payment year is appropriate because it encourages increased participation and prepares clinicians for the additional participation requirements to meet or exceed the performance thresholds that will be set for later years. Additionally, we do not believe that keeping the performance threshold at 15 points (which was the performance threshold for the 2020 MIPS payment year) would provide the gradual and incremental transition to the performance threshold for the 2024 MIPS payment year required by section 1848(q)(6)(D)(iv) of the Act.

We also note that eligible clinicians have received performance feedback based on their performance in year 1 of MIPS. As previously finalized in the CY 2018 Quality Payment Program final rule (82 FR 53801 through 53802), on an annual basis, beginning July 1, 2018, performance feedback will be provided to MIPS eligible clinicians and groups for the quality and cost performance categories for the 2017 performance period, and if technically feasible, for the improvement activities and advancing care information (now known as Promoting Interoperability) performance categories. For details on the release of the feedback reports for the first year of MIPS, we refer readers to section III.I.3.g. of this final rule.

Comment: Several commenters did not support the proposed performance threshold of 30 points, stating their belief that it burdens smaller practices, especially individual clinicians who are unable to afford CEHRT. A few commenters recommended that CMS consider a bonus for solo practitioners.

Response: We acknowledge the concerns of commenters regarding the potential burden on small practices, particularly solo practitioners. We also recognize the unique challenges for solo practitioners who participate in MIPS and have established a set of policies for small practices that apply to solo practitioners as well. The special policies available for small practices include the small practice bonus which is finalized in section III.I.3.i.(1)(b)(viii) of this final rule; the provisions related to the assignment of 3 points for measures that do not meet data completeness criteria which are finalized in section III.I.3.i.(1)(b)(v) of this final rule; the significant hardship exception for Promoting Interoperability performance category and the associated reweighting policies available for small practices (CY 2018 Quality Payment Program final rule (82 FR 53683)); and special scoring provisions available for the improvement activities performance category (81 FR 77185, 77188; 82 FR 53656. We also note that clinicians in small practices are more likely than clinicians in larger practices to fall below one of the low-volume criteria and would not be required to submit to MIPS; however, if they exceed at least one, but not all, of the low volume criteria, then they would be able to take advantage of the opt-in policy. We refer readers to section III.I.3.c. of this final rule for more details.

Comment: A few commenters recommended a more modest increase to the performance threshold and asked us to consider specialty-specific performance thresholds, or special scoring policies for clinicians in specialty practices, stating this would allow for more fair comparisons among clinicians. One commenter stated concerns with ambulatory surgical center-based clinicians being able to meet a 30-point threshold and requested that CMS consider scoring relief for ambulatory surgical center-based clinicians and groups. One commenter stated concerns for certified registered nurse anesthetists (CRNAs) meeting the performance threshold, citing the lack of anesthesia-related measures, low achievable points due to quality measure benchmarking, the lack of applicable cost measures, and the inability of CRNAs to participate in the Promoting Interoperability performance category that places a significant amount of time, money and resources into achieving performance scores to meet the minimum performance threshold. One commenter did not support the proposed performance threshold and believed that clinicians who are not capable of submitting data for more than one MIPS performance category could not meet the performance threshold.

Response: We appreciate the unique challenges faced by MIPS eligible clinicians that are in specialty practices, including clinicians based in ambulatory surgical centers and CRNAs. However, we believe that different performance criteria for certain types of clinicians would create more confusion and burden than a cohesive set of criteria. We also do not believe the

proposed increase in the performance threshold is overly aggressive or unfair to specialty practices and note that there are multiple pathways for clinicians, including specialty practices, to meet or exceed the performance threshold. We also believe that except for a few circumstances, such as extreme and uncontrollable circumstances, rare cases where there are no quality measures, or clinicians joining an existing practice (existing TIN) during the final 3 months of the calendar year in which the performance period occurs (the performance period year) that is not participating in MIPS as a group, most MIPS eligible clinicians would have sufficient measures and activities available and applicable to them for the quality and improvement activities performance categories and would be scored on these two categories. We also have policies in place, such as data validation process discussed in section III.I.3.i.(1)(b)(vii) of this final rule, to assess if clinicians have fewer than 6 measures available and applicable for the quality performance category. We refer the readers to the discussion of our reweighting policies for extreme and uncontrollable circumstances at section III.I.3.i.(2)(b)(ii) of this final rule.

Comment: A few commenters supported keeping a performance threshold of 15 points to minimize administrative burdens as part of the ''Patients over Paperwork'' initiative and to give clinicians adequate time to adjust their practice to meet the program's requirements.

Response: We are mindful of the efforts and requirements for eligible clinician participation in MIPS and agree that many clinicians need time to become familiar with the program's policies and requirements and gain experience with increased participation under the MIPS program. However, we do not believe that maintaining the performance threshold at 15 points for the 2019 performance period/2021 MIPS payment year appropriately encourages clinicians to actively participate in MIPS and incentivizes clinicians to transition to value-based care with a focus on the delivery of high-value care. Additionally, we do not believe that keeping the performance threshold at 15 points (which was the performance threshold for the 2020 MIPS payment year) would provide the gradual and incremental transition to the performance threshold for the 2024 MIPS payment year that the statute requires. We believe a meaningful increase to a performance threshold of 30 points maintains appropriate flexibility for clinicians to meet or exceed the performance threshold, while requiring increased participation over the level of engagement required to meet or exceed the 15-point threshold for year 2 of MIPS. We also believe the increased participation better prepares clinicians to succeed under MIPS in future years, will encourage a transition to the MIPS program's focus on value-based care, and will improve the overall quality, cost, and care coordination of services to Medicare beneficiaries.

Comment: Several commenters recommended a higher performance threshold believing that the proposed performance threshold punishes eligible clinicians who have invested time and money to achieve high MIPS performance, compromises the ability of high performers to earn the maximum payment adjustment, and dilutes program effectiveness to drive quality improvement and reduce spending growth. A few commenters recommended a performance threshold between 30 points and 60 points. One commenter recommended a performance threshold of 50 points, stating it would better reward clinicians and groups who are engaged with the program and encourage the examination of alternative payment models.

Response: The MIPS statute requires budget neutrality, and clinicians will receive a positive, negative, or neutral payment adjustment factor that is determined by their performance and the distribution of final scores across all MIPS eligible clinicians; accordingly, high performers would likely receive higher payment adjustments if fewer MIPS eligible clinicians meet or exceed the performance threshold. While a higher performance threshold provides a greater financial reward for high performers, we believe the proposal of 30 points is warranted to encourage clinician participation in MIPS and to encourage a movement toward value-based care with a focus on the delivery of high quality care. We also believe that the additional performance threshold for exceptional performance discussed later in section III.I.3.j.(3) of this final rule provides an additional financial incentive and financial reward for high performers and will continue to incentivize their exceptional performance. Moreover, we believe setting the performance threshold higher than 30 points would not provide a gradual and incremental transition to the performance threshold for the 2024 MIPS payment year, as required by the statute, but rather would result in a sharp increase over the performance threshold of 15 points for the 2020 MIPS payment year.

After consideration of the comments, we are finalizing our proposal to set the performance threshold at 30 points for the 2021 MIPS payment year as proposed. We are codifying the performance threshold for the 2021 MIPS payment year and finalizing the regulation text at § 414.1405(b)(6) as proposed.

We also solicited comment on our approach to estimating the performance threshold for the 2024 MIPS payment year, which in the CY 2019 PFS proposed rule we based on the estimated mean final score for the 2019 MIPS payment year (83 FR 35972). We were particularly interested in whether we should use the median, instead of the mean, and whether in the future we should estimate the mean or median based on the final scores for another MIPS payment year. We also solicited comment on whether establishing a path forward to a performance threshold for the 2024 MIPS payment year that provides certainty to clinicians and ensures a gradual and incremental increase from the performance threshold for the 2021 MIPS payment year to the estimated performance threshold for the 2024 MIPS payment year would be beneficial, and whether it would be beneficial for MIPS eligible clinicians to know in advance the performance threshold for the 2022 and 2023 MIPS payment years to encourage and facilitate increased clinician engagement and prepare clinicians for meeting the performance threshold for the 2024 MIPS payment year.

We thank commenters for their input on these topics and will take this input into consideration in future years.

(3) Additional Performance Threshold for Exceptional Performance

Section 1848(q)(6)(D)(ii) of the Act requires the Secretary to compute, for each year of the MIPS, an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors for exceptional performance under section 1848(q)(6)(C) of the Act. For each such year, the Secretary shall apply either of the following methods for computing the additional performance threshold: (1) The threshold shall be the score that is equal to the 25th percentile of the range of possible final scores above the performance threshold determined under section 1848(q)(6)(D)(i) of the Act; or (2) the threshold shall be the score that is equal to the 25th percentile of the actual final scores for MIPS eligible clinicians with final scores at or above the performance threshold for the prior period described in section 1848(q)(6)(D)(i) of the Act.

Under section 1848(q)(6)(C) of the Act, a MIPS eligible clinician with a

final score at or above the additional performance threshold will receive an additional MIPS payment adjustment factor and may share in the $500,000,000 of funding available for the year under section 1848(q)(6)(F)(iv) of the Act.

As we discussed in the CY 2019 PFS proposed rule (83 FR 35971), we relied on the special rule under section 1848(q)(6)(D)(iii) of the Act, as amended by section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018, to propose a performance threshold of 30 points for the 2021 MIPS payment year. The special rule under section 1848(q)(6)(D)(iii) of the Act also applies for purposes of establishing an additional performance threshold for a year. For the 2021 MIPS payment year, we proposed to again decouple the additional performance threshold from the performance threshold (83 FR 35973 through 35974).

During the time period in which we were drafting the CY 2019 PFS proposed rule, we did not have actual MIPS final scores for a prior performance period. We noted in the CY 2019 PFS proposed rule (83 FR 35973) that if we did not decouple the additional performance threshold from the performance threshold, then we would have to set the additional performance threshold at the 25th percentile of possible final scores above the performance threshold. With a performance threshold set at 30 points, the range of total possible points above the performance threshold is 30.01 to 100 points and the 25th percentile of that range is 47.5, which is less than one-half of the possible 100 points in the MIPS final score. We stated that we do not believe it would be appropriate to lower the additional performance threshold to 47.5 points because we do not believe a final score of 47.5 points demonstrates exceptional performance by a MIPS eligible clinician, as these additional incentives should only be available to those clinicians with very high performance on the MIPS measures and activities. Therefore, we relied on the special rule under section 1848(q)(6)(D)(iii) of the Act and proposed at § 414.1405(d)(5) to set the additional performance threshold at 80 points for the 2021 MIPS payment year, which is higher than the 25th percentile of the range of the possible final scores above the performance threshold (83 FR 35973).

As required by section 1848(q)(6)(D)(iii) of the Act, we took into account the data available and the modeling described in the CY 2019 PFS proposed rule to estimate final scores for the 2021 MIPS payment year (83 FR 35973). We stated that we believed 80 points was appropriate to incentivize clinicians who have made greater strides to meaningfully participate in the MIPS program to perform at even higher levels. An additional performance threshold of 80 points would require a MIPS eligible clinician to perform well on at least two performance categories. We stated that, generally, a MIPS eligible clinician could receive a maximum score of 45 points for the quality performance category, which is below the 80-point additional performance threshold. In addition, 80 points is at a high enough level that MIPS eligible clinicians must submit data for the quality performance category to achieve this target. We noted the additional performance threshold at 80 points could increase the incentive for excellent performance while keeping the focus on quality performance.

We also stated an increase would encourage increased engagement and further incentivize clinicians whose performance meets or exceeds the additional performance threshold, recognizing that a fixed amount is available for a year under section 1848(q)(6)(F)(iv) of the Act to fund the additional MIPS payment adjustments and that the more clinicians who receive an additional MIPS payment adjustment, the lower the average clinician's additional MIPS payment adjustment will be.

For future years, we stated that we may consider additional increases to the additional performance threshold.

We solicited comments on these proposals.

Comment: Many commenters recommended the additional performance threshold remain at 70 points. Several commenters stated it would be more difficult to reach 80 points rather than 70 points because of proposed changes to the Promoting Interoperability performance category, changes to quality measures, more topped out measures, the increased weighting of the cost performance category, the introduction of episode-based cost measures, and the removal of bonus points. One commenter recommended that the additional performance threshold remain at 70 points for at least another year because clinicians are still learning to interpret their feedback reports and make adjustments to their practices accordingly. One commenter stated that clinicians in specialty practices without a significant breadth of reportable measures would be adversely affected while those specialties that do have large numbers of measures with full scoring potential would benefit and that this was unfair and would discourage high performance for those clinicians and groups within specialties. One commenter indicated that the increase may cause more clinicians to report on measures that bring more points rather than the most value to their patients and practice. Another commenter stated the increase seemed arbitrary and that clinicians who earn 70 points should be considered exceptional. One commenter stated that keeping the additional performance threshold at 70 points would allow the payment adjustment to be spread more evenly rather than to only a select few and alleviate some of the lack of positive payment adjustment incentive due to the very low 30-point performance threshold.

A few commenters stated the additional performance threshold should not be increased until information is available and data shared with clinicians from the first 2 years of the program about the number of eligible clinicians who were able to earn the additional payment adjustment, including the number of psychiatrists who exceeded the additional performance threshold during the 2017 MIPS performance period.

Response: We note that many commenters recommended that we maintain 70 points for the additional performance threshold for the 2019 performance period/2021 MIPS payment year. However, we believe for year 3 it is appropriate to raise the bar on what is rewarded as exceptional performance and that increasing the additional performance threshold will encourage clinicians to increase their focus on value-based care and enhance the delivery of high quality care for Medicare beneficiaries. Based on our current data, our belief that raising the additional performance threshold will incentivize continued improved performance, and our concern that policy changes may make it challenging for clinicians to reach an additional performance threshold of 80 points while they are becoming familiar and comfortable with the policy changes, we believe it is important to raise the additional performance threshold, but by less than the original amount proposed. Therefore, for year 3 of the MIPS program, we are finalizing the additional performance threshold at 75 points, which is halfway between our proposal of 80 points and the level recommended by many commenters of 70 points.

We appreciate commenters' concerns about the proposed policy changes for MIPS impacting clinicians' ability to exceed the additional performance threshold. While we recognize that some of the policy changes being

finalized in this rule, including new scoring policies for the Promoting Interoperability performance category, changes to quality measures, the identification of more topped out measures, the increased weighting of the cost performance category, and the introduction of episode-based cost measures, may make it more challenging for clinicians to achieve higher scores while they are becoming more familiar and comfortable with these new policies, we also believe these policy changes help simplify and streamline the MIPS program and reduce overall burden after an initial adjustment period. Thus, we believe it is appropriate to slightly increase the additional performance threshold for year 3 and will consider raising it more in future years.

In addition, despite these changes, we believe that 75 points is achievable for many clinicians. Based on our most current data, we estimated for the 2019 performance period/2021 MIPS payment year a mean final score of 69.53 points and a median final score of 78.72 points as discussed elsewhere in this section and in section VII.F.8.d. of the RIA of this final rule. We also believe a modest increase above the additional performance threshold for the 2018 MIPS performance period/2020 MIPS payment year would result in an additional performance threshold that is attainable and that would allow for multiple pathways for clinicians, including clinicians in specialty practices whose choice of applicable and available measures will likely vary according to specialty, to perform exceptionally well and would encourage higher performance by clinicians for year 3 of the MIPS program.

We acknowledge that the number of quality measures available to clinicians can vary by specialty and practice. We believe our quality performance category scoring validation policy accounts for certain instances where clinicians have less than 6 measure available. We believe these adjustments allow us to develop a fair comparison across different MIPS eligible clinicians and would not preclude clinicians from reaching the final additional performance threshold.

We also note that we have shared performance feedback with clinicians and groups based on their performance in year 1 of MIPS and recognize that clinicians may make adjustments to their clinical practice in response to that feedback, and because we are trying to balance that year 3 is a transition year with the goal of encouraging clinicians to improve their performance and to deliver value-based, high quality care, we believe that a moderate increase to 75 points is appropriate.

Comment: Many commenters supported the proposal to increase the additional performance threshold for exceptional performance to 80 points for the 2021 MIPS payment year and stated it encourages strong performance from clinicians and health systems, supports continuous performance improvement, motivates and holds clinicians accountable to deliver quality care, creates a competitive playing field for high performers, rewards clinicians who have invested time and resources and have demonstrated success under MIPS performance standards, seems reasonable, and is an appropriate increase for year 3 of the program. One commenter supported the proposal because it ensures clinicians are considering both cost and quality. One commenter stated that raising the threshold may help with flattening the overall cost performance score. One commenter supported the proposal because it is high enough to identify exceptional scores, but was uncertain if it would translate into improved patient outcomes or would meet CMS objectives. One commenter supported the proposal should CMS continue its policies that provide bonus points in the MIPS program and allow for claims-based reporting.

Response: We received many comments in support of our proposal for an additional performance threshold of 80 points. We agree with the commenters that raising the performance threshold encourages strong clinician performance, participation in multiple performance categories, and continuous performance improvement; provides an appropriate financial reward for high performers; and promotes a focus on the delivery of high quality, value-based care by clinicians.

We also note that there were many commenters recommending that the additional performance threshold remain at 70 points and other commenters recommending 75 points. We have considered the totality of the comments and are swayed by the comments requesting a more modest increase to the additional performance threshold. We have also considered the updated regulatory impact analysis which incorporates Quality Payment Program year 1 data to estimate performance for the 2019 performance period/2021 MIPS payment year in section VII.F.8.d. of this final rule and found a mean score of 69.53 points and a median final score of 78.72 points. Given these findings, we believe that a small decrease from the proposed additional performance threshold of 80 points that would fall between the mean and the median would help the additional performance threshold remain attainable and would allow for a larger number of clinicians to receive the additional payment adjustment.

We also believe an increase in the additional performance threshold would incentivize clinicians to increase their focus on value-based care with an emphasis on the delivery of high quality care for patients, but that an increase of 10 points is too steep, and thus, are finalizing an additional performance threshold of 75 points that is midway between our original proposal of 80 points and the additional performance threshold for the 2018 MIPS performance period/2020 MIPS payment year of 70 points.

Comment: A few commenters stated an increase to 80 points would disproportionately impact small practices and make it difficult for them to participate successfully in the MIPS program. One commenter recommended CMS should not increase the additional performance threshold until data was available to consider the impact on small practices and then set a fair threshold.

Response: We recognize the unique challenges to eligible clinicians in small practices participating in MIPS and believe the special policies for small practices provide some relief for small practices seeking to perform well. We refer readers to special policies for small practices including: The small practice bonus which is finalized in section III.I.3.i.(1)(b)(viii) of this final rule; the significant hardship exception for the Promoting Interoperability performance category available for small practices (CY 2018 Quality Payment Program final rule 82 FR 53683); the special scoring provisions available for the improvement activities performance category (81 FR 77185, 77188; 82 FR 53656); and the provisions related to the assignment of 3 points for measures that do not meet data completeness criteria which are finalized in section III.I.3.i.(1)(b)(v) of this final rule). We also note that small practices are more likely than larger practices to fall below one or more of the provisions related to the low-volume threshold and would be able to take advantage of the opt-in policy and refer readers to a discussion of the low-volume threshold at section III.I.3.c. of this final rule.

We also analyzed the data referenced in section VII.F.8.d. of the RIA of this final rule, and found that more small practices than larger practices may find it harder to meet or exceed the additional performance threshold. We

agree with commenters referenced here and elsewhere in this section that an additional performance threshold of 80 points is too steep of an increase from 70 points, but we believe that an increase is appropriate for year 3 and that the current policies that provide flexibilities for small practice provide a pathway for a successful transition for clinicians who have made a commitment toward value and the delivery of high quality care in the MIPS program. Based on these competing concerns, as noted above, we are finalizing an additional performance threshold of 75 points.

We also note that the additional performance threshold rewards exceptional performance in the MIPS program and a clinician could successfully participate in MIPS by meeting or exceeding the performance threshold and receive a neutral or positive payment adjustment.

Comment: A few commenters recommended 75 points because it is a more modest, 5-point increase from the previous performance threshold of 70 points. One commenter supported 75 points believing the increase seems fair because the threshold is more attainable for many eligible clinicians who are specialists, such as those practicing interventional pain management, who may have difficulty identifying relevant measures that improve patient quality of care. One commenter supported 75 points should CMS finalize its proposal to remove claims-based reporting and finalize its proposal to remove bonus points for improvement activities completed using CEHRT.

Response: We agree with an additional performance threshold of 75 points. We believe for year 3 it is appropriate to raise the bar on what is rewarded as exceptional performance and that increasing the additional performance threshold will encourage clinicians to increase their focus on value-based care and promote the delivery of high quality care for patients. We also believe that a more modest increase of 5 points, rather than an increase of 10 points, over the additional performance threshold for year 2 is appropriate because year 3 is still a transition year and we want to encourage increased clinician engagement and increased performance in the MIPS program that drives toward the delivery of value-based, high quality care for Medicare beneficiaries. We also note that some commenters stated that the proposed 10-point increase may have unintended consequences especially because of the impact that proposed policy changes could have on final scores as clinicians are becoming familiar with these changes. We want to reward exceptional performance that, given the impact of the policy changes in this final rule, could be less than 80 points. As such, we are swayed by comments that an increase to 75 points is more modest and a reasonable half-way point that still would raise the bar on what is rewarded as exceptional performance for the 2019 MIPS performance period.

We note that a lower additional performance threshold could reduce the maximum additional payment adjustment that a MIPS eligible clinician could potentially receive if the funds available (up to $500 million for the year) are distributed over more clinicians that score above the lower additional performance threshold. For the reasons discussed above, we believe 75 points is appropriate for year 3 and note that the additional performance threshold will be raised in future years.

Comment: A few commenters recommended a higher additional performance threshold for exceptional performers. One commenter recommended an additional performance threshold of 85 points to further efforts to engage clinicians and groups through financial incentives tied to metric performance. One commenter recommended a steeper scale for awarding exceptional performance for scores of 90 points or greater.

Response: We believe that a steeper increase in the additional performance threshold is not appropriate given that MIPS is still in a transition period and because of the MIPS policy changes we are making in this final rule that include scoring changes to the Promoting Interoperability performance category and the addition of episode-based cost measures to the cost performance category, that could impact final scores for year 3 of the MIPS program as eligible clinicians become more familiar and comfortable with these policy changes. We want to reward exceptional performance that, given the impact of our policy changes in this final rule, could include performance below 85 or 90 points, particularly for small practices which may not have sufficient case minimum to achieve maximum quality performance category score. We recognize a higher additional performance threshold will allow for a higher financial reward for high performers, but we want to encourage participation with wider availability of this funding.

Comment: One commenter recommended that CMS increase the thresholds in the CY 2020 performance period and going forward because higher thresholds will result in a wider array of payment adjustments, thereby encouraging more participation and rewarding those that invest in improving their quality of care.

Response: We thank the commenter for the input and will take this comment into consideration in future rule-making.

After consideration of the comments, we are not finalizing our proposal of 80 points for the additional performance threshold and instead are finalizing 75 points for the additional performance threshold for the 2021 MIPS payment year. We are codifying the additional performance threshold for the 2021 MIPS payment year and finalizing the proposed regulation text at § 414.1405(d)(5) with modification to reflect 75 points instead of 80 points.

(4) Application of the MIPS Payment Adjustment Factors

(a) Application to the Medicare Paid Amount for Covered Professional Services

In the CY 2018 Quality Payment Program final rule (82 FR 53795), we finalized the application of the MIPS payment adjustment factor, and if applicable, the additional MIPS payment adjustment factor, to the Medicare paid amount for items and services paid under Part B and furnished by the MIPS eligible clinician during the year. Sections 51003(a)(1)(A)(i) and 51003(a)(1)(E) of the Bipartisan Budget Act of 2018 amended sections 1848(q)(1)(B) and 1848(q)(6)(E) of the Act, respectively, by replacing the references to ''items and services'' with ''covered professional services'' (as defined in section 1848(k)(3)(A) of the Act). Covered professional services as defined in section 1848(k)(3)(A) of the Act are those services for which payment is made under, or is based on, the Medicare PFS and which are furnished by an eligible professional. As a result of these changes, the MIPS payment adjustment factor determined under section 1848(q)(6)(A), and as applicable, the additional MIPS payment adjustment factor determined under section 1848(q)(6)(C) of the Act, will be applied to Part B payments for covered professional services furnished by a MIPS eligible clinician during a year beginning with the 2019 MIPS payment year and not to Part B payments for other items and services.

To conform with these amendments to the statute, we proposed to revise § 414.1405(e) to apply the MIPS payment adjustment factor and, if applicable, the additional MIPS payment adjustment factor, to the

Medicare Part B paid amount for covered professional services furnished by a MIPS eligible clinician during a MIPS payment year (beginning with 2019) (83 FR 35973 through 35974). We also *proposed* to revise § 414.1405(e) to specify the formula for applying these adjustment factors in a manner that more closely tracks the statutory formula under section 1848(q)(6)(E) of the Act (83 FR 35973 through 35974). Specifically, we proposed the following formula: In the case of covered professional services (as defined in section 1848(k)(3)(A) of the Act) furnished by a MIPS eligible clinician during a MIPS payment year beginning with 2019, the amount otherwise paid under Part B with respect to such covered professional services and MIPS eligible clinician for such year, is multiplied by 1, plus the sum of: The MIPS payment adjustment factor divided by 100, and as applicable, the additional MIPS payment adjustment factor divided by 100 (83 FR 35974).

We did not receive any comments on this proposal.

We are finalizing our proposed changes to the regulation text at § 414.1405(e) as proposed. We also refer readers to section III.I.3.a. of this final rule where we discuss the covered professional services to which the MIPS payment adjustment could be applied. We also refer readers to section III.I.3.c.(3) of this final rule where we discuss other conforming edits to the regulation text at §§ 414.1310(a), 414.1310(b), and 414.1310(d) that specify the circumstances when the MIPS payment adjustment would not apply to payments for covered professional services furnished by MIPS eligible clinicians on or after January 1, 2019.

(b) Application for Non-Assigned Claims for Non-Participating Clinicians

In the CY 2018 Quality Payment Program final rule, we did not address the application of the MIPS payment adjustment for non-assigned claims for non-participating clinicians. In the CY 2018 Quality Payment Program final rule (82 FR 53795), we responded to a comment requesting guidance on how the MIPS payment adjustment and the calculation of the Medicare limiting charge amount would be applied for non-participating clinicians, and we stated our intention to address these issues in future rulemaking. Beginning with the 2019 MIPS payment year, we proposed that the MIPS payment adjustment does not apply for non-assigned claims for non-participating clinicians (83 FR 35974). This approach is consistent with the policy for application of the value modifier that was finalized in the CY 2015 PFS final rule (79 FR 67950 through 67951). Sections 1848(q)(6)(A) and 1848(q)(6)(C) of the Act require that we specify a MIPS payment adjustment factor, and if applicable, an additional MIPS payment adjustment factor for each MIPS eligible clinician, and section 1848(q)(6)(E) of the Act (as amended by section 51003(a)(1)(E) of the Bipartisan Budget Act of 2018) requires that these payment adjustment factor(s) be applied to adjust the amount otherwise paid under Part B for covered professional services furnished by the MIPS eligible clinician during the MIPS payment year. When non-participating clinicians choose not to accept assignment for a claim, Medicare makes payment directly to the beneficiary, and the clinician collects payment from the beneficiary. This is referred to as a non-assigned claim. Application of the MIPS payment adjustment to these non-assigned claims would not affect payment to the MIPS eligible clinician. Rather, it would only affect Medicare payment to the beneficiary. If the MIPS payment adjustment were to be applied to non-assigned services, then the Medicare payment to a beneficiary would be increased when the MIPS payment adjustment is positive and decreased when the MIPS payment adjustment is negative. Although the statute does not directly address this situation, it does suggest that the MIPS payment adjustment is directed toward payment to the MIPS eligible clinician and the covered professional services they furnish. We continue to believe that it is important that beneficiary liability not be affected by the MIPS payment adjustment and that the MIPS payment adjustment should be applied to the amount that Medicare pays to MIPS eligible clinicians.

On that basis, we proposed to apply the MIPS payment adjustment to claims that are billed and paid on an assignment-related basis, and not to any non-assigned claims, beginning with the 2019 MIPS payment year (83 FR 35974). We do not expect this proposal would be likely to affect a clinician's decision to participate in Medicare or to otherwise accept assignment for a particular claim, but we solicited comment on whether stakeholders and others believe clinician behavior would change as a result of this policy.

We solicited comments on the above proposal.

Comment: A few commenters supported the proposal to apply the adjustment to claims that are billed and paid on an assignment-related basis and not to any non-assigned claims.

Response: We thank the commenters for their support.

Comment: One commenter recommended that this policy be revisited in the next year and evaluated for unintended consequences, including whether there are any adverse effects on Medicare beneficiaries who see a non-participating clinician who does not accept assignment for a claim.

Response: We thank the commenter for the input and will take this comment into consideration in future rulemaking.

After consideration of the comments, we are finalizing our proposal to apply the MIPS payment adjustment to claims that are billed and paid on an assignment-related basis, and not to any non-assigned claims, beginning with the 2019 MIPS payment year.

(c) Waiver of the Requirement To Apply the MIPS Payment Adjustment Factors to Certain Payments in Models Tested Under Section 1115A of the Act

(i) Overview

CMS tests models under section 1115A of the Act that may include model-specific payments made only to model participants under the terms of the model and not to any other providers of services or suppliers. Some of these model-specific payments may be considered payments for covered professional services furnished by a MIPS eligible clinician, meaning that the MIPS payment adjustment factor, and, as applicable, the additional MIPS payment adjustment factor (collectively referred to as the MIPS payment adjustment factors) applied under § 414.1405(e) of our regulations would normally apply to those payments.

(ii) Summary of Proposals and Comments Received

Section 1115A(d)(1) of the Act authorizes the Secretary to waive requirements of Title XVIII of the Act (and certain other requirements) as may be necessary solely for the purposes of testing models under section 1115A. We stated in the proposed rule (83 FR 35974 through 35975) that we believe it is necessary to waive the requirement to apply the MIPS payment adjustment factors to a model-specific payment or payments (to the extent such a payment or payments are subject to the requirement to apply the MIPS payment adjustment factors) for purposes of testing a section 1115A model under which such model-specific payment or payments are made in a specified payment amount (for example, $160 per-beneficiary, per-month); or paid according to a methodology for calculating a model-specific payment

that is applied in a consistent manner to all model participants. In both cases, applying the MIPS payment adjustment factors to these model-specific payments would introduce variation in the amounts of model-specific payments paid across model participants, which could compromise the model test and the evaluation thereof.

We proposed to amend § 414.1405 to add a new paragraph (f) to specify that the MIPS payment adjustment factors applied under § 414.1405(e) would not apply to certain model-specific payments as described above for the duration of a section 1115A model's testing beginning in the 2019 MIPS payment year (83 FR 35974 through 35975). We proposed to use the authority under section 1115A(d)(1) of the Act to waive the requirement to apply the MIPS payment adjustment factors under section 1848(q)(6)(E) of the Act and § 414.1405(e) specifically for these types of payments because the waiver is necessary solely for purposes of testing models that involve such payments (83 FR 35974 through 35975). To illustrate how the proposed waiver would apply, and to provide notice regarding one model-specific payment to which this proposed waiver would apply, we included an example in the proposed rule involving the Monthly Enhanced Oncology Services (MEOS) payment in the Oncology Care Model (OCM) (83 FR 35975).

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: A few commenters supported our proposal to waive the application of the MIPS payment adjustment factors to certain model-specific payments. The commenters agreed that these waivers are necessary to test models that would involve these types of model-specific payments, and without such waivers the evaluation of certain models could be compromised.

Response: We appreciate the commenters' support.

Comment: One commenter noted that the proposed amendment at § 414.1405(f) is ambiguous as to whether paragraphs (l), (2), and (3) refer to three different classes of payments, or to one class of payments that meet all three conditions. The commenter suggested that we clarify our intended policy.

Response: We clarify that only payments meeting all three conditions set forth at § 414.1405(f) will qualify for the waiver of the MIPS payment adjustment factors under section 1848(q)(6)(E) of the Act and § 414.1405(e). We have amended § 414.1405(f) to specify that payments must meet all three conditions to reduce any potential ambiguity, and made further amendments to § 414.1405(f) for greater clarity and readability and to more closely align with the policy described in the preamble text of the proposed rule, including to clarify that the regulatory text in § 414.1405(f)(3) refers to payments made in a consistent manner to all model participants, including those participants subject to the MIPS payment adjustment factors and participants not subject to the MIPS payment adjustment factors.

After considering public comments, we are finalizing our proposal to use the authority under section 1115A(d)(1) of the Act to waive the requirement to apply the MIPS payment adjustment factors under section 1848(q)(6)(E) of the Act and § 414.1405(e) specifically for payments specified at § 414.1405(f) with the clarifying amendments described herein. As discussed in the CY 2019 PFS proposed rule (83 FR 35975), one model-specific payment to which this finalized waiver will apply is the Monthly Enhanced Oncology Services (MEOS) payment in the Oncology Care Model (OCM). The duration of this waiver will begin with the 2019 MIPS payment year and continue for the duration of OCM.

We proposed to provide the public with notice that this proposed new regulation applies to model-specific payments that the Innovation Center elects to test in the future in two ways: first, we would update the Quality Payment Program website (*www.qpp.cms.gov*) when new model-specific payments subject to this proposed waiver are announced; and second, we would provide a notice in the **Federal Register** to update the public on any new model-specific payments to which this waiver would apply (83 FR 35974 through 35975).

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: One commenter urged CMS to denote which models and model specific payments are subject to this new policy on the Quality Payment Program website and **Federal Register** as soon as possible.

Response: We plan to provide the public with notice as soon as practicable for model-specific payments subject to this waiver via the Quality Payment Program website (*www.qpp.cms.gov*), and separate notice in the **Federal Register**.

After considering public comments, we are finalizing our policy as proposed to provide the public with notice in the following two ways: (1) We will update the Quality Payment Program website (*www.qpp.cms.gov*) when new model-specific payments subject to this waiver are announced; and (2) we will provide a notice in the **Federal Register** to update the public on any new model-specific payments to which this waiver will apply.

(d) CY 2018 Exclusion of MIPS Eligible Clinicians Participating in the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration

(i) Overview

In conjunction with releasing the CY 2019 PFS proposed rule, CMS announced the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration, established by CMS using our demonstration authority under section 402 of the Social Security Amendments of 1967 (as amended). The MAQI Demonstration is designed to test whether excluding MIPS eligible clinicians who participate to a sufficient degree in certain payment arrangements with Medicare Advantage Organizations (MAOs) from the MIPS reporting requirements and payment adjustments will increase or maintain participation in payment arrangements similar to Advanced APMs with MAOs and change the manner in which clinicians deliver care.

(ii) Summary of Proposals

We proposed to use the authority in section 402(b) of the Social Security Amendments of 1967 (as amended) to waive requirements of section 1848(q)(6)(E) of the Act and the regulations implementing it in order to waive the payment consequences (positive, negative or neutral adjustments) of the MIPS and to waive the associated MIPS reporting requirements in 42 CFR part 414 adopted to implement the payment consequences, subject to conditions outlined in the Demonstration. We noted, relating to our proposal to waive payment consequences, that the Demonstration would have the effect of removing MIPS eligible clinicians from the population across which positive and negative payment adjustments are calculated under MIPS, and because of the requirement to ensure budget neutrality with regard to the MIPS payment adjustments under section 1848(q)(6)(F)(ii) of the Act, the Demonstration may affect the payment

adjustments for other MIPS eligible clinicians.

We proposed that these waivers would be applicable for a MIPS eligible clinician participating in the Demonstration if they meet combined thresholds for Medicare payments or patients through Qualifying Payment Arrangements with MAOs and Advanced APMs, and that these thresholds would match the thresholds for participation in Advanced APMs under the Medicare Option of the Quality Payment Program. We also proposed to calculate thresholds based on aggregate participation in Advanced APMs and Qualifying Payment Arrangements with MAOs, without applying a specific minimum threshold to participation in either type of payment arrangement. For purposes of the Demonstration, we proposed to make determinations about clinicians' Qualifying Payment Arrangements with MAOs, consistent with the criteria used for Other Payer Advanced APMs under the Quality Payment Program and as set forth in § 414.1420. We proposed to begin the MAQI Demonstration in CY 2018, with the 2018 Performance Period, and operate the project for a total of 5 years.

We also noted in the proposed rule that, for eligible clinicians who are excluded from the MIPS reporting requirements and payment adjustment under the MAQI Demonstration, we would waive the provision in section 1848(q)(1)(A)(iii) of the Act requiring that the Secretary shall permit any eligible clinician to voluntarily report on applicable measures and activities. We clarify that, with this waiver, the Demonstration will prohibit voluntary reporting under the MIPS by eligible clinicians who participate in the Demonstration and are not subject to the MIPS reporting requirements and payment adjustment for a given year. This last waiver is intended to prevent potential gaming in the form of an eligible clinician intentionally submitting data showing poor performance for a year for which they are not subject to the MIPS reporting requirements and payment adjustment pursuant to the terms of the Demonstration in order to show improvement in their performance in future years when that improvement could result in higher MIPS scoring.

(iii) Applicable Waivers

Section 402(b) of the Social Security Amendments of 1967 (as amended) authorizes the Secretary to waive requirements of Title XVIII that relate to payment and reimbursement in order to carry out demonstrations under section 402(a). We proposed to use this authority to waive certain requirements of section 1848(q) of the Act and the regulations implementing it, specifically the payment consequences (positive, negative or neutral adjustments) of the MIPS and the associated MIPS reporting requirements in 42 CFR part 414 (adopted to implement the payment consequences), subject to conditions outlined in the Demonstration.

We solicited comment on these proposals.

The following is a summary of the public comments, relating to proposed waivers, received in response to our request for comment and our responses:

Comment: Many commenters supported the proposal to use demonstration waiver authority (under section 402 of the Social Security Amendments of 1967 (as amended)) to test the MAQI Demonstration.

Response: We appreciate the commenters' support of the MAQI Demonstration.

Comment: Many commenters urged CMS to use its waiver authority in the MAQI Demonstration to allow another path towards QP status and provide eligible clinicians with the 5 percent incentive payment offered to QPs.

Response: Demonstration projects under the authority of section 402(a)(1)(A) of the Social Security Amendments of 1967 are intended to test whether changes in payment or reimbursement will increase the efficiency or economy of health care services. Our actuarial analyses determined that a demonstration design that would grant QP status, including a 5 percent incentive payment, to eligible clinicians who met the thresholds would have introduced a significant level of new costs to CMS, without adequate evidence for realizing an equal amount of savings from the proposed interventions. Without a basis to believe that the economy or efficiency of health care services would be increased, we do not believe that it is appropriate to design a demonstration with such parameters. Considering that the proposed exclusions from MIPS reporting and payment consequences under the MAQI Demonstration are not anticipated to have a net cost to CMS, we plan to test whether these exclusions will increase or maintain clinician participation in payment arrangements with MAOs that are similar to Advanced APMs and change the manner in which clinicians deliver care. This test is consistent with the standards set forth in section 402(a)(1)(A) of the Social Security Amendments of 1967.

Comment: Some commenters urged CMS to monitor the impact of the Demonstration on MIPS payment adjustments, including one commenter that expressed concern that the MIPS-eligible population pool would be reduced and another commenter that expressed concern about whether the potential benefits being tested under the MAQI Demonstration outweigh any potential impacts on the level of MIPS payment adjustments.

Response: We agree that it will be important to monitor the impact of the Demonstration on payments received by MIPS eligible clinicians to whom the waivers do not apply, but we note that it may be challenging to draw significant conclusions from such monitoring as there are many variables that may impact and influence a clinician's final MIPS payment adjustment. We plan to share information on participation levels in the MAQI Demonstration with the public as soon as this information is available.

Comment: A few commenters commended CMS on starting the MAQI Demonstration in 2018, while a few commenters advised CMS to clarify the timeline associated with a CY 2018 implementation of the Demonstration and when determinations would be made under the Demonstration to identify participating eligible clinicians who are excluded from the MIPS reporting requirements and payment adjustments.

Response: We appreciate certain commenters' support for beginning the Demonstration in CY 2018, and note that by doing so, clinicians that meet threshold levels of participation in Qualifying Payment Arrangements with MAOs in 2018 can be considered for exclusion from the MIPS reporting requirements and payment adjustment under the Demonstration a year before participation in such Qualifying Payment Arrangements could be considered under the All-Payer Combination Option. We anticipate collecting Qualifying Payment Arrangement and threshold information for eligible clinicians participating in the Demonstration starting in late fall of 2018, and making final CMS determinations on whether eligible clinicians meet the criteria to be excluded from the MIPS reporting requirements and payment adjustment, based on this submitted information, by December 2018 or (January 2019 at the latest). We note that eligible clinicians participating in the MAQI Demonstration in 2018 will be evaluated to determine whether they meet the criteria to be excluded from MIPS reporting requirements for the 2018 MIPS performance year, and from the

MIPS payment adjustment for the corresponding 2020 MIPS payment year.

Comment: Some commenters recommended that CMS make changes to the Demonstration criteria relating to clinician eligibility for the exclusion from the MIPS reporting requirements and payment adjustment, such as Qualifying Payment Arrangements and thresholds.

Response: As noted in the proposed rule, we intend to use criteria and requirements that are consistent with the Medicare and Other Payer Advanced APM Options under the Quality Payment Program. Changing the clinician eligibility for exclusion from the MIPS reporting requirements and payment adjustment would not be consistent with this intent.

We also received comments on other provisions associated with the Demonstration.

Comment: Some commenters advised CMS to make changes to the Demonstration application and data collection process.

Response: The application and data collection process are outside the scope of the proposals in the CY 2019 PFS proposed rule; however, we will seek to balance reporting burden with the need to solicit information necessary to ensure that the demonstration is being implemented, tested and evaluated appropriately.

Comment: A few commenters requested additional agency focus in helping physicians and practices better understand their options under Medicare, Medicare Advantage, the Quality Payment Program, the MAQI Demonstration and other value-based payment arrangements.

Response: We are committed to reaching our stakeholders, including clinicians, the technology community, private payers, and beneficiaries, to raise awareness that Medicare is evolving quickly to a value-based system. In addition to raising awareness that change is occurring, we will continue current efforts to engage in a learning process with stakeholders where they may voice opinions and suggestions to help collaboratively drive the goals of the Quality Payment Program. We will continue to set expectations that this will be an iterative process, and, while change will not happen overnight, we are committed to continuing our work to improve how Medicare pays for quality and value, instead of the quantity of services. We will continue to reach out to the clinician community and others to partner in the development of ongoing education, support, and technical assistance materials and activities to help clinicians understand program and model requirements, how to use available tools to enhance their practices, improve quality, reduce expenditures, and progress to participation in Advanced APMs if that is the best choice for their practice.

We are offering support in the form of fact sheets, webinars, online courses, and direct technical assistance to help clinicians successfully participate in the Quality Payment Program, the MIPS or the Advanced APM track. This range of support to help clinician practices actively participate in the Quality Payment Program that can be found at the following website at *https://qpp.cms.gov/*.

We also discussed that the Demonstration would waive the provision in section 1848(q)(1)(A)(iii) of the Act that the Secretary shall permit any eligible clinician to voluntarily report on applicable measures and activities, so that the Demonstration would prohibit reporting under the MIPS by eligible clinicians who participate in the Demonstration and meet the thresholds to be excluded from the MIPS reporting requirements and payment adjustment for a given year. We did not receive any comments on this proposal. We explained that this waiver is necessary to prevent the potential gaming opportunity wherein participating clinicians could intentionally report artificially poor performance under the MIPS for years in which they receive waivers from MIPS payment consequences, then receive artificially inflated quality improvement points under MIPS in later years when they do not receive waivers from MIPS payment consequences. We note here that by prohibiting reporting under MIPS we are also, in effect, disallowing MIPS performance feedback for those clinicians who participate in the Demonstration and meet the criteria to be excluded from the MIPS reporting requirements and payment adjustments. Eligible clinicians who participate in the Demonstration but are not excluded from the MIPS reporting requirements and payment adjustment (whether through participation in the Demonstration or otherwise) would continue to be MIPS eligible clinicians who are subject to the MIPS reporting requirements and payment adjustment as usual.

(iv) Summary of Finalized Policies

After considering public comments, we are finalizing our proposals to implement the MAQI Demonstration in CY 2018 and use the authority in section 402(b) of the Social Security Amendments of 1967 (as amended) to waive certain requirements of section 1848(q)(6)(E) of the Act, specifically the payment consequences (positive, negative or neutral adjustments) of the MIPS and the associated MIPS reporting requirements in 42 CFR part 414 adopted to implement the payment consequences, subject to conditions outlined in the Demonstration. We are also finalizing that we will waive the provision in section 1848(q)(1)(A)(iii) of the Act that the Secretary shall permit any eligible clinician to voluntarily report on applicable measures and activities, so that the Demonstration will prohibit reporting under the MIPS by eligible clinicians who participate in the Demonstration and meet the thresholds that will trigger application of the waivers from the MIPS reporting requirements and payment adjustment for a given year. Related to this waiver of the last sentence of section 1848(q)(1)(A)(iii) of the Act, MAQI Participants who are not subject to the MIPS reporting requirements and payment adjustments will therefore not receive MIPS performance feedback under section 1848(q)(12) of the Act.

In addition, we are also announcing our final policies that, under the waivers identified previously: (1) Eligibility for exclusion from the MIPS reporting requirements and payment adjustment under the MAQI Demonstration will be determined using thresholds of combined participation in Qualifying Payment Arrangements and Advanced APMs that are the same as the QP thresholds under the Medicare Option of the Quality Payment Program codified at § 414.1430(a); and (2) Qualifying Payment Arrangements under the MAQI Demonstration will be identified using criteria consistent with those used to identify Other Payer Advanced APMs codified at § 414.1420. To qualify for exclusion from the MIPS reporting requirements and payment adjustment under the MAQI Demonstration, a MAQI participating clinician must meet combined thresholds for Medicare payments or patients through Qualifying Payment Arrangements with MAOs and Advanced APMs, using Demonstration thresholds that match the thresholds for participation in Advanced APMs under the Medicare Option of the Quality Payment Program, and based on aggregate participation in Advanced APMs and Qualifying Payment Arrangements with MAOs, without applying a specific minimum threshold to participation in either type of payment arrangement.

(e) Example of Adjustment Factors

In the CY 2019 PFS proposed rule (83 FR 35978 through 35981), we provided a figure and several tables as illustrative examples of how various final scores would be converted to a MIPS payment adjustment factor, and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on our proposed policies for the 2021 MIPS payment year. We updated the figure and tables based on the policies we are adopting in this final rule, as follows.

Figure 3 provides an example of how various final scores would be converted to a MIPS payment adjustment factor, and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on the policies adopted in this final rule for the 2021 MIPS payment year. In Figure 3, the performance threshold is 30 points. The applicable percentage is 7 percent for the 2021 MIPS payment year. The MIPS payment adjustment factor is determined on a linear sliding scale from zero to 100, with zero being the lowest possible score which receives the negative applicable percentage (negative 7 percent for the 2021 MIPS payment year) and resulting in the lowest payment adjustment, and 100 being the highest possible score which receives the highest positive applicable percentage and resulting in the highest payment adjustment. However, there are two modifications to this linear sliding scale. First, there is an exception for a final score between zero and one-fourth of the performance threshold (zero and 7.5 points based on the performance threshold of 30 points for the 2021 MIPS payment year). All MIPS eligible clinicians with a final score in this range would receive the lowest negative applicable percentage (negative 7 percent for the 2021 MIPS payment year). Second, the linear sliding scale line for the positive MIPS payment adjustment factor is adjusted by the scaling factor, which cannot be higher than 3.0.

If the scaling factor is greater than zero and less than or equal to 1.0, then the MIPS payment adjustment factor for a final score of 100 would be less than or equal to 7 percent. If the scaling factor is above 1.0, but less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 would be higher than 7 percent.

Only those MIPS eligible clinicians with a final score equal to 30 points (which is the performance threshold in this example) would receive a neutral MIPS payment adjustment. Because the performance threshold is 30 points, we anticipate that more clinicians will receive a positive adjustment than a negative adjustment and that the scaling factor would be less than 1 and the MIPS payment adjustment factor for each MIPS eligible clinician with a final score of 100 points would be less than 7 percent.

Figure 3 illustrates an example of the slope of the line for the linear adjustments and has been updated from prior rules, but it could change considerably as new information becomes available. In this example, the scaling factor for the MIPS payment adjustment factor is 0.159. In this example, MIPS eligible clinicians with a final score equal to 100 would have a MIPS payment adjustment factor of 1.11 percent (7 percent $\times$ 0.159). (Note that this is prior to adding the additional payment adjustment for exceptional performance, which is explained below.)

The additional performance threshold is 75 points. An additional MIPS payment adjustment factor of 0.5 percent starts at the additional performance threshold and increases on a linear sliding scale up to 10 percent. This linear sliding scale line is also multiplied by a scaling factor that is greater than zero and less than or equal to 1.0. The scaling factor will be determined so that the estimated aggregate increase in payments associated with the application of the additional MIPS payment adjustment factors is equal to $500,000,000. In Figure 3, the example scaling factor for the additional MIPS payment adjustment factor is 0.358. Therefore, MIPS eligible clinicians with a final score of 100 would have an additional MIPS payment adjustment factor of 3.58 percent (10 percent $\times$ 0.358). The total adjustment for a MIPS eligible clinician with a final score equal to 100 would be 1 + 0.0111 + 0.0358 = 1.0469, for a total positive MIPS payment adjustment of 4.69 percent.

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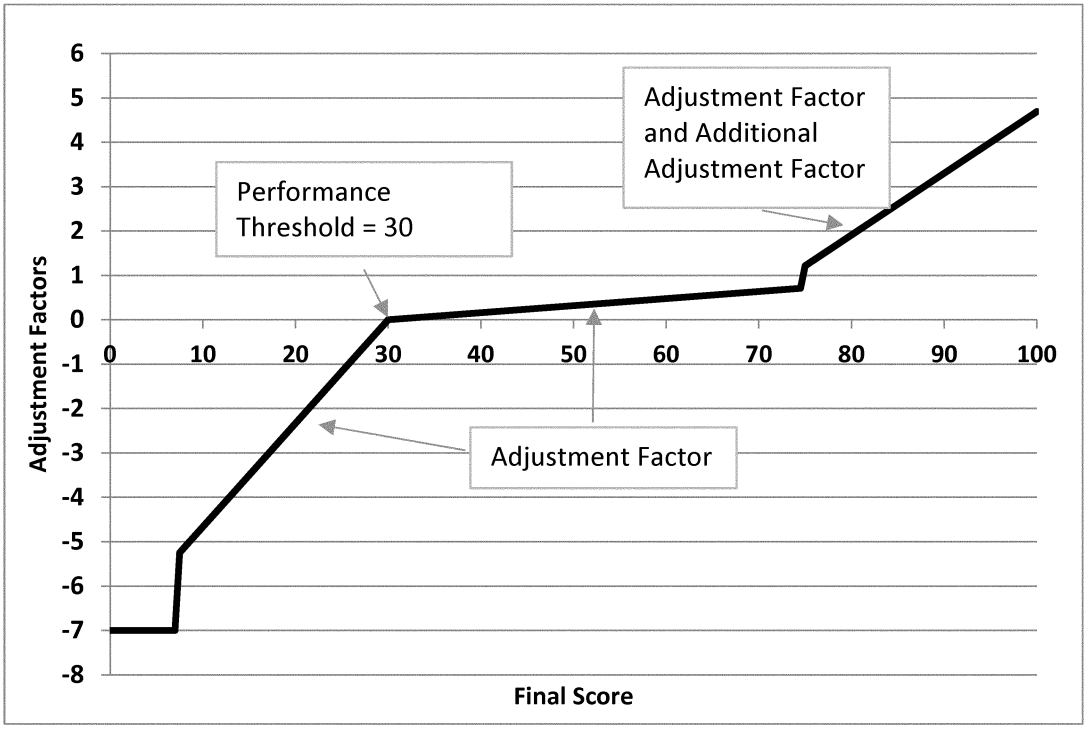
FIGURE 3: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold and Additional Performance Threshold for the 2021 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustrative. For MIPS eligible clinicians with a final score of 100, the adjustment factor would be 7 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is intended to ensure budget neutrality, but cannot be higher than 3.0. MIPS clinicians with a final score of at least 75 points would also receive an additional adjustment factor for exceptional performance. The additional adjustment factor is also illustrative. The additional adjustment factor starts at 0.5 percent and cannot exceed 10 percent and is also multiplied by a scaling factor that is greater than zero and less than or equal to 1. MIPS eligible clinicians at or above the additional performance threshold will receive the amount of the adjustment factor plus the additional adjustment factor. This example is illustrative as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

The final MIPS payment adjustments will be determined by the distribution of final scores across MIPS eligible clinicians and the performance threshold. More MIPS eligible clinicians above the performance threshold means the scaling factors would decrease because more MIPS eligible clinicians receive a positive MIPS payment adjustment factor. More MIPS eligible clinicians below the performance threshold means the scaling factors would increase because more MIPS eligible clinicians would receive a negative MIPS payment adjustment factor and relatively fewer MIPS eligible clinicians would receive a positive MIPS payment adjustment factor.

Table 56 illustrates the changes in payment adjustments based on the final policies from the 2019 MIPS payment year and the 2020 MIPS payment year, and on final policies for the 2021 MIPS payment year adopted in this final rule, as well as the statutorily required increase in the applicable percent as required by section 1848(q)(6)(B) of the Act.

TABLE 56: Illustration of Point System and Associated Adjustments Comparison Between the 2019 MIPS payment year, the 2020 MIPS payment year and 2021 MIPS payment year

2019 MIPS payment year		2020 MIPS payment year		2021 MIPS payment year	
Final score points	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**
0.0-0.75	Negative 4%	0.0-3.75	Negative 5%	0.0-7.5	Negative 7%
0.76-2.99	Negative MIPS payment adjustment greater than negative 4% and less than 0% on a linear sliding scale	3.76-14.99	Negative MIPS payment adjustment greater than negative 5% and less than 0% on a linear sliding scale	7.51-29.99	Negative MIPS payment adjustment greater than negative 7% and less than 0% on a linear sliding scale
3.00	0% adjustment	15.0	0% adjustment	30.0	0% adjustment
3.01-69.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 4% for scores from 3.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.	15.01-69.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 5% for scores from 15.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality	30.01-74.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 7% for scores from 30.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality
70.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 4% for scores from 3.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 70.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.	70.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 5% for scores from 15.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 70.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.	75.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 7% for scores from 30.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 75.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.

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We note that in this final rule, with the exception of the increase in our small practice bonus in the quality performance category from 3 measure bonus points to 6 measure bonus points, our scoring algorithms have not changed from the CY 2019 PFS proposed rule and that the only policy change from the CY 2019 PFS proposed rule reflected in Figure 3 and Table 56 is that final scores greater than or equal to 75 points qualify for the additional payment adjustment for exceptional performance discussed at section III.I.3.j.(3) of this final rule. Please refer to the CY 2019 PFS proposed rule (83 FR 35979 through 35981) for examples of scenarios in

which MIPS eligible clinicians can achieve a final score at or above the performance threshold of 30 points for the 2021 MIPS payment year.

k. Third Party Intermediaries

We refer readers to § 414.1400, the CY 2017 Quality Payment Program final rule (81 FR 77362 through 77390) and the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819) for our previously established policies regarding third party intermediaries.

In the CY 2019 PFS proposed rule (83 FR 35981 through 35986), we proposed to: (1) Define third party intermediary and require third party intermediaries to be based in the U.S.; (2) update certification requirements for data submission; (3) update the definition of Qualified Clinical Data Registry (QCDR); revise the self-nomination period for QCDRs; update of information required for QCDRs at the time of self-nomination; update consideration criteria for approval of QCDR measures; define the topped out timeline for QCDR measures; (4) revise the self-nomination period for qualified registries; (5) define health IT vendor; (6) update the definition, criteria, and requirements for CMS-approved survey vendor; auditing criteria; and (7) revise probation and disqualification criteria. We finalize these proposals in the manner discussed herein.

(1) Third Party Intermediaries Definition

In the CY 2019 PFS proposed rule (83 FR 35981), at § 414.1305, we proposed a new definition to define a third party intermediary as an entity that has been approved under § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the quality, improvement activities, and Promoting Interoperability performance categories. A QCDR, qualified registry, health IT vendor, or CMS-approved survey vendor are considered third party intermediaries. We also proposed to change the section heading at § 414.1400 from ''Third party data submissions'' to ''Third party intermediaries'' to elucidate the definition and function of a third party intermediary (83 FR 35981).

As discussed in the CY 2019 PFS proposed rule (83 FR 35981), CMS IT systems are required to adhere to multiple agency and federal security standards and policy. CMS policy prohibits non-U.S. citizens from accessing CMS IT systems, and also requires all CMS program data to be retained in accordance with U.S. Federal policy, specifically National Institute of Standards and Technology (NIST) Special Publication (SP) 800–63, which outlines enrollment and identity proofing requirements (levels of assurance) for federal IT system access. Access to the Quality Payment Program would necessitate passing a remote or in-person Federated Identity Proofing process (that is, Equifax or equivalent). A non-U.S. based third party intermediary's potential lack of a SSN, TIN, U.S. based address, and other elements required for identity proofing and identity verification would impact their ability to pass the necessary background checks. An inability to pass identity proofing may limit or fully deny access to the Quality Payment Program if the intent is to interact with the Quality Payment Program outside of the U.S. for the purposes of reporting and storing data.

These requirements are existing federal policies applicable to all HHS/CMS FISMA systems and assets, and the requirements are not specific to the Quality Payment Program. More information on these policies is available at the following websites: HHS Information Security and Privacy Policy (IS2P) (*https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/index.html*); CMS Information Systems Security and Privacy Policy (IS2P2) (*https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Info-Security-Library-Items/CMS-Information-Systems-Security-and-Privacy-Policy-IS2P2.html*); OMB Memorandum 04–04, E-Authentication Guidance for Federal Agencies (*https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy04/m04-04.pdf*); and NIST SP 800–63 Digital Identity Guidelines (*https://pages.nist.gov/800-63-3/*). Therefore, in the CY 2019 PFS proposed rule (83 FR 35982) we proposed to amend § 414.1400(a)(4) to indicate that a third party intermediary's principle place of business and retention of associated CMS data must be within the U.S.

We would like to note, third party intermediaries that are authorized by us to submit data on behalf of MIPS eligible clinicians, groups, or virtual groups have not otherwise been evaluated for the capabilities, quality, or any other features or its products. The United States Government and CMS do not endorse or recommend any third party intermediary or its products. Prior to selecting or using any third party intermediary or its products, MIPS eligible clinicians, groups or virtual groups should perform their own due diligence on the entity and its products, including contacting the entity directly to learn more about its products.

The following is a summary of the public comments received on the ''Third Party Intermediaries Definition'' proposals and our responses:

Comment: One commenter appeared to advocate that clinicians who must comply with MACRA should be prohibited from using online and/or software-based third party intermediaries that do not use attorneys to advise clinicians on the law. The commenter stated that, in order to protect clinicians from failure to comply with MACRA and to achieve higher MACRA compliance rates, CMS should restrict MIPS participants from using online or software-based third party intermediaries entirely unless the use is through an EMR/EHR dashboard. In addition, the commenter stated that CMS should only allow clinicians to achieve compliance themselves or to achieve compliance through the use of an attorney or an EMR/EHR dashboard.

Response: We do not believe it is appropriate to require third party intermediaries to furnish legal advice to clinicians. If a clinician wishes to receive legal advice regarding compliance with MACRA, or any other law or regulation, the clinician may hire his or her own legal counsel. To the extent the commenter is advocating to eliminate a clinician's ability to report MIPS data through a third party intermediary, the comment is outside the scope of the rulemaking.

Comment: One commenter provided a comment related to the proposed opt-in policy. The commenter encouraged us to allow third-party intermediaries, such as qualified registries, to opt-in on behalf of clinicians and groups as a function of the services they provide and that the clinician opt-in should be at the TIN/NPI level.

Response: The opt-in policy is discussed in section III.I.3.c.(5) in this final rule, where we finalized that a clinician who is eligible to opt-in would be required to make an affirmative election to opt-in to participate in MIPS, elect to be a voluntary reporter, or by not submitting any data the clinician is choosing to not report. We believe that an election to opt-in to MIPS must be made by the clinician or group through a definitive opt-in decision to participate in MIPS regardless of the way in which the data is submitted. We agree that after this decision is confirmed by the clinician or group it should be deliverable through a third party intermediary, if a clinician or group is utilizing a third party intermediary for their data submission. As a result, the third party intermediary

should be able to transmit the clinician's opt-in decision to CMS. Therefore, we are amending § 414.1400(a)(4)(iv) that if the clinician chooses to opt-in in accordance with § 414.1310, the third party intermediary must be able to transmit that decision to CMS. We refer readers to section III.I.3.c.(5) of this final rule for more information regarding low volume threshold exclusion.

After consideration of the public comments received, we are finalizing our proposal, as proposed, at § 414.1305, to define a third party intermediary as an entity that has been approved under § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the quality, improvement activities, and Promoting Interoperability performance categories. A QCDR, qualified registry, health IT vendor, or CMS-approved survey vendor are considered third party intermediaries. We are also finalizing our proposal, as proposed, to change the section heading at § 414.1400 from ''Third party data submissions'' to ''Third party intermediaries'' to elucidate the definition and function of a third party intermediary. In addition, we are finalizing our proposal, as proposed, to amend previously finalized policies at § 414.1400(a)(4) to indicate that a third party intermediary's principle place of business and retention of associated CMS data must be within the U.S. Lastly, we are amending § 414.1400(a)(4)(iv) to state that if the clinician chooses to opt-in in accordance with § 414.1310, the third party intermediary must be able to transmit that decision to CMS.

(2) Certification

We previously finalized in the CY 2018 Quality Payment Program final rule (82 FR 53807) at § 414.1400(a)(5), that all data submitted to us by a third party intermediary on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary to the best of its knowledge as true, accurate, and complete; and that this certification must occur at the time of the submission and accompany the submission. We have discovered it is not operationally feasible to require certification at the time of submission, or to require that the certification accompany the submission, for submission types by third party intermediaries, including data via direct, login and upload, login and attest, CMS Web Interface or Medicare Part B claims. We refer readers to section III.I.3.h.(1)(b) of this final rule for our proposed modifications to the previously established data submission terminology. In order to address these various submission types that are currently available, in the CY 2019 PFS proposed rule (83 FR 35982), we proposed to amend § 414.1400(a)(5) to state that all data submitted to CMS by a third party intermediary must be certified as true, accurate, and complete to the best of its knowledge and that such certification must be made in a form and manner and at such time as specified by CMS.

We did not receive any public comments on our proposed amendments to the certification requirement imposed on third party intermediaries.

We are finalizing our proposal, as proposed, at § 414.1400(a)(5) to state that all data submitted to CMS by a third party intermediary on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge, and that such certification must be made in a form and manner and at such time as specified by CMS.

(3) Qualified Clinical Data Registries (QCDRs)

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53807 through 53815) and § 414.1400 for our previously finalized policies regarding QCDRs. In the CY 2019 PFS proposed rule (83 FR 35982 through 35984) we proposed to update the following: The definition of QCDR, the self-nomination period for QCDRs, information required for QCDRs at the time of self-nomination, and consideration of criteria for approval of QCDR measures.

(a) Proposed Update to the Definition of a QCDR

In the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) at § 414.1305, we finalized the definition of a QCDR to be a CMS-approved entity that has self-nominated and successfully completed a qualification process to determine whether the entity may collect medical or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

As described in the CY 2019 PFS proposed rule (83 FR 35982), we want to ensure that QCDRs that participate in MIPS have access to clinical expertise in quality measurement and are able to provide and demonstrate an understanding of the clinical medicine, evidence-based gaps in care, and opportunities for improvement in the quality of care delivered to patients and priorities that are important to MIPS eligible clinicians. From our experiences with QCDRs to date, we have discovered that certain entities with predominantly technical backgrounds have limited understanding of medical quality metrics or the process for developing quality measures are seeking approval as a QCDR. A large number of entities that do not have the necessary clinical expertise to foster quality improvement have self-nominated or indicated their interest in becoming QCDRs. In reviewing previous QCDR measure submissions during the self-nomination and QCDR measure review and approval cycles in MIPS, we have observed that some entities were developing QCDR measures without a complete understanding of measure constructs (such as what is required of a composite measure or what it means to risk-adjust), and in some instances, QCDRs were developing QCDR measures in clinical areas in which they did not have expertise. We are concerned that QCDR measures submitted by such entities for approval have not undergone the same consensus development, scientific rigor, and clinical assessment that is required for measure development, compared to those QCDR measures that are developed by specialty societies and other entities with clinical expertise.

We recognize the importance of these organizations' expertise within the Quality Payment Program; however, do not believe that these types of entities with the absence of clinical expertise in quality measurement, meet the intent of QCDRs. We believe that with the increasing interest in QCDRs and QCDR measure development, it is important to ensure that QCDRs that participate in MIPS are first and foremost in the business of improving the quality of care clinicians provide to their patients through quality measurement and/or disease tracking and have the clinical expertise to do so.

In the CY 2019 PFS proposed rule (83 FR 35982 through 35983), we proposed beginning with the 2022 MIPS payment year, to amend § 414.1305 to modify the definition of a QCDR to state that the approved entity must have clinical expertise in medicine and quality measure development. Specifically, a QCDR would be defined as an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

As described in the CY 2019 PFS proposed rule (83 FR 35983), under § 414.1400(b)(2)(ii), an entity that uses an external organization for purposes of data collection, calculation, or transmission may meet the definition of a QCDR as long as the entity has a signed, written agreement that specifically details the relationship and responsibilities of the entity with the external organization effective as of September 1 the year prior to the year for which the entity seeks to become a QCDR. Thus, we expect entities without clinical expertise in medicine and quality measure development that want to become QCDRs would collaborate or align with entities with such expertise in accordance with § 414.1400(b)(2)(ii).

As a part of the self-nomination process, we will look for entities that have quality improvement, measure development, as well as clinical expertise. We will also follow up with the entity via, for example, email or teleconference, should we question whether or not the entity meets our standards. Alternatively, such entities may seek to qualify as another type of third party intermediary, such as a qualified registry. Becoming a qualified registry does not require the level of measure development expertise that is needed to be a QCDR that develops measures.

The following is a summary of the public comments received on the proposal to update the definition of a QCDR and our responses:

Comment: Many commenters supported the proposal to modify the definition of a QCDR to limit approval to entities that have clinical expertise in medicine and quality measure development. Several commenters recommended CMS provide clarification on how such clinical and quality measure development expertise will be evaluated, with one commenter suggesting the definition of clinical expertise include having a majority-led physician Board of Directors or governing body and that expertise in clinical measure development include demonstrated QCDR measure development processes that take into account the CMS Blueprint for measure development and maintenance activities. A few commenters stated that CMS should establish processes for denying applications and/or measures that appear to not have had any clinical influence rather than requiring the entire entity to have ''expertise'' and provide a definition of what constitutes ''clinical expertise in medicine and quality measure development.''

Response: We appreciate the commenters' support to update the definition of a QCDR, limiting approval to entities that have clinical expertise in medicine and quality measure development. Specifically, we proposed that a QCDR would be defined as an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. We appreciate the commenters' suggestion that CMS provide more clarification on how such clinical and quality measure development expertise will be evaluated. For example, while not exhaustive, some aspects that may be considered during our evaluation are a QCDR's: Previous measure development experience (serving on an NQF TEP, for example); experience with the measure development Blueprint process, which can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint-130.pdf;* ability to create and use multi-strata and composite measures where appropriate; ability to risk adjust its own QCDR outcomes measures; technical expertise to run a registry; and ability to reliably collect, retain, aggregate, disseminate, and analyze data from their clinicians. We appreciate the commenter's suggestion to include having a majority-led physician Board of Directors or governing body, but we do not mandate that the QCDR be led by a majority of physicians. We do consider clinical expertise and experience in QCDR measure development and maintenance important, as shown in our updated definition of a QCDR.

Comment: One commenter expressed concern regarding how CMS will allow technical entities to partner with an external organization to gain clinical expertise, citing its opinion that doing so would render the policy ineffective if this enables technical entities to bypass this requirement too easily. Another commenter stated that neither small nor large EHR vendors should be allowed to enter the QCDR space due to the former potentially collecting skewed data related to certain practice arrangements and patient populations and the latter potentially lacking the perspective of care improvement in medical specialties.

Response: We disagree that allowing technical entities to partner with an external organization to gain clinical expertise would render the policy ineffective. The policy is intended to include entities that are able to meet the definition, whether that be by a partnership with a clinical entity, or on their own. In addition, we disagree that neither small nor large EHR vendors should be allowed to collaborate to become a QCDR. As stated in the proposed rule, entities without clinical expertise in medicine and quality measure development, such as small or large EHR vendors, may collaborate or align with entities with such expertise in accordance with § 414.1400(b)(2)(ii). In general, we do not believe that Health IT vendors, including EHR vendors, alone have the necessary clinical expertise. Having the option to collaborate could alleviate the likelihood of skewed data or the absence of perspective regarding care improvement in medical specialties, because a collaboration with a clinical organization would provide knowledge of patient populations, practice arrangements, and care improvement.

Comment: A few commenters disagreed with the proposed update to the definition of a QCDR, citing their beliefs that the updated definition is contrary to the promotion of the benefits of technology; will impose artificial barriers to entry into the market; dictate who can provide services to physicians instead of letting the free market decide; and discriminate against potential vendors because of a perceived advantage at quality measurement based on education, experience, etc. The commenters stated that CMS should only require QCDRs to collaborate with specialty societies in the development of measures to ensure validity, clinical relevance, and proper risk adjustment.

Response: We disagree that the modified definition of QCDR opposes promoting the benefits of technology because there are many options through which MIPS eligible clinicians can utilize different third-party intermediaries to submit data, and this proposed change will not impact the ability for MIPS eligible clinicians to use these mechanisms. We also disagree that the modified definition of QCDR imposes barriers into the market or discriminates against potential vendors because we offer vendors with more of a technical background the opportunity to partner with an organization with greater clinical expertise in order to meet the new QCDR definition. The intent of the modified definition is to promote useful measure development and to emphasize that clinical expertise is critical in gaining useful measures. Furthermore, we believe that updating the definition of a QCDR will help organizations understand the criteria in which we evaluate them against. We want to ensure that the vendors we approve to participate as a QCDR are of

a higher standard and understand the clinical science based off which they develop measures. It is important that QCDRs also understand how to construct measures, the analytics, and are able to ensure the measures are reliable and valid, not doing so may negatively impact the clinician's reporting and final score. Health IT vendors and/or EHR vendors should collaborate with clinical organizations such as specialty societies for their experience not only in measure development but for their clinical expertise as well.

Comment: Some commenters stated that CMS should develop a process by which a clinician who believes they are unsupported by a QCDR can submit information to CMS for further investigation.

Response: If an eligible clinician would like to bring information to CMS' attention regarding a QCDR being unsupportive as it pertains to reporting issues, we suggest the clinician contact the Quality Payment Program Service Center by emailing: *QPP@cms.hhs.gov.*

Comment: One commenter noted that the proposed change may preclude its continued approval by CMS as a QCDR because it does not dictate the timeline in which specialty societies perform measure development and without this approval, it would not be able to assist them in measure development when necessary.

Response: Our updated definition of a QCDR would be effective beginning with the 2022 MIPS payment year; and to clarify, we will not be ''grandfathering'' in existing QCDRs who do not meet the updated QCDR definition for the 2020 performance period. In coordination with the finalization of the new QCDR definition and the publication of the CY 2019 PFS final rule, we intend to notify existing QCDRs as to whether they would meet the new QCDR definition or not based on information submitted for a previous MIPS payment year.

Comment: A few commenters stated that CMS should finalize its proposal for the 2019 performance year instead of the 2020 performance year because removing non-clinician led vendors from the list of QCDRs will not pose a significant burden on eligible clinicians or group practices in 2019.

Response: While we appreciate commenters' support, we would like to keep the effective timeframe of this policy (that is, the 2020 performance year) as proposed to provide existing QCDRs that would not meet the updated QCDR definition with an appropriate amount of time to comply or take other paths.

Comment: Many commenters who supported the proposal to update the definition of a QCDR also provided recommendations including: Development of a separate definition for QCDRs put forth by technology companies to differentiate them from QCDRs managed by specialty societies; requiring third-party entities that are not specialty societies that would like to become QCDRs to collaborate with specialty society QCDRs; and expansion of the definition of a QCDR to align with the 21st Century Cures Act (especially with regard to entities being clinician-led) or at minimum, revision of the definition to include clinical expertise in medicine, quality improvement, and quality measure/guideline development, as well as providing methods to ensure data quality, routine metric reporting, and quality improvement consultation.

Response: We do not agree that separate definitions are necessary to differentiate between QCDRs, as the definition includes criteria set for all QCDRs; or that the definition requires criteria as prescriptive as entities being clinician-led. There are flexibilities in place, such as collaboration with other entities such as large healthcare systems, regional collaboratives, or specialty societies, in order for vendors to meet the criteria in the definition. We believe we cover the areas of clinical expertise, measure development, and quality improvement work through this new definition. We believe that experience with data quality and routine metric reporting is related to their measure development experience and their registry experience, which is covered by the new QCDR definition and the criteria of requiring that the vendor must exist by January 1 of the performance period and have 25 participants submitting data to the QCDR (not necessarily for purposes of MIPS).

After consideration of the public comments received, we are finalizing our proposal to update the definition of a QCDR at § 414.1305 beginning with the 2022 MIPS payment year, as proposed, to state that a QCDR is an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

(b) Establishment of an Entity Seeking To Qualify as a QCDR

In the CY 2017 Quality Payment Program final rule (81 FR 77364), we require at § 414.1400(c)(2) that the QCDR must have at least 25 participants by January 1 of the performance period. These participants do not need to use the QCDR to report MIPS data to us; rather, they need to submit data to the QCDR for quality improvement. We realize that a QCDR's lack of preparedness to accept data from MIPS eligible clinicians and groups beginning on January 1 of the performance period may negatively impact a clinician's ability to use a QCDR to report, monitor the quality of care they provide to their patients (and act on these results) and may inadvertently increase clinician burden. For these reasons, we proposed to redesignate § 414.1400(c)(2) as § 414.1400(b)(2)(i) to state that beginning with the 2022 MIPS Payment Year, the QCDR must have at least 25 participants by January 1 of the year prior to the performance period (83 FR 35983). These participants do not need to use the QCDR to report MIPS data to us; rather, they need to submit data to the QCDR for quality improvement.

The following is a summary of the public comments received on the ''Establishment of an Entity Seeking To Qualify as a QCDR'' proposals and our responses:

Comment: Many commenters disagreed with the proposal to require QCDRs to have 25 participants by January 1 of the year prior to performance period. Commenters noted it would place an undue burden on QCDRs serving small specialties and inhibit the ability of new registries to qualify as QCDRs, thus discouraging the use of QCDRs to report MIPS data. One commenter suggested CMS work with stakeholders to develop a timeline that is feasible and leads to properly functioning QCDRs that can meet the goals of the MIPS program and the requirements of the MACRA law. Another commenter stated that the existing requirement is sufficient to ensure QCDR preparedness, while another commenter stated that the threshold should be lowered or removed completely, at least for those QCDRs that have already been in operation and have lost participants when the low volume threshold increased significantly.

Response: We disagree with commenters that this proposed policy would cause undue burden or the ability of new entities to qualify as QCDRs. To clarify, this requirement would demonstrate that the entity has prior registry experience and the capability to accept, aggregate, calculate, provide feedback to their participants on, retain, and submit the data to CMS on the behalf of MIPS eligible clinicians. We have previously experienced during

the past two performance periods that there have been instances of new QCDRs that are not ready to accept data from eligible clinicians from the start of the performance period due to operational issues within the QCDR, including instances of QCDRs withdrawing during the performance period because of reporting inexperience. We proposed this requirement to ensure that organizations have this experience prior to self-nomination. We continue to provide educational materials for QCDRs on what is necessary to meet program criteria and requirements. We clarify that the requirement to have at least 25 participants by January 1 of the year prior to performance period does not require that the entity's prior registry experience be under MIPS or any other CMS program or that the participants be MIPS eligible clinicians. With increasing stakeholder interest in the use of third-party intermediaries to report for MIPS, we believe the threshold of 25 participants is a reasonable thresholds for QCDRs to attain.

After consideration of the public comments received, we are finalizing our proposal, as proposed, to redesignate § 414.1400(c)(2) as § 414.1400(b)(2)(i) to state that beginning with the 2022 MIPS Payment Year, the QCDR must have at least 25 participants by January 1 of the year prior to the applicable performance period.

(c) Self-Nomination Process

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53808 through 53813) for our previously established policies regarding the simplified self-nomination process for existing QCDRs in MIPS that are in good standing and web-based submission of self-nomination forms. We did not propose any changes to those policies in this final rule; however, in the CY 2019 PFS proposed rule (83 FR 35983), we proposed to update: (1) The self-nomination period; and (2) information required at the time of self-nomination.

(i) Self-Nomination Period

Under § 414.1400(b), QCDRs must self-nominate from September 1 of the year prior to the applicable performance period until November 1 of the same year and must, among other things, provide all information requested by us at the time of self-nomination. As indicated in the CY 2017 Quality Payment Program final rule (81 FR 77366), our goal has been to publish the list of approved QCDRs along with their approved QCDR measures prior to the beginning of the applicable performance period.

We have received feedback from entities that have self-nominated to be a QCDR about the need for additional time to respond to requests for information during the review process, particularly with respect to QCDR measures that the entity intends to submit to us for the applicable performance period. In addition, based on our observations of the previous two self-nomination cycles, we anticipate an increase in the number of QCDR measure submissions for our review and consideration. For the transition year of MIPS, we received over 1,000 QCDR measure submissions for review, and for the CY 2018 performance period, we received over 1,400 QCDR measure submissions. In order for us to process, review, and approve the QCDR measure submissions and provide QCDRs with sufficient time to respond to requests for information during the review process, while still meeting our goal to publish the list of approved QCDRs along with their approved QCDR measures prior to the start of the applicable performance period, we believe that an earlier self-nomination period is needed.

Therefore, in the CY 2019 PFS proposed rule (83 FR 35983), we proposed to update the self-nomination period from September 1 of the year prior to the applicable performance period until November 1 to July 1 of the calendar year prior to the applicable performance period until September 1. Therefore, in the CY 2019 PFS proposed rule (83 FR 35983), we also proposed to amend § 414.1400(b)(1) to provide that, beginning with the 2022 MIPS payment year, entities seeking to qualify as QCDRs must self-nominate during a 60-day period beginning on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year; must provide all information required by us at the time of self-nomination; and must provide any additional information requested by us during the review process. For example, for the 2022 MIPS payment year, the applicable performance period would be CY 2020, as discussed in section III.I.3.g. of this final rule. Therefore for the CY 2020 performance period, the self-nomination period would begin on July 1st, 2019 and end on September 1st, 2019, and we will make QCDRs aware of this through our normal communication channels. We believe that updating the self-nomination period would allow for additional review time and measure discussions with QCDRs.

We refer readers to section III.I.3.k.(3)(c)(ii) of this final rule for a summary of the public comments received on these proposals and our responses.

(ii) Information Required at the Time of Self-Nomination

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53814), where we finalized that as a part of the self-nomination review and approval process for the CY 2018 performance period and future years, we will assign QCDR measure IDs to approved QCDR measures, and the same measure ID must be used by any other QCDRs that have received permission to also report the measure. We have received some questions from stakeholders as to whether the QCDR measure ID must be utilized or whether it is optional. As stated in the CY 2018 Quality Payment Program final rule, QCDRs, including any other QCDRs that have received permission to also report the measure, must use the CMS-assigned QDCR measure ID. It is important that the CMS-assigned QCDR measure ID is posted and used accordingly, because without this ID we are not able to accurately identify and calculate the QCDR measures according to their specifications. Therefore, in the CY 2019 PFS proposed rule (83 FR 35983), we proposed to update § 414.1400(b)(3)(iii) to state that QCDRs must include their CMS-assigned QCDR measure ID number when posting their approved QCDR measure specifications, and also when submitting data on the QCDR measures to us.

The following is a summary of the public comments received on the ''Self-Nomination Process'' proposals and our responses:

Comment: Several commenters noted they would support the proposed change to the self-nomination timeline if CMS would adopt multi-year approval of QCDRs as they noted doing so would reduce burden, alleviate a shortened nomination timeline, potentially strengthen the measure development process in future years, encourage uptake of new measures, allow for uninterrupted data collection, and allow for more consistent and robust data collection and benchmarking.

Response: In the CY 2018 Quality Payment Program final rule (82 FR 53808), we discussed our concerns with multi-year approval and sought comment from stakeholders as to how to mitigate our concerns. Moreover, a multi-year approval process would not take into consideration potential changes in criteria or requirements of participation for QCDRs that may occur

as the MIPS program develops through future program years. We did not receive any suggestions or responses from stakeholders that would alleviate our concerns with adopting this policy. Therefore, we continue to believe multi-year approval of QCDRs is inappropriate at this time.

Comment: One commenter stated that in order to encourage QCDRs to continue seeking QCDR status, CMS should work with specialty-led QCDR stewards to further improve the self-nomination process and ensure a viable and private sector-run reporting option to alleviate burden and increase evidence-based decisions.

Response: We value stakeholder input and conduct process improvement on an ongoing basis. We will continue to seek opportunities to receive input throughout the year.

Comment: Many commenters disagreed with the proposal to change the QCDR self-nomination period, citing their beliefs that maintaining the September 1 through November 1 self-nomination period without change is necessary to minimize additional burden and constraints on QCDRs; provide QCDRs the time to prepare data to support measures in the application process; provide QCDRs an opportunity to gain insight into recent policy changes; and negate potentially adverse impacts to the life cycle of QCDRs, the maintenance process for existing QCDR measures, and/or development of new measures. One commenter stated that due to additional data being required as part of the self-nomination process, the revised self-nomination period would be more difficult. Another commenter suggested the change should not be implemented until the CY 2021 performance period and noted QCDR approval will need to expand beyond 12 months to avoid a scenario where a QCDR is only approved for a few months before they must go through the self-nomination process again. Finally, another commenter suggested the self-nomination period be extended to 90 days due to its belief that the 60-day period is excessively challenging and burdensome in terms of the information required and additional requests to which QCDRs must be respond.

Response: As described in the CY 2019 PFS proposed rule (83 FR 35983), we have heard from QCDRs that they need additional time to respond to our requests for additional information during the QCDR measure review process, as well as requests for feedback or measure harmonization across QCDRs in a more extensive manner that would not be feasible with the current timeline. We believe with sufficient notice, providing stakeholders with educational material, and the implementation of the simplified self-nomination process we are minimalizing additional burden on QCDRs. Through the publication of self-nomination reference material prior to the self-nomination period, as we have done for the 2019 self-nomination period, we intend on giving QCDRs the utmost resources and support as they prepare to self-nominate prior to the closing of the self-nomination period. We plan to post self-nomination material prior to the start of the self-nomination period in July, thereby giving stakeholders' time to prepare the necessary materials needed, inclusive of the additional information requested as a part of the self-nomination process. As we develop QCDR and qualified registry related policies for future rulemaking, we will factor in how the proposals impact an entity's ability to self-nominate and participate in the program prior to deciding what year to implement the policies for. We do not believe that delaying the finalization of this proposal until the 2021 performance period of MIPS would benefit the QCDRs, as we have previously explained, QCDR self-nomination must occur on an annual basis to take into consideration policy, participation requirement, and considerations to a QCDR or registry's standing (if they are on probation or have been precluded).

We believe the benefits of moving up the self-nomination period to allow for additional time and discussion of QCDR measures is beneficial for both QCDRs and CMS. We disagree that the self-nomination period needs to be extended to a 90-day period, we believe with the resource materials provided, as well as us offering to meet with QCDRs prior to self-nomination to discuss their QCDR measures and receive preliminary feedback, QCDRs have the ability to better prepare for the self-nomination period.

Comment: A few commenters supported the proposal to update the QCDR self-nomination timeline. One commenter stated that CMS should use the updated nomination period to facilitate additional discussion with QCDRs regarding measure development. Another commenter stated that CMS should change its expectations for providing data for measures accordingly and allow a transition year to lessen the impact on the measure development life cycle and maintenance of existing measures.

Response: We agree that this change in the self-nomination period will allow for additional conversations on measure development and QCDR measure feedback. We disagree with the implementation of a transition year, considering that on annual basis we must review performance data to evaluate whether the measure demonstrates a gap in performance or whether the measure demonstrates topped out performance where no meaningful measurement can be obtained. As previously mentioned, QCDR measures do not have to go through the NQF's Measures Application Partnership (MAP) committee prior to implementing them in MIPS. If a QCDR is unable to provide performance data reflecting a gap, the QCDR may provide for our consideration citations to recent studies or clinical journals that demonstrate a need for measurement.

Comment: One commenter suggested CMS provide a definition of ''minimal changes'' regarding the QCDR self-nomination process as well as specifications around data requests to support QCDR measures.

Response: In the CY 2018 Quality Payment Program final rule (82 FR 53811), we stated that minimal changes include, but are not limited to: Limited changes to performance categories, adding or removing MIPS quality measures, and adding or updating existing services and/or cost information. Additional educational resources are available in the QPP resource library at *https://qpp.cms.gov/.*

Comment: One commenter recommended changes to the QCDR self-nomination process, including updating QCDR self-nomination application and materials to outline all of the information needed to determine QCDR status to avoid delays and misunderstandings and providing at least a 60-day notice of any changes to the QCDR vetting process, including review of measures and a minimum of 30 days to appeal changes. The commenter further stated that changes to the 2019 QCDR application requirements should not be made until after the final rule is released due to the current QCDR application timeline closing on November 1 coinciding with publication of the final rule and that since the majority of specialty QCDRs stewards are currently submitting QCDR applications, CMS should allow these QCDRs to fully comment on these new proposed standards to which they are being held and which they may not support. Alternatively, the commenter suggested CMS allow for a nimble 2019 QCDR application process, including changes to the licensing standards given

the significant changes CMS proposes for 2019.

Response: To clarify, we proposed that the self-nomination period be moved for the 2020 performance period, not the 2019 performance period as indicated by the commenter, to allow for sufficient time and notice of the changes. We will continue to provide educational materials that will outline all of the information needed to evaluate a QCDR's ability to meet participation standards and QCDR measure evaluation criteria prior to the start of the self-nomination period. With the publication of this final rule, we intend on communicating any changes to the review process. For the 2019 performance period, it is not feasible to allow for a minimum of 30 days to appeal changes due to our goal of approving and publicizing the QCDRs by the start of the performance period. By moving up the self-nomination period, we will be able to allow QCDRs to have more time to consider our QCDR measure feedback. Additionally, moving the timeline to earlier in the year will allow CMS to review the measures fully and provide feedback to the QCDR who submitted the measures. The earlier self-nomination will also allow QCDRs who submit clinically similar measures to another QCDR and whose measure(s) are rejected to reach out to the QCDR whose measures are approved to attempt to enter into a licensing use agreement with the QCDR with the approved measures if desired. It is the goal of CMS to post the most comprehensive list of approved QCDRs and their measures before the start of the performance period so that eligible clinicians intending to use a QCDR can review these materials and select the QCDR that best meets their needs. In this way, the eligible clinician may begin submitting data to the QCDR at the start of the performance period. By doing so, the clinician will be more likely to receive timely feedback from the QCDR regarding his/her performance (earlier in the year) which will allow for quality improvement to occur during the performance period instead of receiving this data later in the year or after the conclusion of the performance period.

The CY 2019 performance period self-nomination form reflects the proposed MIPS quality measures, Promoting Interoperability measures, and Improvement Activities as proposed in the CY 2019 PFS proposed rule. We include disclaimer language that indicates that measures and activity availability are subject to change, pending upon what is finalized in the final rule. We continuously take into consideration stakeholder feedback as we look into process improvements and policy development for future program years. We appreciate the commenters' suggestions, and ask that they provide more detail as to the changes to the licensing standards that they recommend we implement for future consideration.

After consideration of the public comments received, we are finalizing our proposal to amend § 414.1400(b)(1) to provide that, beginning with the 2022 MIPS payment year, entities seeking to qualify as QCDRs must self-nominate during a 60-day period beginning on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year; must provide all information required by us at the time of self-nomination; and must provide any additional information requested by us during the review process. In addition, we are finalizing our proposal to update § 414.1400(b)(3)(iii) to state that QCDRs must include their CMS-assigned QCDR measure ID number when posting their approved QCDR measure specifications, and also when submitting data on the QCDR measures to us.

(d) QCDR Measure Requirements

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375) for where we previously finalized standards and criteria used for selecting and approving QCDR measures. We finalized that QCDR measures must: Provide specifications for each measure, activity, or objective the QCDR intends to submit to CMS; and provide CMS descriptions and narrative specifications for each measure, activity, or objective no later than November 1 of the applicable performance period for which the QCDR wishes to submit quality measures or other performance category (improvement activities and Promoting Interoperability) data starting with the 2018 performance period and in future program years. In the CY 2019 PFS proposed rule (83 FR 35983), we proposed to consolidate our previously finalized standards and criteria used for selecting and approving QCDR measures at § 414.1400(e) and (f) at § 414.1400(b)(3). We also proposed to apply certain criteria used under the Call for Quality Measures Process when considering QCDR measures for possible inclusion in MIPS beginning with the MIPS 2021 payment year (83 FR 35983).

In the CY 2018 Quality Payment Program final rule (82 FR 53814), we noted our interest in elevating the standards for which QCDR measures are selected and approved for use and sought comment on whether the standards and criteria used for selecting and approving QCDR measures should be more closely aligned with those used for the Call for Quality Measures process described in the CY 2017 Quality Payment Program final rule (81 FR 77151). Some commenters expressed concern with this alignment, stating that the Call for Measures process is cumbersome, and would increase burden. Other commenters expressed the belief that the Call for Measures process does not recognize the uniqueness of QCDRs, and is not agile. We would like to clarify that our intention with any future alignment is to work towards consistent standards and evaluation criteria that would be applicable to all MIPS quality measures, including QCDR measures. We understand that some of the criteria under the Call for Measures process may be difficult for QCDRs to meet prior to submitting a particular measure for approval; however, we believe that the criteria under the Call for Measures process helps ensure that any new measures are reliable and valid for use in the program. Having a greater alignment in measure standards helps ensure that MIPS eligible clinicians and groups are able to select from an array of measures that are considered to be higher quality and provide meaningful measurement. As such, we believe that as we gain additional experience with QCDRs in MIPS, it would be appropriate to further align these criteria for QCDR measures with those of MIPS quality measures in future program years.

Therefore, in addition to the QCDR measure criteria previously finalized at § 414.1400(f), we proposed in the CY 2019 PFS proposed rule (83 FR 35984) to apply select criteria used under the Call for Measures Process, as described in the CY 2018 Quality Payment Program final rule (82 FR 53636). Specifically, in addition to the QCDR measure criteria at proposed § 414.1400(b)(3), we proposed in the CY 2019 PFS proposed rule (83 FR 35984) to apply the following criteria beginning with the 2021 MIPS payment year when considering QCDR measures for possible inclusion in MIPS:

- Measures that are beyond the measure concept phase of development.
- Preference given to measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that address the domain for care coordination.

• Measures that address the domain for patient and caregiver experience.
• Measures that address efficiency, cost and resource use.
• Measures that address significant variation in performance.

We believe that as we gain additional experience with QCDRs in MIPS, it would be appropriate to further align these criteria for QCDR measures with those of MIPS quality measures in future program years. Specifically, we are considering proposing to require reliability and feasibility testing as an added criteria in order for a QCDR measure to be considered for MIPS in future rulemaking.

In addition, we refer readers to the CMS Quality Measure Development Plan at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Final-MDP.pdf* for more information regarding the measure development process.

The following is a summary of the public comments received on the ''QCDR Measure Requirements'' proposals and our responses:

Comment: A few commenters stated that CMS should offer multi-year approval of QCDR measures to maximize stability and predictability while minimizing redundancy. The commenters further stated that QCDRs should be allowed to make minor modifications to measures under this multi-year approval process based on updated guidelines, evidence, or measure methodologies and if QCDR measures were approved for 2 to 3 years, the earlier self-nomination deadline would not be as problematic for registry vendors and would streamline CMS' process.

Response: We disagree that offering multi-year approval of QCDR measures would minimize redundancy, as this may actually lead to duplicative measures which is counter intuitive to our meaningful measures initiative. Multi-year approvals of QCDR measures does not account for the possibility of there being more robust QCDR measures of similar concepts being submitted for CMS consideration. We may consider a similar process for future years, which is used with MIPS quality measures, where we'd continue to evaluate all the measures on an annual basis and compare them to those submitted during the measure consideration period (self-nomination period) to determine what QCDR measures would be best to include for the upcoming performance period. QCDRs making changes to their measures would have to self-nominate those changes for CMS' approval, and if we receive measures of similar concept that are more robust they may be considered to replace the existing approved QCDR measures.

Comment: One commenter supported the proposal to include the CMS-assigned QCDR measure ID number when posting the approved QCDR measure specifications, and also when submitting data on the QCDR measures to CMS.

Response: We appreciate the commenter's support.

Comment: One commenter stated that CMS should not approve highly duplicative measure concepts submitted at a later time as doing so increases confusion among physicians and competition among QCDRs while disregarding the time, resources, and intellectual property rights of the measure owners. Some commenters noted that measures are misaligned, overlapping and duplicative across QCDR and MIPS measures.

Response: We agree that duplicative measures are counterintuitive to the Meaningful Measures initiative that promotes more focused quality measure development towards outcomes that are meaningful to patients, families and their providers. It is our intent to move toward measure harmonization, which supports our efforts to increase measure alignment and eliminate redundancy both within the MIPS measure set and across CMS programs.

Comment: A few commenters supported the proposal to update QCDR measure criteria and encouraged CMS to have dialogue with QCDRs regarding the submission of measures. One commenter stated that CMS should expand the policy toward having a common national framework for endorsement of measures by a national consensus body (which currently is the National Quality Forum) and set expectations when accepting QCDR measures that measure stewards would be expected to get endorsement after a certain defined time period.

Response: We will continue dialogue with QCDRs during our scheduled calls. As far as expanding our policy toward having a common national framework for endorsement of measures by a national consensus body, we agree this would be valuable and encourage QCDRs to have their measures NQF endorsed. However, it is not a necessary requirement at this time because of its potential increase in burden and potential unintended impacts on the ability of QCDRs to adapt their measures.

Comment: A few commenters stated that CMS should work with both specialty societies and vendors in facilitating the time and effort needed to successfully encourage reporting of specialty-specific process and outcome measures while ensuring proper review and that appropriate data can be collected and shared. One commenter suggested CMS develop a review process where CMS and its contractor consult with appropriate physician experts and QCDR stewards to ensure sufficient clinical expert review on the importance and relevancy of a measure.

Response: We hold QCDR measure preview calls to provide a forum to work with both specialty societies and vendors wishing to self-nominate QCDR measures. New entities wishing to review QCDR measure concepts with CMS, may request a meeting with CMS by contacting the Quality Payment Program Service Center at *QPP@cms.hhs.gov*. Existing QCDRs may contact our contractor support team to set up a QCDR measure preview call. We have several measure experts as part of our review process, many of which have specialty specific expertise. Furthermore, we hold calls prior to self-nomination to allow experts to discuss their QCDR measure concepts, and will also continue to schedule calls with QCDRs after the self-nomination period closes to provide feedback, which provides time for QCDRs to invite their clinical experts to provide additional information and explanation that would provide us with clarifications that may lead to a QCDR measure reexamination.

Comment: Many commenters did not support the proposal to align QCDR measure requirements with the criteria used under the Call for Quality Measures Process due to their beliefs that applying this criteria to QCDR measures fails to recognize the unique role of QCDRs who fill critical gaps in traditional quality measure sets as they support different specialties, and that doing so would limit the number of measures available for QCDR participants, would create more stringent standards for QCDR measures resulting in additional burden, and be counterproductive toward the goal of encouraging the use of QCDRs. Commenters stated that rather than require these criteria, the criteria should be made optional, but strongly preferred, as there are existing evidence-based process measures that are still valuable to improving patient care and should still be considered for inclusion in the QCDR program; and that since some outcome measures which evaluate degenerative or rare incidences, conditions that are terminal with limited treatment options, or conditions which result in increased co-morbidities require measurement over the course of multiple years to have sufficient

statistical power, CMS should continue the use of certain process measures until they can be easily converted to meaningful outcome measures.

Response: We believe that our process seeks to ensure reliable measures and expect all measures in the program, including QCDRs, to be held to that standard. We believe that it is imperative to raise the bar with QCDR measures in order to ensure that we move away from standard of care, low-bar, process, and/or duplicative measures. Specifically, we are considering proposing to require reliability and feasibility testing as an added criteria in order for a QCDR measure to be considered for MIPS in future rulemaking. In the CY 2018 Quality Payment Program final rule (82 FR 53814), we state that as the MIPS program progresses in its implementation, we are interested in elevating the standards for which QCDR measures are selected and approved for use. As a part of our QCDR measure review process, we do consider the complexity of what is being measured, while being mindful that measures with high performance do not provide value with regards to the quality performance category in MIPS. There are process measures in MIPS that are considered high priority, we believe it is important to retain those so long as they demonstrate room for improvement and lead to meaningful outcomes.

Comment: One commenter suggested CMS clarify the process by which a measure would be assigned within the domains provided under the proposed alignment with the Call for Quality Measures process and offer greater transparency in the rationale for this assignment or outcome status. In addition, the commenter recommended that CMS defer to the rationale and status identified by the QCDR, in particular for clinician-led registries.

Response: During the self-nomination process, we ask the QCDR to assign their QCDR measure a NQS domain, Meaningful Measure Area, whether or not their measure is high priority and/or an outcome measure. As a part of the vetting process, we review those selections and will reach out to the QCDR should we not agree with their assignment.

Comment: One commenter stated that due to the announcement of approved measures continuing to occur on a fixed schedule shortly before the start of each MIPS performance period despite the rolling submission process for new MIPS measures through the Call for Quality Measures Process, CMS should transition to a rolling review and approval process for QCDR measures to allow stakeholders more time to implement new measures prior to the MIPS performance period. This commenter also stated that if CMS is unwilling to move to a rolling review and approval process, the quality category performance period should be reduced. The commenter noted that the rolling submission process has not benefited measure owners, QCDRs, registries, and EHR vendors, all of which have very little time to modify their systems to include new measures post-approval and prior to the start of the next MIPS performance period.

Response: We note that a rolling review basis would adversely impact our ability to limit the number of duplicative measures that are similar in concept, which is inconsistent with the meaningful measure initiative. We believe that the change in the self-nomination period would allow for increased time in the measure review process, as well as provide additional time for QCDRs to respond to feedback provided by CMS. We do not believe a rolling review and approval process is appropriate, as it is not a process that is used for MIPS quality measures. We do not agree that the quality performance period should be reduced dependent on whether or not a rolling review and approval process is implemented as there is no correlation between the two processes.

Comment: One commenter suggested CMS should require measure developers to include a section in each measure that specifies how eligible clinicians and TINs should be attributed for that measure to assist in preventing different interpretations for measure attribution which could lead to TIN/NPI mismatches and resulting determinations by CMS that submitted data is inaccurate.

Response: We agree that attribution should be clearly stated in the QCDR measure specifications and appreciate the commenter's feedback. We will take this suggestion into consideration as we review QCDR measure concepts, and will share this feedback with the QCDRs for their consideration.

After consideration of the public comments received, we are finalizing our proposal to consolidate our previously finalized standards and criteria used for selecting and approving QCDR measures at § 414.1400(e) and (f) at § 414.1400(b)(3) and to apply certain criteria used under the Call for Quality Measures Process when considering QCDR measures for possible inclusion in MIPS beginning with the MIPS 2021 payment year. We are also finalizing our proposal to apply select criteria used under the Call for Measures Process, as described in the CY 2018 Quality Payment Program final rule (82 FR 53636) in addition to the QCDR measure criteria previously finalized at § 414.1400(f). Specifically, in addition to the QCDR measure criteria that we are finalizing at § 414.1400(b)(3), we are also finalizing our proposal to apply the following criteria beginning with the 2021 MIPS payment year when considering QCDR measures for possible inclusion in MIPS:

- Measures that are beyond the measure concept phase of development.
- Preference given to measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that address the domain for care coordination.
- Measures that address the domain for patient and caregiver experience.
- Measures that address efficiency, cost and resource use.
- Measures that address significant variation in performance.

(e) QCDRs Seeking Permission From Another QCDR To Use an Existing, Approved QCDR Measure

In the CY 2018 Quality Payment Program final rule (82 FR 53813), we finalized that beginning with the 2018 performance period and for future program years, QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR. We intended for this policy to help reduce the number of QCDR measures that are similar in concept or clinical topic, or duplicative of other QCDR measures that are being approved. Furthermore, having multiple QCDRs report on the same QCDR measure allows for a larger cohort of clinicians to report on the measure, which helps establish more reliable benchmarks and may give some eligible clinicians or group a better chance of obtaining a higher score on a particular measure. However, we have experienced that this policy has created unintended financial burden for QCDRs requesting permission from other QCDRs who own QCDR measures, as some QCDRs charge a fee for the use of their QCDR measures. MIPS quality measures, while stewarded by specific specialty societies or organizations, are generally available for third party intermediaries, MIPS eligible clinicians, and groups to report on for purposes of MIPS without a fee for use. Similarly, we believe, that once a QCDR measure is approved for reporting in MIPS, it should be generally available for other

QCDRs to report on for purposes of MIPS without a fee for use. In the CY 2019 PFS proposed rule (83 FR 35984), we proposed at § 414.1400(b)(3)(ii)(C) that beginning with the 2021 MIPS payment year, as a condition of a QCDR measure's approval for purposes of MIPS, the QCDR measure owner would be required to agree to enter into a license agreement with CMS permitting any approved QCDR to submit data on the QCDR measure (without modification) for purposes of MIPS and each applicable MIPS payment year. In the CY 2019 PFS proposed rule (83 FR 35984) we also proposed at § 414.1400(b)(3)(iii) that other QCDRs would be required to use the same CMS-assigned QCDR measure ID. If a QCDR refuses to enter into such a license agreement, the QCDR measure would be rejected and another QCDR measure of similar clinical concept or topic may be approved in its place.

The following is a summary of the public comments received on the ''QCDRs Seeking Permission from another QCDR to Use an Existing, Approved QCDR Measure'' proposals and our responses:

Comment: Many commenters disagreed with CMS' proposal to require QCDRs to enter into a measure licensing agreement with CMS beginning with the 2021 MIPS payment year, stating that QCDRs would be required to attest to these measures before knowledge that this proposal would be finalized and that they, therefore, did not know that they would be required to enter into mandatory licensing agreements for these measures at the time of attestation. Commenters specifically stated that this timeline would violate the Administrative Procedure Act. Other commenters stated that should the proposal be finalized, it would be unreasonable for QCDR measure stewards to implement the policy by January 1 of the 2019 performance period given that the self-nomination period closes prior to publication of the CY 2019 PFS final rule. Commenters stated that the proposal, if it is finalized, should be delayed at least 1 year to give QCDRs an opportunity to decide whether to continue participating in the program. One commenter stated that some specialty societies may delay their QCDR application until this issue has been addressed by CMS.

Response: Based on the feedback and concerns raised by stakeholders, in the interim, we are not finalizing this proposal. Rather, while we believe our proposal is consistent with the Administrative Procedure Act, we are persuaded by the other concerns raised by stakeholders on the implementation of this policy and are therefore retaining our existing policy that QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR (82 FR 53813).

Comment: Many commenters disagreed with the proposal to require QCDR measure owners to allow other QCDRs to submit data on the QCDR measure as a condition of measure approval. Reasons cited for disagreeing with the proposal include beliefs that it does not acknowledge the cost in developing complex measures; would unfairly reduce costs for QCDRs that do not develop their own measures while increasing costs for QCDRs that do; would compromise the intellectual property of measure stewards as CMS would have a mandatory, exclusive, and unfettered right to sublicense their QCDR measures for MIPS purposes as a condition of measure approval; would undermine the smooth operation of the QCDR measure market; is an arbitrary and capricious reversal of existing policy; violates intellectual property law, judicial precedent, executive order, and copyrights; nullifies the rights of copyright owners to collect reasonable royalties, maintain measure integrity, and limit inappropriate use; might remove the right of QCDR developers to have input into how CMS uses their measures; may result in a developer having to seek CMS's approval prior to working with another payer entity for reporting of its measures; and ignores the time and resources spent in developing and maintaining measures.

Response: As noted above we are not finalizing this proposal. We note that we do not believe this proposal would have violated intellectual property rights or law, as QCDRs would not have been required to submit QCDR measures for approval, and if a QCDR had refused to enter into such a license agreement, the QCDR measure would have been rejected and another QCDR measure of similar clinical concept or topic may have been approved in its place. We will take the many concerns raised by commenters into consideration as we work with stakeholders to address this issue in the future.

Comment: Many commenters disagreed with the proposal to require QCDR measure owners to allow other QCDRs to submit data on the QCDR measure as a condition of measure approval believing it contradicts the intent of the Meaningful Measure Initiative by eliminating the incentive to develop innovative quality measures that focus on meaningful outcomes; will disincentivize societies from investing in the development of new and improved measures; may increase the incidence of inappropriate use of measures by QCDRs lacking the necessary clinical breadth of exposure/experience resulting in lower quality data being collected, decreased reliability and validity of results, and potential misclassification of providers; would negatively impact the quality of available measures and physician community support for the Quality Payment Program in general; would disincentivize QCDRs from remaining in business, resulting in loss of significant private sector knowledge and experience, as well as increasing the financial burden on the government to hire more federal contractors to replace lost innovation and creativity; and disregards the original intent of QCDRs to submit data on non-MIPS measures focused on disease, condition, procedure, or therapy-specific patient populations.

Response: We do not believe this proposed policy contradicts the Meaningful Measure Initiative, which seeks to reduce the number of duplicative measures in quality performance programs, thereby reducing clinician burden and complexity. However, as noted above we are not finalizing this proposal. We also note that with the finalization of the updated QCDR definition, we believe we will be able to negate any concerns of inappropriate use of QCDR measures by QCDRs who do not have the clinical expertise needed to understand the measure at hand. We have observed increasing interest in stakeholders becoming QCDRs, and believe that they will continue to drive innovation and competition within the market.

Comment: A few commenters suggested alternatives to the proposal to require QCDRs to license their measures to CMS. These alternatives include encourage licensing agreements between QCDRs and reinforcing the ability of QCDRs to develop their own measures should they elect not to license them from other QCDRs. One commenter suggested that CMS should create a ''measure complexity score'' with a corresponding, volume-based, licensing fee payable to the QCDR holding the original measure in conjunction with an annual consolidation of measures to support harmonization requiring stakeholders to collaborate on a ''shared'' measure creation (with licensing fees split evenly) or lose the opportunity for future licensing fee payments. Another commenter recommended CMS propose including a cost-based algorithm that would be used to determine a specific QCDR measure fee which would protect organizations

that could not afford the development of a quality measure or that were not able to develop a measure because a similar measure exists, as well as preventing QCDR measure developers from assigning unreasonable fees to their measures. One commenter recommended CMS establish a pilot program that would encourage collaboration across QCDRs and require users of QCDR measures to agree to adhere to certain requirements of the measure steward, as well as share measure performance information to implement and test measure changes, progressing all concepts to patient-centered outcome measures through measure retirement. Another commenter recommended that CMS follow NQF's example that anyone can report the measure scores and there has to be public/free access for the measures to be used in clinical care, but the measure steward should be permitted to require licensing and fees for anyone who wants to use the measures for more sophisticated purposes, such as programming into software that will result in sales/profit. Other commenters cited their opinions that should the proposal be finalized, it should be done with modification to require a standard data dictionary be used for all QCDR measures and include risk adjustment as well as the same standard methodology used by the measure developer.

Response: We note that the suggestion to encourage licensing agreements between QCDRs was implemented in the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814); however, we have decided not to finalize the measure licensure policy at this time. Our goal in enacting such a policy was to promote measure harmonization and decrease the number of duplicative QCDR measures in the program. We appreciate the suggestion of a ''measure complexity score'' but envision such an approach would be difficult to implement. We would need additional information from stakeholders prior to implementing such a policy, such as how would CMS know how to correlate the volume and complexity to a specific score? What would that entail if on an annual basis the number of QCDRs who submit a similar measure concept increases, and what would they have to do in order to be a part of the harmonization effort? We request clarification on how a cost-based algorithm can be developed, and would also like to clarify that CMS does not regulate the minimum or maximum amounts that a QCDR may charge as a licensing fee.

We thank the commenter for their suggestion of implementing a pilot program where QCDRs would need to share measure performance information, test and implement measure changes, and work towards patient-centered outcome measures. We agree that the sharing of performance data, testing results, and moving towards outcome based measures are all important, but will need to look into the feasibility and operations of implementing such requirements. With regards to the development of a standard data dictionary, as described in the CY 2018 Quality Payment Program final rule (82 FR 53813), we encourage QCDR measure developer to utilize the current Measure Development Plan available at *https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/2018-MDP-annual-report.PDF.* Furthermore, as explained through posted sub-regulatory documents for the 2019 self-nomination period, the current Blueprint for the CMS Measures Management System available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/BlueprintVer14.pdf.* Both resources provide information on standardized terminology, measure concepts and constructs.

Comment: Many commenters requested CMS work with them to adopt a market-based solution to create safeguards to protect the proper implementation of QCDR measures and enforce the intellectual property rights of developers of QCDR measures, while also ensuring that the measures are readily available to other QCDRs with clinical expertise and experience in quality measure development.

Response: We will look to provide listening sessions to better understand and explore the feasibility of this approach.

Comment: Many commenters expressed concern with CMS' requests for harmonization of similar MIPS measures due to their belief that some vendors may be misusing measures and diminishing the integrity of the data, the quality of feedback to physicians, and ability to compare performance. The commenters further cited their belief that such harmonization can lead to inconsistencies in implementation, yielding incomparable results and inaccurate benchmarking due to lack of accountability and standardization across registries which may be employing different methods for obtaining, risk adjusting, and aggregating data, thereby creating variations in how clinicians are measured and how their care is classified.

Response: To clarify, in the CY 2019 PFS proposed rule (83 FR 35984), we indicated that the QCDRs would be required to use the QCDR measure without any modification, and would have to report on the measure utilizing the CMS assigned measure ID. We encourage QCDRs to work together through measure harmonization, and to reach out to QCDR measure owners when they believe a revision to the measure specification is appropriate, for the QCDR measure owner to consider.

Comment: A few commenters suggested the proposal to require QCDRs to license measures to CMS should include allowing qualified registries and other non-QCDR submitter types to also report QCDR measures; only counting measures developed by a QCDR to count toward the 30 measure threshold; and requiring QCDR measure owners to provide detailed specifications including ICD–10–CM codes, CPT codes, required clinical data elements, et cetera, so that all QCDR registries administer the specification uniformly, and developing a system to properly record and track ownership rights, including making ownership information CMS collects available to QCDRs to better facilitate sharing of QCDR measures between QCDR stewards. Commenters also suggested that CMS reserve the right of the measure owner to review interim performance results of other QCDRs utilizing their measures with full cooperation of the other QCDRs to ensure performance results do not vary significantly between QCDRs, thereby ensuring alignment on execution of the measure specification between QCDRs before performance is scored and future benchmarks are impacted.

Response: To clarify, we are only allowing other QCDRs to report on the QCDR measures. Other submitter types would not have the QCDR measures available for reporting. As discussed in the CY 2018 Quality Payment Program final rule (82 FR 53811), QCDRs have the capability to develop and submit for consideration up to 30 QCDR measures per performance period. However, there is no limit as to the number of MIPS quality measures they intend on supporting for a given performance period. We disagree that QCDR measures should be available for reporting by non-QCDR submitter types. As we provide QCDRs with feedback on harmonizing or using QCDR measures owned by other QCDRs, we encourage them to reach out to the QCDRs specifically for the detailed specification inclusive of ICD–10 and CPT codes, as each measure owner is responsible for tracking ownership

rights. The MIPS quality measures provide a detailed measure specification to allow consistency in implementation, but data abstraction may include multiple methods. We would require QCDRs to follow a similar approach, where QCDRs would need to provide a detailed specification to the QCDRs approved to submit the QCDR measure. This would include any applicable ICD–10–CM codes, CPT codes, required clinical data elements, et cetera, to allow implementation with minimal variance. We would like to hear from QCDRs on whether or not they would find this useful; and if this effort will increase burden on their end regarding measure specification development. We will take the suggestion that CMS reserve the right of the measure owner to review interim performance results of other QCDRs utilizing their measures into consideration for future rulemaking.

Comment: A few commenters stated that the proposal blurs the line between QCDR measures and Quality Payment Program measures and would eliminate the ability for a QCDR to ''test'' a measure in the sandbox of their own QCDR before submitting it to CMS to become a Quality Payment Program measure under the Measures Under Consideration (MUC) process. Finally, one commenter suggested that if a measure owner was ready to make a measure available for reporting by all of the Quality Payment Program, they should submit it to CMS under the MUC process.

Response: The QCDR measure approval process is not intended to act as a test bed for measure concepts, we expect QCDRs to have measures that are analytically sound, are reliable, and feasible. Furthermore, we certainly encourage that if a measure owner is ready to make a measure available for reporting by all of the Quality Payment Program, they should submit it to CMS under the MUC process as discussed in section III.I.3.h.(2)(b)(i) of the CY 2019 PFS proposed rule (83 FR 35898 through 35899).

Comment: One commenter stated its belief that the proposal does not align with the intended purpose of the MACRA grant for measure development, which they further noted demonstrates the federal government's recognition of measure development expense. A second commenter stated that the proposal lacks provisions on how to determine whether a specific measure is intended for another population and that the absence of such provisions can lead to inappropriate implementations in patient populations with the inability of the measure owner to review data collected on their measures and maintain the measures appropriately.

Response: We do not believe this policy would not align with the MACRA grant for measure development, since generally across all quality programs we are looking to reduce the number of duplicative measures available for reporting and to transition to more outcomes based measures. We believe that QCDRs exist to address measurement gaps as identified by the specialists and that QCDRs are intended to address gaps in measurement that would better reflect a clinician's scope of practice. Based on the updates to the QCDR definition we have finalized in this final rule (in the above section) for the 2020 performance period of MIPS, we believe we will be able to further vet QCDR applications to ensure that approved QCDRs would have the clinical expertise and measure development experience. We are also streamlining the number of measures available to clinicians in order to align with our Meaningful Measures initiative. We note that our review and approval of the QCDR measures will follow our existing process utilizing the QCDR measure evaluation criteria as detailed through sub-regulatory guidance in the 2019 QCDR Measure Development Handbook, located in the 2019 Self-Nomination Toolkit on the Quality Payment Program Resource Library web page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Resources.html*. Once the QCDR measures have been finalized for the performance period, and the specification has been finalized, we intend to post the list of QCDR measure specifications for QCDRs to review and consider prior to deciding whether or not they wish to support additional QCDR measures. As a part of this consideration, we encourage QCDRs to review the measure specifications to determine the populations addressed.

Comment: A few commenters supported the proposal to require QCDRs to enter into licensing agreements with CMS as a condition of approval. Reasons cited include their beliefs that the proposal allows different vendors to have the ability to address different specialty needs appropriately thereby providing greater choice to eligible clinicians, increases the effectiveness of quality measurement, and increases the relevance and usefulness of measures in evaluating the quality of care provided to patients nationally by increasing the number of providers reporting data.

Response: We thank the commenters for their support but as noted previously we are not finalizing this policy at this time.

Comment: A few commenters stated that CMS should adopt a model where one measure is supported by one entity that represents a single clinical domain or subspecialty as they noted doing so will enhance consistency and validity across measurements; allow for a single method for data aggregation, analytics, and reporting; reduce benchmarking issues; decrease the risk of clinicians being misclassified in the quality of care they provide; and remedy CMS' lack of ability to co-aggregate data from multiple data sources and properly risk-adjust measures. The commenters noted that the approved registry should be required to meet standards for data which include rigor in explicitly defining data elements used in the measurement, serve as a single source of data aggregation and data normalization to secure data integrity, apply approved and consistent statistical standards for analytics, respond to clinical and methodological questions, and be responsible for reporting requirements as defined by CMS. One commenter further noted that CMS policy should require QCDRs to always refer eligible clinician questions on specific measures back to the measure steward, prohibit vendors and other QCDRs from specifying CQMs into eCQMs without permission, require QCDRs to use current measure specifications, and require CMS to publicly post complete measure specifications, where appropriate, to the CMS Quality Payment Program resources website to ensure all registries are implementing the most updated measure specifications.

Response: We are not looking to set limitations, such as, one clinical domain being assigned to one entity. We have multiple instances where there are a few QCDRs covering similar areas (that is, surgery, anesthesia, rheumatology). We would appreciate thoughts on how we can reduce benchmarking issues to thereby incentivize QCDR measure reporting. QCDRs are required to meet CMS data aggregation and reporting requirements and agree that it is important that QCDRs are able to meet data integrity standards in using data elements for purposes of measurement. We believe there are circumstances out of CMS' control where the clinician will reach out to the QPP service center for assistance with a measure related question or to the QCDR they are specifically working with. It would not be feasible to set such a requirement when we could not monitor that it would be followed. We encourage clinicians who have questions on the

QCDR measure specifications to reach out directly to the QCDR measure owner in order to gain clarity on their questions. We agree, however, that the QCDR must use the measure in its original state. QCDRs have to use the measure in its ''as is'' state; meaning, how it was approved for the given performance period. We post QCDR measure specifications, inclusive of: The measure's specialty; QCDR name; measure title; measure description; denominator; numerator; denominator exclusions; denominator exceptions; numerator exclusions; data source used; NQF number (if applicable); NQS domain; whether the measure is high priority, outcome; measure type; whether the measure is inverse, proportional, continuous variable, ratio; the range of scores if the measure is continuous variable or ratio measures; number of performance rates submitted; overall performance rate; whether the measure is risk-adjusted; if risk-adjusted, and which score is risk-adjusted within the QPP resource library. The systems are programmed on an annual basis to only accept those QCDR measures and correlated specifications as approved for the upcoming performance period.

Based on the feedback and concerns raised by stakeholders, in the interim, we are not finalizing at § 414.1400(b)(3)(ii)(C) that as a condition of a QCDR measure's approval for purposes of MIPS, the QCDR measure owner would be required to agree to enter into a license agreement with CMS, permitting any approved QCDR to submit data on the QCDR measure (without modification) for purposes of MIPS and each applicable MIPS payment year. Rather we are retaining our existing policy that QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR (82 FR 53813). We remain very concerned about duplicative measures and their impact to our meaningful measures initiative. We are eager to work with the stakeholder community to determine solutions for this issue and will continue to look for policy resolutions to address this issue.

We are finalizing our proposal at § 414.1400(b)(3)(iii) that other QCDRs would be required to use the same CMS-assigned QCDR measure ID.

(4) Qualified Registries

We refer readers to § 414.1400 and the CY 2018 Quality Payment Program final rule (82 FR 53815 through 53818) for our previously finalized policies regarding qualified registries. In the CY 2019 PFS proposed rule (83 FR 35984), we proposed to update: Information required for qualified registries at the time of self-nomination and the self-nomination period for qualified registries.

(a) Establishment of an Entity Seeking To Qualify as a Qualified Registry

In the CY 2017 Quality Payment Program final rule (81 FR 77383), we state at § 414.1400(h)(2) that the qualified registry must have at least 25 participants by January 1 of the performance period. These participants do not need to use the qualified registry to report MIPS data to us; rather, they need to submit data to the qualified registry for quality improvement. We realize that a qualified registry's lack of preparedness to accept data from MIPS eligible clinicians and groups beginning on January 1 of the performance period may negatively impact a clinician's ability to use a Qualified Registry to report, monitor the quality of care they provide to their patients (and act on these results) and may inadvertently increase clinician burden. For these reasons, in the CY 2019 PFS proposed rule (83 FR 35984), we proposed to redesignate § 414.1400(h)(2) as § 414.1400(c)(2) to state that beginning with the 2022 MIPS Payment Year, the qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period. These participants do not need to use the qualified registry to report MIPS data to us; rather, they need to submit data to the qualified registry for quality improvement.

We did not receive any comments on the ''Establishment of an Entity Seeking To Qualify as a Qualified Registry.'' We are finalizing our proposal to redesignate § 414.1400(h)(2) as § 414.1400(c)(2) to state that beginning with the 2022 MIPS Payment Year, the qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period.

(b) Self-Nomination Process

We refer readers to § 414.1400(g), the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77383 and 82 FR 53815, respectively) for our previously established policies regarding the self-nomination process for qualified registries. We did not propose any changes to this policy.

(c) Self-Nomination Period

Under the previously finalized policy at § 414.1400(g), qualified registries must self-nominate from September 1 of the year prior to the applicable performance period until November 1 of the same year and must, among other things, provide all information requested by us at the time of self-nomination. To maintain alignment with the timelines proposed for QCDR self-nomination, as discussed in section III.I.3.k.(3)(c) of this final rule, we also proposed in the CY 2019 PFS proposed rule (83 FR 35985) to update the self-nomination period from September 1 of the year prior to the applicable performance period until November 1 to July 1 of the calendar year prior to the applicable performance period until September 1. Specifically, we proposed in the CY 2019 PFS proposed rule (83 FR 35985) at § 414.1400(c)(1) that, beginning with the 2022 MIPS payment year, entities seeking to qualify as qualified registries must self-nominate during a 60-day period beginning on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year; must provide all information required by us at the time of self-nomination; and must provide any additional information requested by us during the review process. For example, for the 2022 MIPS payment year, the applicable performance period would be CY 2020, as discussed in section III.I.3.g. of this final rule. Therefore, the self-nomination period for qualified registries would begin on July 1, 2019 and end on September 1, 2019.

We did not receive any comments on the ''Self-nomination Period'' for Qualified Registries. We are finalizing our proposal to amend § 414.1400(c)(1) to provide that, beginning with the 2022 MIPS payment year, entities seeking to qualify as qualified registries must self-nominate during a 60-day period beginning on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year; must provide all information required by us at the time of self-nomination; and must provide any additional information requested by us during the review process.

(5) Health IT Vendors or Other Authorized Third Parties That Obtain Data From MIPS Eligible Clinicians' Certified EHR Technology (CEHRT)

We refer readers to § 414.1400 and the CY 2017 Quality Payment Program final rule (81 FR 77377 through 77382) for our previously finalized policies regarding health IT vendors or other authorized third parties that obtain data from MIPS eligible clinicians. We finalized that health IT vendors that obtain data from a MIPS eligible clinician, like other third party intermediaries, would have to meet all criteria designated by us as a condition

of their qualification or approval to participate in MIPS as a third party intermediary. This includes submitting data in the form and manner specified by us. In the CY 2019 PFS proposed rule (83 FR 35985), we proposed to codify these policies at § 414.1400(d). Although we specified criteria for a health IT vendor in the CY 2017 Quality Payment Program final rule, we failed to codify the definition of a health IT vendor. Therefore, in the CY 2019 PFS proposed rule (83 FR 35985), we proposed to define at § 414.1305, that health IT vendor means an entity that supports the health IT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician's CEHRT).

As indicated in footnote 1 of the CY 2017 Quality Payment Program final rule (81 FR 77014 through 77015), the term ''health IT vendor'' encompasses many types of entities that support the health IT requirements on behalf of a MIPS eligible clinician. A ''health IT vendor'' may or may not also be a ''health IT developer'' for the purposes of the ONC Health IT Certification Program (Program), and, in some cases, the developer and the vendor of a single product may be different entities. Under the Program, a health IT developer constitutes a vendor, self-developer, or other entity that presents health IT for certification or has health IT certified under the Program. Other health IT vendors may maintain a range of data transmission, aggregation, and calculation services or functions, such as organizations which facilitate health information exchange.

We did not receive any comments on the ''Health IT Vendors or Other Authorized Third Parties That Obtain Data From MIPS Eligible Clinicians' Certified EHR Technology (CEHRT).'' Therefore, we are finalizing our proposal to codify our previously established policies at § 414.1400(d). We are also finalizing our proposal to define at § 414.1305, that health IT vendor means an entity that supports the health IT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician's CEHRT).

(6) CMS-Approved Survey Vendors

In the CY 2017 Quality Payment Program final rule (81 FR 77386), we finalized the criteria, required forms, and vendor business requirements needed to participate in MIPS as a CMS-approved survey vendor. In the CY 2019 PFS proposed rule (83 FR 35985), we proposed at § 414.1400(e) to codify these previously finalized criteria and requirements. Accordingly, we proposed in the CY 2019 PFS proposed rule (83 FR 35985) at § 414.1400(e) that an entity seeking to be a CMS-approved survey vendor for any MIPS performance period must submit a survey vendor application to CMS in a form and manner specified by CMS for each MIPS performance period for which it wishes to transmit such data. We also proposed to require that the application and any supplemental information requested by CMS must be submitted by deadlines specified by CMS. In addition, we proposed that a CMS-approved survey vendor must meet several criteria. First, we proposed to require that an entity have sufficient experience, capability, and capacity to accurately report CAHPS data, including:

- At least 3 years of experience administering mixed-mode surveys (surveys that employ multiple modes to collect data) that include mail survey administration followed by survey administration via Computer Assisted Telephone Interview (CATI);
- At least 3 years of experience administering surveys to a Medicare population;
- At least 3 years of experience administering CAHPS surveys within the past 5 years;
- Experience administering surveys in English and one of the following languages: Cantonese; Korean; Mandarin; Russian; or Vietnamese;
- Use of equipment, software, computer programs, systems, and facilities that can verify addresses and phone numbers of sampled beneficiaries, monitor interviewers, collect data via CATI, electronically administer the survey and schedule call-backs to beneficiaries at varying times of the day and week, track fielded surveys, assign final disposition codes to reflect the outcome of data collection of each sampled case, and track cases from mail surveys through telephone follow-up activities; and
- Employment of a program manager, information systems specialist, call center supervisor and mail center supervisor to administer the survey.

Furthermore, we proposed in the CY 2019 PFS proposed rule (83 FR 35985) that to be a CMS-approved survey vendor, the entity must also meet the following criteria:

- It must have certified that it has the ability to maintain and transmit quality data in a manner that preserves the security and integrity of the data;
- The entity must have successfully completed, and required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors;
- The entity must have submitted a quality assurance plan and other materials relevant to survey administration, as determined by CMS, including cover letters, questionnaires and telephone scripts;
- The entity must have agreed to participate and cooperate, and have required its subcontractors to participate and cooperate, in all oversight activities related to survey administration conducted by CMS or its contractors; and
- The entity must have sent an interim survey data file to CMS that establishes the entity's ability to accurately report CAHPS data.

We also refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53818 through 53819) for our previously established policies regarding the updated survey vendor application deadline.

The following is a summary of the public comments received on the ''CMS-Approved Survey Vendors'' proposals and our responses:

Comment: A few commenters commended CMS for making the CAHPS for Physician Quality Reporting System (PQRS) survey available in Cantonese, Korean, Mandarin, Russian, Spanish, and Vietnamese and for making the Medicare Accountable Care Organization CAHPS survey available in Cantonese, Korean, Mandarin, Portuguese, Russian, Spanish, and Vietnamese. These commenters encouraged CMS to work with stakeholders to develop validated translations of all CAHPS surveys used in MIPS and APMs in at least the top ten primary languages among Medicare beneficiaries.

Response: We appreciate the commenters' feedback. We have made the CAHPS for MIPS survey available in Spanish and we will continue to work with stakeholders to develop additional translations of the surveys. In addition, because the CAHPS for MIPS survey is available in Spanish and may become available in other languages in the future, we believe it is appropriate to modify our proposed requirement at § 414.1400(e)(1)(iv) to more broadly state that an entity must have experience administering surveys in English and at least one other language for which a translation of the CAHPS for MIPS survey is available. These languages currently consist of Cantonese, Korean, Mandarin, Russian, Spanish, and Vietnamese.

After consideration of the public comments received, we are finalizing our proposal at § 414.1400(e) to state that entities seeking to be a CMS-approved survey vendor for any MIPS

performance period must submit a survey vendor application to CMS in a form and manner specified by CMS for each MIPS performance period for which it wishes to transmit such data; and that the application and any supplemental information requested by CMS must be submitted by deadlines specified by CMS. We are also finalizing our proposal at § 414.1400(e) that a CMS-approved survey vendor must meet several criteria that consists of the following:

An entity must have sufficient experience, capability, and capacity to accurately report CAHPS data, including:

- At least 3 years of experience administering mixed-mode surveys (surveys that employ multiple modes to collect data) that include mail survey administration followed by survey administration via Computer Assisted Telephone Interview (CATI);
- At least 3 years of experience administering surveys to a Medicare population;
- At least 3 years of experience administering CAHPS surveys within the past 5 years;
- Experience administering CAHPS surveys in English and at least one other language for which a translation of the CAHPS for MIPS survey is available. These languages currently consist of Cantonese, Korean, Mandarin, Russian, Spanish or Vietnamese;
- Use of equipment, software, computer programs, systems, and facilities that can verify addresses and phone numbers of sampled beneficiaries, monitor interviewers, collect data via CATI, electronically administer the survey and schedule call-backs to beneficiaries at varying times of the day and week, track fielded surveys, assign final disposition codes to reflect the outcome of data collection of each sampled case, and track cases from mail surveys through telephone follow-up activities; and
- Employment of a program manager, information systems specialist, call center supervisor and mail center supervisor to administer the survey.

In addition, we are finalizing without change our proposal that an entity must have certified that it has the ability to maintain and transmit quality data in a manner that preserves the security and integrity of the data; the entity must have successfully completed, and has required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors; the entity must have submitted a quality assurance plan and other materials relevant to survey administration, as determined by CMS, including cover letters, questionnaires and telephone scripts; the entity must have agreed to participate and cooperate, and have required its subcontractors to participate and cooperate, in all oversight activities related to survey administration conducted by CMS or its contractors; and the entity must have sent an interim survey data file to CMS that establishes the entity's ability to accurately report CAHPS data.

(7) Auditing of Third Party Intermediaries Submitting MIPS Data

In the CY 2018 Quality Payment Program final rule (82 FR 53819), we established at § 414.1400(j) policies regarding auditing of third party intermediaries submitting MIPS data. In the CY 2019 PFS proposed rule (83 FR 35985), we did not propose any changes to these policies. In this final rule, the provision that currently appears at § 414.1400(j) is redesignated as § 414.1400(g) and contains no substantive changes.

(8) Remedial Action and Termination of Third Party Intermediaries

In the CY 2017 Quality Payment Program final rule (81 FR 77548), we finalized the criteria for probation and disqualification for third party intermediaries at § 414.1400(k). In the CY 2019 PFS proposed rule (83 FR 35986), we proposed to revise the numbering of this section and the title to more accurately describe the policies in this section. Specifically, we proposed to renumber this section as § 414.1400(f) and to rename it as ''remedial action and termination of third party intermediaries.'' Additionally, we proposed in the CY 2019 PFS proposed rule (83 FR 35986) changes to § 414.1400(f) to amend, clarify, and streamline our policies related to remedial action and termination.

Our intent with these policies is to identify and remedy noncompliance with the applicable third party intermediary criteria, as well as identify issues that may impact the accuracy of or our ability to use the data submitted by third party intermediaries. Accordingly, in the CY 2019 PFS proposed rule (83 FR 35986), we proposed to amend § 414.1400(f)(1) to state that we may take remedial action for noncompliance with applicable third party intermediary criteria for approval (a deficiency) or for the submission of inaccurate, unusable, or otherwise compromised data. In the CY 2017 Quality Payment Program final rule, we finalized our policy regarding data inaccuracies at § 414.1400(k)(4). In the CY 2019 PFS proposed rule (83 FR 35986), we proposed at § 414.1400(f)(3) to expand data inaccuracies to include a determination by us that data is inaccurate, unusable, or otherwise compromised. However, we did not propose to change the factors we may consider to make such a determination. In the CY 2019 PFS proposed rule (83 FR 35986), we also proposed to move the notification requirement at § 414.1400(k)(6) to § 414.1400(f)(1) and to apply the requirement to all deficiencies and data errors.

Based on our early experience with third party intermediaries under MIPS and the challenges for both third party intermediaries and us in regards to timing and trying to resolve deficiencies and data errors within the various reporting and performance periods, we proposed in the CY 2019 PFS proposed rule (83 FR 35986) to amend the timeframes by which a third party intermediary must submit a Corrective Action Plan (CAP) to us or come into compliance. Specifically, we proposed § 414.1400(f)(2), which requires third party intermediaries to submit a CAP or correct the deficiencies or data errors by the date specified by us (83 FR 35986).

Additionally, we proposed in the CY 2019 PFS proposed rule (83 FR 35986) to consolidate at § 414.1400(f)(1) the grounds for remedial action against a third party intermediary currently specified at § 414.1400(k)(1) and (4) and to consolidate at § 414.1400(f)(2) the grounds for terminating a third party intermediary currently found at § 414.1400(k)(3), (5) and (7). Therefore, we proposed at § 414.1400(f)(1) that if at any time we determine that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, or has submitted data that is inaccurate, unusable, or otherwise compromised, we may take certain remedial actions (for example, request a CAP) (83 FR 35986). In the CY 2019 PFS proposed rule (83 FR 35986), we also proposed at § 414.1400(f)(2) that we may terminate, immediately or with advance notice, the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the following reasons: We have grounds to impose remedial action, we have not received a CAP within the specified time period or the CAP is not accepted by us, or the third party intermediary fails to correct the deficiencies or data errors by the date specified by us.

Additionally, in the CY 2019 PFS proposed rule (83 FR 35986), we proposed to consolidate at § 414.1400(f)(1) the actions we may take

if we identify a deficiency or data error that are set forth at § 414.1400(k)(3) and (7). Thus, we proposed at § 414.1400(f)(1) in the CY 2019 PFS proposed rule (83 FR 35986) that if we determine a third party intermediary has ceased to meet one or more of the applicable criteria for approval, or has submitted data that is inaccurate, unusable, or otherwise compromised, we may require the third party intermediary to submit a CAP to us to address the identified deficiencies or data issue, including the actions it will take to prevent the deficiencies or data issues from recurring. We proposed to require that the CAP be submitted to CMS by a date specified by CMS.

In the CY 2019 PFS proposed rule (83 FR 35986), we also proposed that CMS may determine that submitted data is inaccurate, unusable, or otherwise compromised if the submitted data: (1) Includes, without limitation, TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies; and (2) affects more than 3 percent (but less than 5 percent) of the total number of MIPS eligible clinicians or group for which data was submitted by the third party intermediary. In addition, we proposed in the CY 2019 PFS proposed rule (83 FR 35986) that if the third party intermediary has a data error rate of 3 percent or more, we will publicly disclose the entity's data error rate on the CMS website until the data error rate falls below 3 percent.

We clarify in this final rule that CMS may determine that submitted data is inaccurate, unusable, or otherwise compromised if the submitted data affects more than 3 percent of the total number of MIPS eligible clinicians or group for which data was submitted by the third party intermediary. In the CY 2017 Quality Payment Program final rule (81 FR 77387 through 77388), we explained that if a third party intermediary has data inaccuracies including (but not limited to) TIN/NPI mismatches, formatting issues, calculation errors, data audit discrepancies affecting in excess of 3 percent (but less than 5 percent) of the total number of MIPS eligible clinicians or groups submitted by the third party intermediary, we would annotate on the CMS qualified posting that the third party intermediary furnished data of poor quality and would place the entity on probation for the subsequent MIPS performance period. If a third party intermediary does not reduce their data error rate below 3 percent for the subsequent performance period, the third party intermediary would continue to be on probation and have their listing on the CMS website continue to note the poor quality of the data they are submitting for MIPS for one additional performance year. After 2 years on probation, the third party intermediary would be disqualified for the subsequent performance year. We also explained that data errors affecting in excess of 5 percent of MIPS eligible clinicians or group submitted by the third party intermediary may lead to the disqualification of the third party intermediary from participation for the following performance period (that is, without first placing the third party intermediary on probation).

Accordingly, it was always our intent that data errors affecting in excess of 3 percent of the MIPS eligible clinicians or group submitted by a third party intermediary would result in remedial action or disqualification (termination) of the third party intermediary. In this final rule, we are correcting an obvious error in the regulation text we proposed at § 414.1400(f)(3)(ii) to clarify that if submitted data is inaccurate, unusable, or otherwise compromised if errors in the submitted data affect more than 3 percent of the total number of MIPS eligible clinicians or group for which data was submitted by the third party intermediary.

Finally, we proposed to remove our probation policy. Therefore, we proposed in the CY 2019 PFS proposed rule (83 FR 35986) to remove the definition of probation at § 414.1400(k)(2) and references to probation in § 414.1400(k)(1), (3) and (5).

The following is a summary of the public comments received on the ''Remedial Action and Termination of Third Party Intermediaries'' proposals and our responses:

Comment: One commenter stated that CMS should put in place a safe harbor policy in order to minimize the impact on clinicians when a data issue outside of a clinician's or group's control occurs due to a third party intermediary. The commenter indicated that, under those circumstances, CMS should automatically consider the clinician or group to have satisfied the quality performance category. The commenter cited concerns with the transition and upgrade to 2015 CEHRT and references data issues under 2016 PQRS related to the 2014 CEHRT upgrade.

Response: We do not agree that we should create a safe harbor policy to address the circumstances described by the commenter. Instead, we believe it would be appropriate to address data issues on a case-by-case basis. As we discussed in the CY 2018 Quality Payment Program final rule (82 FR 53807), we expect third party intermediaries to develop processes to ensure that the data and information they submit to CMS on behalf of MIPS eligible clinicians, groups, and virtual groups are true, accurate, and complete; we also rely on the third party intermediaries to address these issues in its arrangements and agreements with other entities, including MIPS eligible clinicians, groups, and virtual groups.

Comment: One commenter agreed with the proposal to remove the probation policy.

Response: We appreciate the commenter's support.

Comment: A few commenters disagreed with our proposal at § 414.1400(f)(2) because it would allow us to immediately or with advance notice terminate a third party intermediary's ability to submit MIPS data without first placing the third party intermediary on probation. The commenters believe that termination should occur only with advance notice through a clearly defined process that reflects the current procedure set forth at § 414.1400(f). Commenters suggested that CMS' termination procedure include formal consideration of a CAP.

Response: We appreciate the commenters' concerns, and therefore, we expect that in most circumstances, we would take remedial action, including imposition of a CAP, prior to terminating the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible clinician, group, or virtual group. Before deciding whether to terminate a third party intermediary's ability to submit MIPS data, we would take into account a third party intermediary's actions, the severity of the non-compliance or errors at issue, and the potential for undue hardship or negative impact on affected eligible clinicians. In addition, we would expect to provide advance notice of most terminations; we would likely impose immediate termination on a third party intermediary's ability to submit MIPS data only in circumstances where egregious non-compliance or data errors have occurred. However, if we have not received a CAP within the specified time period or the CAP is not accepted by us, or the third party intermediary fails to correct the deficiencies or data errors by the date specified by us, we may terminate the third party intermediary, immediately or with advance notice.

Comment: A few commenters stated that the proposed termination policy could result in undue hardship on or negatively impact affected eligible clinicians should termination occur during a performance period.

Response: We recognize that termination of a third party intermediary's ability to submit MIPS data during a performance period may result in undue hardship on eligible clinicians who are supported by the third party intermediary. Therefore, we would consider whether a third party intermediary is supporting eligible clinicians in deciding when to terminate the ability of the third party intermediary to submit MIPS data. In addition, we will consider for future rulemaking whether a third party intermediary should be required to submit to CMS a transition plan that addresses how submission of data would be handled in the event that termination occurs during a performance period.

Comment: A few commenters representing QCDRs and qualified registries stated that CMS should clearly define, and provide examples of, a ''data error'' for purposes of determining a third party intermediary's data error rate, which may be disclosed publicly by CMS if it exceeds 3 percent. In addition, the commenters stated that CMS should set forth how the data error rate is calculated and develop a report that describes and differentiates data errors and other ''issues'' that should be brought to a third party intermediary's attention.

Response: The ''data error rate'' measures the amount of data submitted by a third party intermediary that was ''inaccurate, unusable, or otherwise compromised.'' Additional material regarding data inaccuracies and error rates is available in the ''2019 Qualified Clinical Data Registry (QCDR) Fact Sheet'' and the ''2019 Qualified Registry Fact Sheet'' in the 2019 Self-Nomination Toolkit for QCDRs & Registries, located in the Quality Payment Program Resource Library at *https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Resources.html*. We appreciate the suggestion of creating a report that describes data errors and ''other issues,'' however, we believe that our existing material addresses the commenters' concern.

After consideration of the public comments received, we are finalizing our proposal to revise the numbering of § 414.1400(k) as § 414.1400(f) and to rename it as ''remedial action and termination of third party intermediaries.'' We are also finalizing our proposal to amend, clarify, and streamline our policies related to remedial action and termination as follows:

- We are finalizing § 414.1400(f)(1) to state that CMS may take one or more of the following remedial actions if we determine that a third party intermediary has ceased to meet one or more of the applicable third party intermediary criteria for approval or has submitted data that is inaccurate, unusable, or otherwise compromised: We will require the third party intermediary to submit by a deadline specified by CMS a CAP that addressed the identified deficiencies or data issue, including the actions it will take to prevent the deficiencies or data issues from recurring; or we will publicly disclose the entity's data error rate on the CMS website until the data error rate falls below 3 percent.
- We are finalizing § 414.1400(f)(2) to state that CMS may immediately or with advance notice terminate the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible clinician group, or virtual group for one or more of the following reasons: CMS has grounds to impose remedial action; CMS has not received a CAP within the specified time period or the CAP is not accepted by CMS; or, the third party intermediary fails to correct the deficiencies or data errors by the date specified by CMS.
- We are finalizing § 414.1400(f)(3) to state that, for purposes of paragraph (f), CMS may determine that submitted data is inaccurate, unusable, or otherwise compromised if it: Includes, without limitation, TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies; and affects more than 3 percent of the total number of MIPS eligible clinicians or group for which data was submitted by the third party intermediary.

l. Public Reporting on Physician Compare

This section contains our approach for public reporting on Physician Compare for year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020) and future years, including MIPS, APMs, and other information as required by the MACRA and building on our previously finalized public reporting policies (see 82 FR 53819 through 53832).

Physician Compare (*http://www.medicare.gov/physiciancompare*) draws its operating authority from section 10331(a)(1) of the Affordable Care Act. Consistent with section 10331(a)(2) of the Affordable Care Act, Physician Compare initiated a phased approach to publicly reporting performance scores that provide comparable information on quality and patient experience measures. A complete history of public reporting on Physician Compare is detailed in the CY 2016 PFS final rule (80 FR 71117 through 71122). More information about Physician Compare, including the history of public reporting and regular updates about what information is currently available, can also be accessed on the Physician Compare Initiative website at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/*.

As discussed in the CY 2018 Quality Payment Program final rule (82 FR 53820), Physician Compare has continued to pursue a phased approach to public reporting under the MACRA in accordance with section 1848(q)(9) of the Act. Generally, all data available for public reporting on Physician Compare must meet our established public reporting standards under § 414.1395(b). In addition, for each program year, CMS provides a 30-day preview period for any clinician or group with Quality Payment Program data before the data are publicly reported on Physician Compare under § 414.1395(d). All data available for public reporting—measure rates, scores, and attestations, objectives, etc.—are available for review and correction during the targeted review process. See the CY 2018 Quality Payment Program final rule for details on this process (82 FR 53820).

Lastly, section 104(e) of the MACRA requires the Secretary to make publicly available, on an annual basis, in an easily understandable format, information for physicians and, as appropriate, other eligible clinicians related to items and services furnished to Medicare beneficiaries under Title XVIII of the Act. In accordance with section 104(e) of the MACRA, we finalized a policy in the CY 2016 PFS final rule (80 FR 71131) to add utilization data to the Physician Compare downloadable database.

We believe section 10331 of the Affordable Care Act supports the overarching goals of the MACRA by providing the public with performance information that will help them make informed decisions about their health care, while encouraging clinicians to improve the quality of care they provide to their patients. In accordance with section 10331 of the Affordable Care Act, section 1848(q)(9) of the Act, and section 104(e) of the MACRA, we plan to continue to publicly report performance information on Physician Compare. As such, the following sections discuss the information previously finalized for inclusion on Physician Compare for all program years, as well as our finalized policies for public reporting on Physician Compare for year 3 of the Quality

Payment Program (2019 data available for public reporting in late 2020) and future years.

We received several miscellaneous comments, but since these were not applicable to specific proposals made, these comments are outside the scope of this section and the proposed rule.

(1) Final Score, Performance Categories, and Aggregate Information

In the CY 2018 Quality Payment Program final rule (82 FR 53823), we finalized a policy to publicly report on Physician Compare, either on profile pages or in the downloadable database, the final score for each MIPS eligible clinician and the performance of each MIPS eligible clinician for each performance category, and to periodically post aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of performance of all the MIPS eligible clinicians for each performance category, as technically feasible, for all future years. We will use statistical testing and user testing, as well as consultation with the Physician Compare Technical Expert Panel convened by our contractor, to determine how and where these data are best reported on Physician Compare.

A summary of the previously finalized policies related to each performance category of MIPS data, as well as finalized policies for year 3 and future years, follows. It is important to note just because performance information is available for public reporting, it does not mean all data under all performance categories will be included on either public-facing profile pages or the downloadable database. These data must meet the public reporting standards, first. And, second, we are careful to ensure that we do not include too much information on public-facing profile pages in an effort not to overwhelm website users. Although all information submitted under MIPS is technically available for public reporting, we will continue our phased approach to making this information public.

(2) Quality

In the CY 2018 Quality Payment Program final rule (82 FR 53824), we finalized a policy to make all measures under the MIPS quality performance category available for public reporting on Physician Compare, either on profile pages or in the downloadable database, as technically feasible. This includes all available measures across all collection types for both MIPS eligible clinicians and groups, for all future years. We will use statistical testing and website user testing to determine how and where measures are reported on Physician Compare. We will not publicly report first year quality measures, meaning any measure in its first year of use in the quality performance category, under § 414.1395(c). We will also include the total number of patients reported on for each measure included in the downloadable database (82 FR 53824).

We proposed to modify § 414.1395(b) to reference ''collection types'' instead of ''submission mechanisms'' to accurately update the terminology (83 FR 35987), consistent with the proposal to add this term and its definition under § 414.1305. We also proposed to revise § 414.1395(c) to indicate that we will not publicly report first year quality measures for the first 2 years a measure is in use in the quality performance category (83 FR 35987). We proposed this change to encourage clinicians and groups to report new measures, get feedback on those measures, and learn from the early years of reporting measures before measure are made public. We requested comment on these proposals.

The following is a summary of the comments we received on these proposals and our responses.

Comment: Most commenters supported not publicly reporting first year data on quality measures for the first 2 years to encourage adoption of new measures and allow clinicians and groups to get experience with and feedback on these measures before they are publicly reported. One commenter noted concern with delaying the public reporting of first year quality measures for the first 2 years they are in use, stating it would slow the progress toward full Quality Payment Program implementation and in fostering evaluation of more clinicians reporting a consistent set of measures. A few commenters suggested that 3 years is a more appropriate length of time for delaying publicly reporting first year measures, stating this timeframe would allow CMS to adequately evaluate meaningful trends over time and provide clinicians with an adequate period to fix data collection issues and give clinicians more time to respond to performance feedback. A few commenters requested that public reporting on Physician Compare be delayed until the transition years to full Quality Payment Program implementation end and there is more predictability, continuity, consistency, and decreased complexity in the program. In addition, several commenters submitted suggestions regarding transparency of publicly reported performance data. One commenter requested that Physician Compare note for publicly reported measures if a change to clinical guidelines occurred during the performance year, so that the data provided is not misleading to the public.

Response: We agree that not publicly reporting first year data on quality measures for the first 2 years they are in use is sufficient time to gain experience with them before they are considered for public reporting and believe 2 years also meets the goal of providing more timely and transparent information to the public on clinician performance for making their healthcare decisions. We believe that waiting 3 years to publicly report first year measures unnecessarily hinders the ability to provide the public with transparent performance information after clinicians have already received such feedback and also reduces the non-financial incentive for clinicians to improve their performance. Additionally, we do not believe that delaying the public reporting of first year quality measures for the first 2 years they are in use delays Quality Payment Program implementation or evaluation of more clinicians reporting a consistent set of measures, since, at this time, eligible clinicians and groups have the flexibility to select from a broad list of measures and do not all need to report the exact same measures. Regarding the comment suggesting public reporting be delayed until the Quality Payment Program is fully implemented, we note that we are required under section 1848(q)(9)(A) and (D) of the Act to publicly report certain MIPS eligible clinician and group performance information on Physician Compare. However, we do recognize that we are in early stages of MIPS, which is why we are continuing to publicly report this information under a phased approach. In response to the suggestion to indicate, on Physician Compare, when a measure specification has changed, we note that if there are significant changes to a clinical guideline during the performance year and the measure specifications do not reflect the current standard of care, the measure is suppressed from MIPS scoring. Refer to III.I.3.i.(1)(b)(vii) of this final rule for more information on the scoring policy. Only data that meet our established public reporting standards under § 414.1395(b) will be publically reported on Physician Compare.

Regarding the comments supporting data transparency, we agree that for public reporting to be meaningful to all stakeholders, transparency is key. Each year we strive to actively share information, via the Physician Compare

initiative page and other channels, on our public reporting efforts as testing is completed and measures to be publicly reported are finalized. Last year in response to similar comments, we produced additional educational materials about the 5-star rating methodology and cut-offs, for example. We will continue our educational efforts as public reporting on Physician Compare evolves. We also reiterate our belief in the importance of clinicians reviewing their data for accuracy prior to it being publicly reported. All performance data publicly reported on Physician Compare will reflect the scores eligible clinicians and groups receive in their MIPS performance feedback, which are available for review and correction during the targeted review process.

After consideration of the comments, we are finalizing our proposal to revise § 414.1395(c) to indicate that we will not publicly report first year quality measures for the first 2 years a measure is in use in the quality performance category. We did not receive any comments on changing ''submission mechanism'' to ''collection type'' for the purposes of public reporting, and as a result are finalizing our proposal to modify § 414.1395(b) to reference ''collection types'' instead of ''submission mechanisms''.

(3) Cost

In the CY 2018 Quality Payment Program final rule (82 FR 53825), we finalized a policy to include on Physician Compare a subset of cost measures that meet the public reporting standards at § 414.1395(b), either on profile pages or in the downloadable database, if technically feasible, for all future years. This includes all available cost measures, and applies to both MIPS eligible clinicians and groups. We will use statistical testing and website user testing to determine how and where measures are reported on Physician Compare. We previously finalized that we will not publicly report first year cost measures, meaning any measure in its first year of use in the cost performance category, under § 414.1395(c).

Consistent with our proposal for first year quality measures, we proposed to revise § 414.1395(c) to indicate that we will not publicly report first year cost measures for the first 2 years a measure is in use in the cost performance category (83 FR 35987). We proposed this change to help clinicians and groups get feedback on these measures and learn from the early years of these new measures being calculated before measure are made public (83 FR 35987). We requested comment on this proposal.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Most commenters supported not publicly reporting first year data on cost measures for the first 2 years to encourage adoption of new measures and allow clinicians and groups to get experience with and feedback on these measures before they are publicly reported. One commenter expressed concern that delaying the public reporting of first year cost measures for the first 2 years they are in use, stating it would slow the progress toward full Quality Payment Program implementation and in fostering evaluation of more clinicians reporting a consistent set of measures. Another commenter recommended, separately from the other cost measures, that we consider extending the timeframe for which the new episode-based cost measures are publicly reported, so that there is time to gain experience with collecting and analyzing these measures.

Response: We agree that not publicly reporting first-year data on cost measures for the first 2 years they are in use is sufficient time to gain experience with them, including for the new episode-based cost measures, before they are considered for public reporting and believe 2 years also meets the goal of providing more timely and transparent information to the public on clinician performance for making their healthcare decisions. We believe that waiting 3 years to publicly report first year measures hinders the ability to provide the public with transparent information after clinicians will have already received such feedback and also reduces the non-financial incentive for clinicians to improve their performance. Additionally, we do not believe that delaying the public reporting of first year quality measures for the first 2 years they are in use delays Quality Payment Program implementation and in fostering evaluation of more clinicians reporting a consistent set of measures, as the cost performance category's full implementation is already delayed. We also do not believe there is a need or benefit to set a different timeframe for episode-based measures than there is for other cost measures that will also have 2 years of usage prior to being considered for public reporting.

After consideration of the comments, we are finalizing our proposal to revise § 414.1395(c) to indicate that we will not publicly report first year cost measures for the first 2 years a measure is in use.

(4) Improvement Activities

In the CY 2018 Quality Payment Program final rule (82 FR 53826), we finalized a policy to include a subset of improvement activities information on Physician Compare, either on the profile pages or in the downloadable database, if technically feasible, for all future years. This includes all available activities reported via all available collection types, and applies to both MIPS eligible clinicians and groups. For those eligible clinicians and groups that successfully meet the improvement activities performance category requirements, this information will be posted on Physician Compare as an indicator. We also finalized for all future years to publicly report first year activities if all other public reporting criteria are satisfied.

(5) Promoting Interoperability (PI)

In the CY 2018 Quality Payment Program final rule (82 FR 53827), we finalized a policy to include an indicator on Physician Compare for any eligible clinician or group who successfully meets the Promoting Interoperability performance category, as technically feasible, for all future years. ''Successful'' performance is defined as obtaining the base score of 50 percent (82 FR 53826). We also finalized a policy to include on Physician Compare, either on the profile pages or in the downloadable database, as technically feasible, additional information, including, but not limited to, objectives, activities, or measures specified in the CY 2018 Quality Payment Program final rule (82 FR 53827; see 82 FR 53663 through 53688). This includes all available objectives, activities, or measures reported via all available collection types, and applies to both MIPS eligible clinicians and groups (82 FR 53827). We will use statistical testing and website user testing to determine how and where objectives, activities, and measures are reported on Physician Compare. We also finalized for all future years to publicly report first year Promoting Interoperability objectives, activities, and measures if all other public reporting criteria are satisfied.

In addition, we finalized that we will indicate ''high'' performance, as technically feasible and appropriate, in year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019). ''High'' performance is defined as obtaining a score of 100 percent (82 FR 53826 through 53827).

As the Quality Payment Program progresses into year 3, and consistent with our work to simplify the requirements under the Promoting Interoperability performance category of MIPS, we proposed not to include the indicator of ''high'' performance and to maintain only an indicator for ''successful'' performance in the Promoting Interoperability performance category beginning with year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019) (83 FR 35988). Not including the ''high'' performance indicator while maintaining the ''successful'' performance indicator continues to provide useful information to patients and caregivers without burdening website users with the additional complexity of accurately differentiating between ''successful'' and ''high'' performance, as this proved difficult for users in testing. User testing to date shows that website users value this information overall, however, as they appreciate knowing clinicians and groups are effectively using EHR technology to improve care quality (83 FR 35988).

We requested comment on our proposal not to include the indicator for ''high'' performance in the Promoting Interoperability performance category beginning with year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019) (83 FR 35988).

The following is a summary of the comments we received on our proposal and our responses.

Comment: The majority of commenters supported the proposal to move to a designation of ''successful'' only and to remove the ''high'' designation in the Promoting Interoperability performance category, as it offers a clear indication that clinicians are effectively using EHRs and would make the user experience more straightforward than delineating between multiple indicators. One commenter opposed the proposal to only include a ''successful'' indicator, since in future years it would be difficult to be ''successful,'' as defined, when the base scores, performance scores, and bonus scores are changed or removed. Another commenter requested clarification on how ''successful'' would be defined when the Promoting Interoperability performance category no longer includes a base score.

Response: We agree that moving from having both a ''successful'' and ''high'' indicator of an eligible clinician or group's Promoting Interoperability performance to having a single indicator of ''successful'' not only shows that clinicians are effectively using EHRs, but also is easier for patients to understand. Additionally, it is more technically feasible to designate a single ''successful'' indicator than both a ''successful'' and ''high'' indicator as the Promoting Interoperability performance category scoring methodology evolves and as we evaluate operational facets of the data. We wish to also clarify that having only a ''successful'' indicator will apply to individuals and groups who have a Promoting Interoperability performance category score above zero.

After consideration of the public comments received, we are finalizing our proposal to not include the indicator of ''high'' performance and to maintain only an indicator for ''successful'' performance in the Promoting Interoperability performance category beginning with year 2 of the Quality Payment Program. We note that in the CY 2017 Quality Payment Program final rule (81 FR 77397), we finalized a policy to include, as technically feasible, additional indicators, including but not limited to indicators such as, identifying if the eligible clinician or group scores high performance in patient access, care coordination and patient engagement, or health information exchange. We have since determined that it is not technically feasible to include an indicator of ''high'' performance that meets our public reporting standards as defined at § 414.1395(b) for year 1 of the Quality Payment Program. The reason we are not reporting this indicator, is because based upon conducting analysis against our public reporting standards, the scoring variability in the Promoting Interoperability performance category of the Quality Payment Program (year 1 to year 3) creates challenges that we are still uncovering for making the data useful to Physician Compare's primary patient and caregiver audience. Additionally, in reviewing the year 1 data (which was not available at the time the CY 2019 proposed rule was released) we have learned through user testing that patients and caregivers find clinician and group usage of EHR technology to generally be a meaningful indicator of quality, regardless of whether ''successful'' or ''high'' was noted. That is, including the word ''high'' did not result in patients and caregivers believing the clinician or group to be of higher quality than those that had the word ''successful'' next to their Promoting Interoperability performance category indicator. Therefore, the high performing indicator will not be reported in year 1, 2, 3 or future years of the Quality Payment Program on Physician Compare.

As noted above, we previously defined ''successful'' performance as obtaining the base score of 50 percent (82 FR 53826). As discussed in section III.I.3.h.(5) of this final rule, the Promoting Interoperability performance category will no longer have a base score beginning with year 3. To account for this change, we are finalizing a modified definition of ''successful'' performance to mean a Promoting Interoperability performance category score above zero beginning with year 3. We will include the modified indicator (above zero) for years 1, 2, and 3 to avoid confusion and preserve year-to-year comparability, and the previously finalized indicator (base score) for years 1 and 2 for transparency and consistency with our previously finalized policy, as technically feasible.

We also solicited comment on the type of EHR utilization performance information stakeholders would like CMS to consider adding to Physician Compare. This information may be considered for possible future inclusion on the website. We did not receive any comments.

(6) Achievable Benchmark of Care (ABC™)

Benchmarks are important to ensuring that the quality data published on Physician Compare are accurately understood. A benchmark allows website users to more easily evaluate the information published by providing a point of comparison between groups and between clinicians. In the CY 2018 Quality Payment Program final rule (82 FR 53829), we finalized a policy to use the Achievable Benchmark of Care (ABC™) methodology to determine a benchmark for the quality, cost, improvement activities, and Promoting Interoperability data, as feasible and appropriate, by measure and collection type for each year of the Quality Payment Program based on the most recently available data each year. We also finalized a policy to use this benchmark as the basis of a 5-star rating for each available measure, as feasible and appropriate. For a detailed discussion of the ABC™ methodology, and more information about how this benchmark together with the equal ranges method is currently used to determine the 5-star rating system for Physician Compare, see the CY 2018 Quality Payment Program final rule (82 FR 53827 through 53829). Additional information, including the Benchmark and Star Rating Fact Sheet, is available on the Physician Compare Initiative website at *https://www.cms.gov/*

Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/index.html. We appreciate comments received for this section, but since no proposals were made, these comments are outside the scope of this section and the proposed rule.

(a) Historical Data-Based Benchmarks

Benchmarks, and the resulting star rating, are valuable tools for patients and caregivers to use to best understand the performance information included on Physician Compare. Benchmarks can also help the clinicians and groups reporting performance information understand their performance relative to their peers, and therefore, help foster continuous quality improvement. In the initial years of the Quality Payment Program, we anticipated year-to-year changes in the measures available. As noted, we previously finalized a policy to determine the benchmark using the most recently available data (82 FR 53829). This ensured that a benchmark could be calculated despite potential year-to-year measure changes, but it also meant that the benchmark was not known to clinicians and groups prior to the performance period.

By year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020), we expect enough year-to-year stability in the measures available for reporting across all MIPS performance categories to use historical data to produce a reliable and statistically sound benchmark for most measures, by measure and collection type (83 FR 35988). Therefore, we proposed to modify our existing policy to use the ABC™ methodology to determine benchmarks for the quality, cost, improvement activities, and Promoting Interoperability performance categories based on historical data, as feasible and appropriate, by measure and collection type beginning with year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020) (83 FR 35988). Specifically, benchmarks would be based on performance data from a baseline period or, if such data is not available, performance data from the performance period. The baseline period would be the 12-month calendar year that is 2 years prior to the applicable performance period. The benchmarks would be published prior to the start of the performance period, as technically feasible. For example, for the CY 2019 performance period, the benchmark developed using the ABC™ methodology would be calculated using CY 2017 performance period data and would be published by the start of CY 2019, as feasible and appropriate. If historical data is not available for a particular measure, we would indicate that and calculate the benchmark using performance data from the performance period. In this example, we would use CY 2019 performance period data to calculate the benchmark for CY 2019 performance period measures, as needed. This approach of utilizing historical data would be consistent with how the MIPS benchmarks are calculated for purposes of scoring the quality performance category. But, most importantly, this approach would provide eligible clinicians and groups with valuable information about the benchmark to meet to receive a 5-star rating on Physician Compare before data collection starts for the performance period (83 FR 35988). We requested comment on this proposal.

The following is a summary of the comments we received regarding our proposal to modify our existing policy to use the ABC™ methodology to determine benchmarks for the quality, cost, improvement activities, and Promoting Interoperability performance categories based on historical data, as feasible and appropriate, by measure and collection type beginning with year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020) and our responses.

Comment: Two commenters supported using benchmarks based on performance from a prior period so that clinicians are able to understand how their measure scores will translate into a 5-star rating. One commenter cautioned that historical benchmarks may penalize those clinicians who successfully managed costs at the onset of the benchmark while inadvertently incentivizing high spenders. Another commenter questioned whether there was enough stability year-to-year in MIPS to create valid and reliable benchmarks. Another commenter noted concern that historical benchmarks would be based on data from a small number of clinicians from various legacy programs such as the Physician Quality Reporting System (PQRS). Another commenter cautioned that CMS needs to consider certain clinicians' ability to affect quality and cost when treating patients. One commenter recommended we postpone using benchmarks for measures with no historical data, for example, a new MIPS measure with no performance data from a prior performance year.

Response: Regarding the concern that historical benchmarks would be based on data from a small number of clinicians from various legacy programs such as the PQRS, we wish to clarify that only historical MIPS data will be used to create benchmarks; for example, year 3, which is 2019 data available for public reporting in late 2020, would use year 1 (CY 2017) MIPS data. Additionally, since these benchmarks will be based on the MIPS performance information that eligible clinicians choose to report, we assume that these measures, upon which the benchmarks will be based, reflect the areas in which eligible clinicians and groups believe they can most affect quality of care furnished. Since we are finalizing that we will not publicly report first year measures for the first 2 years they are in the program, new measures, which have no prior MIPS performance data, would not be available for public reporting until the third year they are in use, at which point there should be historical data upon which to set a historical benchmark if eligible clinicians and groups reported them. If, however, a measure does not meet our public reporting standards, for example due to lack of performance data available or insufficient sample size, then the measure would not be available for public reporting, and would not need a benchmark. Regarding the concern about stability of data, we do believe that if a measure is in use for multiple years of MIPS that the performance should stabilize. We do not expect that clinicians and groups who manage costs effectively in 2017 should suffer a penalty by comparing their 2019 data to 2017 benchmarks. We appreciate the comment about high spenders and will plan to analyze impact. That said, we appreciate the concerns raised and will continuously evaluate the data against our public reporting standards for year-to-year stability. We will also monitor whether the historical benchmarking approach inadvertently creates negative incentives, though early testing has not shown this to be the case. Regarding the suggestion to postpone using benchmarks for measures without historical data, we disagree and believe it is important for website users to understand clinician performance in a meaningful way. Our testing and experience to date has shown that the next best way to create benchmarks for information reported on Physician Compare, in the absence of historical data, is by using information from the most recent performance period.

After consideration of the comments, we are finalizing our proposal to modify our existing policy to use the ABC™ methodology to determine benchmarks for the quality, cost, improvement activities, and Promoting Interoperability performance categories

based on historical data, as feasible and appropriate, by measure and collection type beginning with year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020). Specifically, benchmarks will be based on performance data from a baseline period or, if such data is not available, performance data from the performance period. The baseline period will be the 12-month calendar year that is 2 years prior to the applicable performance period. The benchmarks will be published prior to the start of the performance period, as technically feasible.

(b) QCDR Measure Benchmarks

Currently, only MIPS measures are star rated on Physician Compare. QCDR measures, as that term is used in § 414.1400(e), are publicly reported as percent performance rates. As more QCDR measure data is available for public reporting, and appreciating the value of star rating the measures presented to website users, we believe star rating the QCDR measures will greatly benefit patients and caregivers as they work to make informed health care decisions. Particularly in the quality performance category, we believe that reporting all measure data in the same way will ease the burden of interpretation placed on site users and make the data more useful to them. Therefore, we proposed (83 FR 35988 through 35989) to further modify our existing policy to extend the use of the ABC™ methodology and equal ranges method to determine, by measure and collection type, a benchmark and 5-star rating for QCDR measures, as that term is used in proposed § 414.1400(b)(3), as feasible and appropriate, using current performance period data in year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019), and using historical benchmark data when possible as proposed above, beginning with year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020). We requested comment on this proposal.

The following is a summary of the comments we received to further modify our existing policy to extend the use of the ABC™ methodology and equal ranges method to determine, by measure and collection type, a benchmark and 5-star rating for QCDR measures and our responses.

Comment: One commenter supported using the ABC™ methodology to create a benchmark for MIPS and QCDR measures, as well as creating a 5-star rating for QCDR measures, beginning with year 3 of the Quality Payment Program. Several commenters expressed concern about QCDR benchmarks, noting that measure scores could be misinterpreted on Physician Compare, particularly if the ABC™ methodology is used, since it may differ from the QCDR's own rating methodology and further confuse patients. One commenter also noted that use of the ABC™ methodology for QCDR measures would cause clinician confusion and potentially misrepresent clinicians in the public domain if it results in benchmarks that are also different from the ones used in the MIPS scoring methodology. Another commenter noted the sample size for some QCDR measures will be too small for public reporting and encouraged CMS to work with QCDR measure owners in establishing benchmarks for QCDR measures.

Response: We reiterate our belief that star rating the QCDR measures will greatly benefit patients and caregivers. Because the QCDRs do not uniformly measure performance and each uses their own methodology, as commenters pointed out, in our experience it makes it more difficult for patients to use this information to make informed healthcare decisions. Regarding the concern about differences in MIPS scoring benchmarks and public reporting benchmarks, we note that we will continue to evaluate approaches to alignment, but reiterate that it is not always necessary or ideal to use the same methodology for scoring and public reporting given the unique goals of each. QCDR measures will undergo the same statistical testing as other measures do to ensure they meet our public reporting standards before they are publicly reported, and this testing does account for sample size concerns.

After consideration of the comments, we are finalizing our proposal to further modify our existing policy to extend the use of the ABC™ methodology and equal ranges method to determine, by measure and collection type, a benchmark and 5-star rating for QCDR measures, as that term is used in proposed § 414.1400(b)(3), as feasible and appropriate. This benchmark will use current performance period data in year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019), and using historical benchmark data when possible as proposed above, beginning with year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020).

(7) Voluntary Reporting

In the CY 2018 Quality Payment Program final rule (82 FR 53830), we finalized a policy to make available for public reporting all data submitted voluntarily across all MIPS performance categories, regardless of collection type, by eligible clinicians and groups that are not subject to the MIPS payment adjustments, as technically feasible, for all future years. If an eligible clinician or group that is not subject to the MIPS payment adjustment chooses to submit data on quality, cost (if applicable), improvement activities, or Promoting Interoperability, these data are available for public reporting. We also finalized that during the 30-day preview period, these eligible clinicians and groups may opt out of having their data publicly reported on Physician Compare (82 FR 53830). If these eligible clinicians and groups do not opt out during the 30-day preview period, their data will be available for inclusion on Physician Compare if the data meet all public reporting standards at § 414.1395(b).

(8) APM Data

In the CY 2018 Quality Payment Program final rule (82 FR 53830), we finalized a policy to publicly report the names of eligible clinicians in Advanced APMs and the names and performance of Advanced APMs and APMs that are not considered Advanced APMs related to the Quality Payment Program, such as Track 1 Shared Savings Program Accountable Care Organizations (ACOs), as technically feasible, for all future years. We also finalized a policy to link clinicians and groups and the APMs they participate in on Physician Compare, as technically feasible.

4. Overview of the APM Incentive

a. Overview

Section 1833(z) of the Act requires that an incentive payment be made (or, in years after 2025, a different PFS update) to QPs for achieving threshold levels of participation in Advanced APMs. In the CY 2017 Quality Payment Program final rule (81 FR 77399 through 77491), we finalized the following policies:

- Beginning in payment year 2019, if an eligible clinician participated sufficiently in an Advanced APM during the QP Performance Period, that eligible clinician may become a QP for the year. Eligible clinicians who are QPs are excluded from the MIPS reporting requirements for the performance year and payment adjustment for the payment year.
- For payment years from 2019 through 2024, QPs receive a lump sum incentive payment equal to 5 percent of their prior year's estimated aggregate payments for Part B covered

professional services. Beginning in payment year 2026, QPs receive a higher update under the PFS for the year than non-QPs.

- For payment years 2019 and 2020, eligible clinicians may become QPs only through participation in Advanced APMs.
- For payment years 2021 and later, eligible clinicians may become QPs through a combination of participation in Advanced APMs and Other Payer Advanced APMs (which we refer to as the All-Payer Combination Option).

In the CY 2018 Quality Payment Program final rule (82 FR 53832 through 53895), we finalized clarifications, modifications, and additional details pertaining to Advanced APMs, Qualifying APM Participant (QP) and Partial QP determinations, Other Payer Advanced APMs, Determination of Other Payer Advanced APMs, Calculation of All-Payer Combination Option Threshold Scores and QP Determinations, and Physician-Focused Payment Models (PFPMs). In the CY 2019 PFS proposed rule (83 FR 35989 through 36006), we proposed clarifications and modifications to policies that we previously finalized pertaining to Advanced APMs, QP and Partial QP determinations, Other Payer Advanced APMs, Determination of Other Payer Advanced APMs, and the Calculation of All-Payer Combination Option Threshold Scores and QP Determinations. In this CY 2019 PFS final rule, we respond to public comments on those proposals and announce our final policies.

The following is a summary of the general public comments received on Advanced APMs and our responses:

Comment: Many commenters encouraged us to accelerate our efforts to develop more Advanced APM opportunities for clinicians. These commenters noted that Advanced APMs have great potential to incentivize high-quality and coordinated care while driving down overall costs, and encouraged us to continue developing Advanced APMs to offer clinicians more opportunity to participate in value-based payment and care delivery. Some commenters noted concern that no progress has been made in creating more opportunities for specialists and non-physician professionals to participate in Advanced APMs. The commenters encouraged CMS to develop Advanced APMs that provide opportunities for specialists and non-physician professionals, and to create additional pathways for specialists and non-physician professionals to meaningfully participate in existing Advanced APMs.

Response: We agree that APMs represent an important step forward in our efforts to move our healthcare system from volume-based to value-based care. We note that in 2018 a number of additional Advanced APM opportunities were made available, including the introduction of the Medicare ACO Track 1+ Model, and the introduction of new participants into some existing Advanced APMs, such as the Next Generation ACO Model and Comprehensive Primary Care Plus (CPC+) Model. In 2019, there will be even more available Advanced APM opportunities including the Bundled Payments for Care Improvement Advanced Model, which began in October 2018, and the Maryland Total Cost of Care (which includes the Care Redesign Program and the Maryland Primary Care Program). Additionally, we are in the process of developing several new APMs and Advanced APMs, and continue to work with stakeholders on new model concepts.

Comment: Some commenters suggested CMS establish a clear pathway for clinicians to transition from MIPS to MIPS APMs and then to Advanced APMs. The commenters noted that MIPS APMs represent a stepping stone between MIPS and Advanced APMs providing clinicians a necessary glide path into risk-based contracts.

Response: The Quality Payment Program represents a significant opportunity to collaborate with the clinical community to advance policy that pays for what works—both for clinicians and patients—to create a simpler, sustainable Medicare program. We believe that the Quality Payment Program provides new opportunities to improve care delivery by supporting and rewarding clinicians as they find new ways to engage patients, families, and caregivers and to improve care coordination and population health management. In addition, we believe that by developing a program that is flexible instead of one-size-fits-all, clinicians will be able to choose to participate in a way that is best for them, their practice, and their patients. For clinicians interested in APMs, including MIPS APMs and Advanced APMs, we believe that by setting ambitious yet achievable goals, eligible clinicians will move with greater certainty toward these new approaches that incentivize the delivery of high-value care.

We will continue to reach out to the clinician community and others to partner in the development of ongoing education, support, and technical assistance materials and activities to help clinicians understand Quality Payment Program requirements, how to use available tools to enhance their practices, improve quality, reduce cost, and progress to participation in APMs and Advanced APMs if that is the best choice for their practice.

Comment: Many commenters requested that we implement and test new models recommended by the Physician-Focused Payment Model Technical Advisory Committee (PTAC). The commenters noted that the stakeholder community is also well aware the Department has not selected any PTAC recommended models for testing. Specifically, the commenters noted that the PTAC had received 27 proposals for new physician-focused payment models, 15 of which have been reviewed by the PTAC with comments and recommendations sent to the Secretary. Of those, the commenters stated that 10 proposals were recommended favorably with six recommended for limited scale testing and four recommended for implementation, but the agency has taken no action to test or implement any of the recommended models.

Some commenters suggested we provide more direct, regular feedback to the PTAC and stakeholders to ensure they can address concerns and shortcomings earlier in the development process, so that the PTAC comment and recommendation process can yield physician-led APMs that will be tested and implemented. The commenters also requested that we provide technical assistance to stakeholders working to develop proposals for the PTAC, and specifically that we make claims data available to allow for more detailed financial modeling to be part of the development process.

Many commenters requested that we establish a clear process and timeline for responding to PTAC proposals in the future. The commenters suggested that a 60-day window from the date that the Secretary receives a recommendation from the PTAC would be appropriate.

Response: We believe that PTAC can help us make the shift from a healthcare system that pays for volume to one that pays for value. The commitment to health care payment innovation by the PTAC and the broader stakeholder community is evident in the number and types of specialties represented in the proposals being submitted to PTAC. CMS' Center for Medicare and Medicaid Innovation (CMS Innovation Center) staff have met with stakeholders about proposed models, including some stakeholders that have submitted proposed physician-focused payment models to the PTAC.

We note that while it seems unlikely that all of the features of any PTAC-reviewed proposed model will be tested exactly as presented in the proposal, certain features of proposed models may be incorporated into new or existing models. As the CMS Innovation Center launches new value-based payment and service delivery models, the PTAC's critical review of proposals will be a valuable resource. Additionally, the CMS Innovation Center will further engage with stakeholders that have submitted proposals related to new or existing models to leverage their experiences in the field.

While we will not provide technical assistance to individual stakeholders before they submit proposals, we encourage potential submitters to review the detailed responses from the Secretary to past comments and recommenations from the PTAC to guide development of their proposals. We also encourage stakeholders designing proposals to review the data resources available on the Office of the Assistance Secretary for Planning and Evaluation (ASPE) website at *https://aspe.hhs.gov/resources-public-comment-physician-focused-payment-model-technical-advisory-committee*. Lastly, available from the CMS Innovation Center website is a toolkit for Alternative Payment Model Design (APM Toolkit) to serve as a resource for any entities or individuals interested in developing ideas for APMs (*https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Alternative-Payment-Model-APM-Design-Toolkit.pdf* provides a detailed and comprehensive set of resources to help design an APM).

We note that PTAC meets on a periodic basis to review proposals for physician-focused payment models submitted by individuals and stakeholder entities. The PTAC prepares comments and recommendations on proposals that are received, determining whether such models meet the criteria established by the Secretary for physician-focused payment models in the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008, 77496–77499) and codified at § 414.1465. The PTAC's comments and recommendations generally must be discussed during their public meetings and must be submitted to the Secretary. Subsequently, the Secretary reviews the comments and recommendations submitted by PTAC and posts a detailed response to these recommendations on the CMS Innovation Center website at *https://innovation.cms.gov/initiatives/pfpms/*. Given this standard timeline, we do not believe it would be realistic to set a strict 60-day timeframe for responding to physician-focused payment models recommended by the PTAC. As discussed in the CY 2018 Quality Payment Program final rule, the variation in the number and nature of proposals makes it difficult to establish such a deadline. However, HHS will continue to make every effort to respond expeditiously to the PTAC's comments and recommendations.

b. Terms and Definitions

In the CY 2019 PFS proposed rule, we explained that as we continue to develop the Quality Payment Program, we have identified the need to propose changes to some of the previously finalized definitions. A complete list of the original definitions is available in the CY 2017 Quality Payment Program final rule (81 FR 77537 through 77540).

In the CY 2018 Quality Payment Program final rule, to consolidate our regulations and avoid unnecessarily defining a term, we finalized removal of the defined term for ''Advanced APM Entity'' in § 414.1305 and replaced instances of that term throughout the regulation with ''APM Entity.'' Similarly, we finalized replacing ''Advanced APM Entity group'' with ''APM Entity group'' where it appears throughout our regulations (82 FR 53833). We noted that these changes were technical and had no substantive effect on our policies.

In the CY 2019 PFS proposed rule, to further consolidate our regulations and to clarify any potential ambiguity, we proposed to revise the definition of Qualifying APM Participant (QP) at § 414.1305 to provide that a QP is an eligible clinician determined by CMS to have met or exceeded the relevant QP payment amount or QP patient count threshold for the year based on participation in or with an APM Entity that is participating in an Advanced APM. The current definition of QP is based on an eligible clinician's participation in an Advanced APM Entity, which no longer is a defined term. Simply replacing the term ''Advanced APM Entity'' with the term ''APM Entity,'' as we had in the CY 2018 Quality Payment Program final rule, does not fully convey the definition of QP because, as noted at the time, an APM Entity can participate in an APM that is, or is not, an Advanced APM; and QP status is attainable only through participation in an Advanced APM (82 FR 53833). Again we note that this proposed change is technical and will not have a substantive effect on our policies.

We solicited comments on this proposal.

We did not receive any comments in response to this proposal.

We are finalizing our proposal to revise the definition of Qualifying APM Participant (QP) at § 414.1305 to provide that a QP is an eligible clinician determined by CMS to have met or exceeded the relevant QP payment amount or QP patient count threshold for the year based on participation in or with an APM Entity that is participating in an Advanced APM.

c. Advanced APMs

(1) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77408), we finalized the criteria that define an Advanced APM based on the requirements set forth in sections 1833(z)(3)(C) and (D) of the Act. An Advanced APM is an APM that:

- Requires its participants to use certified EHR technology (CEHRT) (81 FR 77409 through 77414);
- Provides for payment for covered professional services based on quality measures comparable to measures under the quality performance category under MIPS (81 FR 77414 through 77418); and
- Either requires its participating APM Entities to bear financial risk for monetary losses that are in excess of a nominal amount, or is a Medical Home Model expanded under section 1115A(c) of the Act (81 FR 77418 through 77431). We refer to this criterion as the financial risk criterion.

(2) Summary of Proposals

In the CY 2019 PFS proposed rule (83 FR 35989–35992), we included the following proposals, each of which is discussed in further detail below:

Use of CEHRT

- We proposed to revise § 414.1415(a)(i) to specify that an Advanced APM must require at least 75 percent of eligible clinicians in each APM Entity use CEHRT as defined at § 414.1305 to document and communicate clinical care with patients and other health care professionals.

MIPS-Comparable Quality Measures

- We proposed to revise § 414.1415(b)(2) to clarify, effective January 1, 2020, that at least one of the quality measures upon which an Advanced APM bases the payment must either be finalized on the MIPS final list of measures, as described in § 414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid.
- We also proposed to revise § 414.1415(b)(3), effective January 1, 2020, to provide that at least one

outcome measure, for which measure results are included as a factor when determining payment to participants under the terms of the APM must either be finalized on the MIPS final list of measures as described in § 414.1330, endorsed by a consensus-based entity; or determined by CMS to be evidence-based, reliable, and valid.

Bearing Financial Risk for Monetary Losses

- We proposed to revise § 414.1415(c)(3)(i)(A) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

(3) Use of CEHRT

(a) Overview

In the CY 2017 Quality Payment Program final rule, we finalized that an Advanced APM must require at least 50 percent of eligible clinicians in each APM Entity to use CEHRT as defined at § 414.1305 to document and communicate clinical care with patients and other health care professionals. Further, we proposed but did not finalize an increase to the requirement wherein Advanced APMs must require 75 percent CEHRT use in the subsequent year. Instead we maintained the 50 percent CEHRT use requirement for the second performance year and beyond and indicated that we would consider making any potential changes through future rulemaking (81 FR 77412).

(b) Increasing the CEHRT Use Criterion for Advanced APMs

In the CY 2019 PFS proposed rule, we proposed that, beginning for CY 2019, to be an Advanced APM, the APM must require at least 75 percent of eligible clinicians in each APM Entity use CEHRT as defined at § 414.1305 to document and communicate clinical care with patients and other health care professionals.

According to data collected by the Office of the National Coordinator for Health Information Technology (ONC), over 3 in 4 office-based physicians adopted a certified EHR in CY 2015,[32] and approximately 9 in 10 clinicians have 2015 Edition certified technology available from their EHR developer.[33] Additionally, in response to the CY 2017 Quality Payment Program proposed rule, commenters encouraged us to raise the CEHRT use criterion to 75 percent (see 81 FR 77411). We believe that this proposed change aligns with the increased adoption of CEHRT among providers and suppliers that is already happening, and will encourage further CEHRT adoption. We further believe that most existing Advanced APMs already include provisions that would require participants to adhere to the level of CEHRT use specified in our regulations, and therefore this increase will not negatively impact the Advanced APM status of those APMs.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Many commenters supported our proposal to increase the Advanced APM minimum CEHRT use threshold from 50 percent to 75 percent in 2019. Some commenters noted that the use of CEHRT is a fundamental component of any Advanced APM and that such APMs are more likely to be successful if physicians are able to receive information on their patients in a seamless manner, as well as document and communicate clinical care with patients and other health care professionals.

Response: We appreciate the commenters' support of our proposal to increase the Advanced APM minimum CEHRT use threshold from 50 percent to 75 percent beginning in 2019.

Comment: Many commenters requested that CMS not finalize the proposed increase in the Advanced APM minimum CEHRT use threshold from 50 percent to 75 percent beginning in 2019. Some commenters stated that such an increase could be too burdensome for some APM participants, especially in light of the regulatory requirement to upgrade from 2014 Edition CEHRT to 2015 Edition CEHRT in CY 2019. Other commenters noted the proposed increase could create a barrier to entry into Advanced APMs or create additional obstacles in designing APMs targeted for small or rural practices.

Response: We do not believe that the proposed increase in the Advanced APM minimum CEHRT use threshold from 50 to 75 percent will be burdensome for APM participants. As noted above, approximately 9 in 10 clinicians have 2015 Edition certified technology available from their most recently reported EHR developer, and we believe it is appropriate to require the use of 2015 Edition CEHRT beginning in CY 2019. Also, in the CY 2017 Quality Payment Program final rule, we acknowledged that eligible clinicians would be expected to upgrade from technology certified to the 2014 Edition to technology certified to the 2015 Edition for use in 2018, and that some eligible clinicians who had not yet adopted CEHRT may wish to delay acquiring CEHRT products until a 2015 Edition certified product is available. We also note that the requirement to use 2015 Edition CEHRT was delayed in the CY 2018 Quality Payment Program final rule (82 FR 53671–53672), to provide eligible clinicians an additional year to upgrade from technology certified to the 2014 Edition to technology certified to the 2015 Edition for use in 2019. Further, we note that most current Advanced APMs already include provisions that would require participants to adhere to this new level of CEHRT use specified in our regulations, and therefore this increase will not negatively impact the Advanced APM status of those APMs. Moving forward, though, we will consider the applicability of the CEHRT requirement for any potential models designed specifically for small or rural practices.

Comment: Many commenters requested that we consider delaying our proposal to increase the Advanced APM minimum CEHRT use threshold from 50 percent to 75 percent until CY 2020. Commenters stated there already is a regulatory requirement to upgrade to 2015 edition CEHRT in CY 2019 and that clinicians participating in Advanced APMs should not be subject to additional health information technology requirements in a single year. Commenters also noted that maintaining the current Advanced APM minimum CEHRT use threshold for an additional year will allow time for organizations and clinicians to implement the upgrade to 2015 edition CEHRT and not discourage smaller practices that are in the process of upgrading their systems from participating in Advanced APMs.

Response: We appreciate commenters' concerns, but as noted previously in this final rule, the requirement to use 2015 Edition CEHRT was delayed in the CY 2018 Quality Payment Program final rule (82 FR 53671 through 53672), to provide eligible clinicians an additional year to upgrade from technology

[32] Office of the National Coordinator for Health Information Technology. 'Office-based Physician Electronic Health Record Adoption,' Health IT Quick-Stat #50. *dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php*. December 2016.

[33] Office of the National Coordinator for Health Information Technology. '2015 Edition Market Readiness for Hospitals and Clinicians,' Health IT Quick-Stat #55. *dashboard.healthit.gov/quickstats/pages/2015-edition-market-readiness-hospitals-clinicians.php*. October 2018.

certified to the 2014 Edition to technology certified to the 2015 Edition for use in 2019. We believe organizations and clinicians had sufficient time to implement upgrades and that it is appropriate to require the use of 2015 Edition CEHRT beginning in CY 2019. Thus, we believe a delay in implementation of the increase in the Advanced APM minimum CEHRT use threshold increase is unnecessary.

Comment: Many commenters requested that CMS phase in the increase in the Advanced APM minimum CEHRT use threshold over time, or develop a glide path more reflective of the multi-year contracting cycles of APMs given that current contracts with Advanced APMs, were signed with the current Advanced APM minimum CEHRT use threshold in place. Some commenters also suggested that CMS could retain the current 50 percent Advanced APM minimum CEHRT use threshold, but allow APM Entities to attest that an additional percentage of eligible clinicians are either using CEHRT or other health information technology that augments or is an extension of CEHRT to achieve the specific goals of the APM.

Response: We reiterate that in the CY 2017 Quality Payment Program final rule, we stated that setting the threshold at 50 percent of eligible clinicians would allow APMs sufficient room to meet this requirement even if the APM includes some participants who do not have internet access, lack face-to-face interactions with patients, or are hospital-based. At that time, we recognized commenters' concerns that raising the threshold to 75 percent in 2018 risked creating an overly rigorous standard for Advanced APMs and that it would be prudent to wait until we have more information on how the threshold would impact specific APMs, such as specialty APMs, before increasing the threshold. As noted previously in this final rule, we now understand that certified EHR adoption has been more widespread, and therefore do not believe that it is necessary to phase in the increase in the Advanced APM minimum CEHRT use threshold over time any more so than we already have by maintaining the threshold at 50 percent for the 2017 and 2018 QP performance periods. We also note that most current Advanced APMs already include provisions that require participants to adhere to this new level of CEHRT use specified in our regulations, and therefore this increase will not negatively impact the Advanced APM status of those APMs.

Comment: One commenter suggested that CMS provide flexibility for APM Entities participating in Advanced APMs by allowing them to include eligible clinicians in the 75 percent threshold calculation who are actively working with their EMR vendors to transition to the 2015 Edition CEHRT. The commenter noted that there may be instances where EMR vendors are finalizing their certification process during the 2019 performance year, and that may prevent an APM Entity from fully complying with the 75 percent threshold.

Response: We reiterate that the Advanced APM CEHRT use criterion applies to APMs and the requirements they impose on participating APM Entities, not to the individual APM Entities participating in APMs. This means that once an APM has been determined to be an Advanced APM (by requiring the specified percentage of eligible clinicians in each of its participating APM Entities to use CEHRT), the methods used in the Advanced APM to ascertain whether the required percentage of CEHRT use is met may be unique to each APM and may not involve a threshold calculation. We acknowledge there may be instances where EMR vendors are finalizing their certification process, but as noted previously, the requirement to use 2015 Edition CEHRT was delayed to provide eligible clinicians an additional year to upgrade from technology certified to the 2014 Edition to technology certified to the 2015 Edition for use in 2019. Therefore, we believe it is appropriate to require the use of 2015 Edition CEHRT beginning in CY 2019.

Comment: Many commenters noted that the proposed increase in the Advanced APM minimum CEHRT use threshold could limit the ability of non-physician professionals, such as physical therapists, occupational therapists, audiologists, and speech-language pathologists, to meaningfully participate in APMs. The commenters noted that current CEHRT requirements are designed for prescribing professionals and do not capture tasks performed by non-physician professionals using different types of EHRs. Specifically, the commenters stated that the EHRs non-physician professionals often use have not been taken into account by ONC in developing the CEHRT standards and certification criteria, and therefore, they would not be able to meet the definition of CEHRT required for purposes of the Advanced APM minimum CEHRT use threshold. The commenters suggested that CMS establish a dedicated CEHRT program for non-physician and non-prescribing professionals and that CMS offer assistance in the form of funding and technical support to help these types of clinicians participate in Advanced APMs.

Response: We reiterate that the Advanced APM minimum CEHRT use threshold applies to APMs and the requirements they impose on participating APM Entities, not to the individual APM Entities participating in APMs. We also note that the Advanced APM minimum CEHRT use threshold does not mean that all eligible clinicians in each participating APM Entity are required to use CEHRT, and that the methods used in the Advanced APM to ascertain whether the required percentage of CEHRT use is met may be unique to each APM. This means there can be a percentage of eligible clinicians participating in an APM Entity who are not using CEHRT and the APM Entity will still be in compliance with the APM's terms and conditions. Understanding this may have a greater effect on non-physician or non-prescribing eligible clinicians, moving forward, we will monitor this issue for new APMs and will consider possible solutions to facilitate participation in Advanced APMs by non-physician or non-prescribing eligible clinicians that may not use CEHRT due to lack of certified systems for that specific specialty.

After considering public comments, we are finalizing our proposal that, for QP Performance Periods beginning in 2019, to be an Advanced APM, the APM must require at least 75 percent of eligible clinicians in each APM Entity (or, for APMs in which hospitals are the APM Entities, each hospital, as specified in our current regulation) to use CEHRT as defined at § 414.1305 to document and communicate clinical care with patients and other health care professionals. We are amending § 414.1414(a)(1) to reflect this change.

(4) MIPS-Comparable Quality Measures

(a) Overview

In the CY 2017 Quality Payment Program final rule, we explained that one of the criteria for an APM to be an Advanced APM is that it must provide for payment for covered professional services based on quality measures comparable to measures under the performance category described in section 1848(q)(2)(A) of the Act, which is the MIPS quality performance category. We generally refer to these measures in the remainder of this discussion as ''MIPS-comparable quality measures.'' We also explained that we interpret this criterion to require the APM to incorporate quality measure results as a factor when determining

payment to participants under the terms of the APM (81 FR 77414).

In the CY 2017 Quality Payment Program proposed rule, we proposed that to be an Advanced APM, an APM must base payment on quality measures that are evidence-based, reliable, and valid; and that at least one measure must be an outcome measure unless there is not an applicable outcome measure on the MIPS quality list at the time the APM is developed. The required outcome measure does not have to be one of those on the MIPS quality measure list. We did not specify that the outcome measure is required to be evidence-based, reliable, and valid. (81 FR 28302). We finalized these policies in the CY 2017 Quality Payment Program final rule and codified at § 414.1415(b).

(b) General Quality Measures: Evidence-Based, Reliable, and Valid

In the CY 2017 Quality Payment Program final rule, we codified at § 414.1415(b)(2) that at least one of the quality measures upon which an Advanced APM bases the payment must have an evidence-based focus, be reliable, and valid, and meet at least one of the following criteria: Used in the MIPS quality performance category as described in § 414.1330; endorsed by a consensus-based entity; developed under section 1848(s) of the Act; submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or any other quality measures that CMS determines to have an evidence-based focus and to be reliable and valid.

It has come to our attention that some have interpreted § 414.1415(b)(2) to mean that measures on the MIPS final list or submitted in response to the MIPS Call for Quality Measures necessarily are MIPS-comparable quality measures, even if they are not evidence-based, reliable, and valid. We did not intend to imply that any measure that was merely submitted in response to the annual call for quality measures or developed using Quality Payment Program funding will automatically qualify as MIPS-comparable even if the measure was never endorsed by a consensus-based entity, adopted under MIPS, or otherwise determined to be evidence-based, reliable, and valid. Although we believe such measures may be evidence-based, reliable, and valid, we did not intend to consider them so for purposes of § 414.1415(b)(2) without independent verification by a consensus-based entity, or based on our own assessment and determination, that they are evidence-based, reliable, and valid. We further believe the same principle applies to Qualified Clinical Data Registry (QCDR) measures. If QCDR measures are endorsed by a consensus-based entity they are presumptively considered MIPS-comparable quality measures for purposes of § 414.1415(b)(2); otherwise we would have needed independent verification, or to make our own assessment and determination, that the measures are evidence-based, reliable, and valid before considering them to be MIPS-comparable quality measures (see 81 FR 77415 through 77417).

Because of the potential ambiguity in the existing definition and out of an abundance of caution to avoid any adverse impact on APM entities, eligible clinicians, or other commenters, we have used the more permissive interpretation of the regulation text, wherein measures developed under section 1848(s) of the Act and submitted in response to the MIPS Call for Quality Measures will meet the quality criterion in implementing the program thus far, and intend to use this interpretation for the 2019 QP Performance Period until our new proposal described, in this final rule, is effective on January 1, 2020. Recognizing that APMs and other payer payment arrangements that we might consider for Advanced APM and Other Payer Advanced APM determinations are well into development for 2019, we proposed to amend § 414.1415(b)(2) to be effective as of January 1, 2020. Specifically, we proposed that at least one of the quality measures upon which an Advanced APM bases payment must be finalized on the MIPS final list of measures, as described in § 414.1330; be endorsed by a consensus-based entity; or otherwise determined by CMS to be evidenced-based, reliable, and valid.

That is, for QP Performance Period 2020 and all future QP Performance Periods, we would treat any measure that is either included in the MIPS final list of measures or has been endorsed by a consensus-based entity as presumptively evidence-based, reliable, and valid. All other measures would need to be independently determined by CMS to be evidence-based, reliable, and valid, to be considered MIPS-comparable quality measures.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Many commenters supported the proposal. Some commenters suggested that Advanced APMs should be required to include more than one MIPS-comparable quality measure.

Response: We appreciate the commenters' support of our proposal. We reiterate that the quality measures criterion stipulates that to be an Advanced APM an APM must require at least one of the quality measures upon which an Advanced APM bases payment to be MIPS-comparable. This does not preclude an Advanced APM from including more than one MIPS-comparable quality measure. However, we also note that under the statute, not all quality measures under which an APM is assessed are required to be MIPS-comparable and not all payments under the APM must be based on MIPS-comparable quality measures. As such, we believe that by requiring only one quality measures upon which an Advanced APM bases payment to be MIPS-comparable, APMs have the latitude to base payment on quality measures that meet the goals of the APM and assess the quality of care provided to the population of patients that the APM participants are serving.

Comment: One commenter suggested that CMS consider Core Quality Measure Collaborative (CQMC) endorsement as meeting the criterion for a measure being endorsed by a consensus-based entity. The commenter noted that as more health care providers move toward the adoption of the CQMC Core Measure Sets, using the CQMC multi-stakeholder, consensus-based process in determining MIPS-comparable measures would further CMS's goal of alignment between its programs and the CQMC Core Measure Sets.

Response: We note that, under MIPS, we currently try to align with the CQMC measures as much as possible. However, for a measure to meet the criterion of MIPS-comparable, only measures on the list of consensus-endorsed measures maintained by the NQF will currently meet the criterion as being endorsed by a consensus-based entity because NQF is the consensus-based entity that endorses standardized healthcare performance measures for CMS as defined under 1890(b)(2) and (3) of the Act. Therefore, CQMC endorsement does not currently meet the criterion for a measure being endorsed by a consensus-based entity.

We also note, that we believe the revised criteria for the MIPS-comparable measures used in Advanced APMs do not prevent an APM from using a core measure set or using measures developed and included in other CMS programs, but instead provides the criteria for what constitutes a MIPS-comparable measure to meet the Advanced APM requirement (81 FR 77417). Not all quality measures upon

which an APM bases payment are required to be MIPS-comparable, and not all payments under the APM must be based on MIPS-comparable measures. However, at least some payments must be tied to MIPS-comparable measures.

Comment: Some commenters expressed concern that designating measures determined to be evidenced-based, reliable, and valid by CMS as MIPS-comparable amounts to bypassing the standard vetting process of consensus-based entities; publishing in applicable specialty-appropriate, peer-reviewed journals; notice-and-comment rulemaking or separate publication in the **Federal Register**. The commenters suggested that all MIPS-comparable quality measures for the Advanced APM pathway should go through a fair and standard vetting process open to the medical profession rather than being independently determined and approved by CMS.

Response: As finalized in the CY 2017 Quality Payment Program final rule, we established an Innovation Center quality measure review process for those measures that are not NQF-endorsed or included on the final MIPS measure list. The sole purpose of this process is to assess for purposes of the Advanced APM MIPS-comparable measure criterion whether these measures have an evidence-based focus, and are reliable and valid (81 FR 77418). In most instances, the Innovation Center internal committee responsible for this review process will make this determination for measures that were tested for use in Innovation Center models using internal analyses and other experts to demonstrate that the measure meets these criteria, and thus can be used as a MIPS-comparable measure before it is considered for inclusion in MIPS or submitted to the consensus based entity for endorsement consideration. The Innovation Center committee is not a substitute for those existing processes but allows the Innovation Center to innovate by using new measures that meet the same standards as MIPS measures. Therefore, we appreciate the commenters' concerns but do not believe that the Innovation Center quality measure review process bypasses the currently established vetting process for quality measures.

After considering public comments, we are finalizing our proposal to revise § 414.1415(b)(2) to clarify, effective January 1, 2020, to clarify that at least one of the quality measures upon which an Advanced APM bases payment must either be finalized on the MIPS final list of measures, as described in § 414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid.

(c) Outcome Measures: Evidence-Based, Reliable, and Valid

In § 414.1415(b)(3), we generally require that the measures upon which an Advanced APM bases payment must include at least one outcome measure, but specify that this requirement does not apply if CMS determines that there are no available or applicable outcome measures in the MIPS quality measure lists for the Advanced APM's first QP Performance Period. We note that the current regulation does not require that the outcome measure be evidence-based, reliable, and valid. Although it was our general expectation when developing the CY 2017 Quality Payment Program final rule that outcome measures will meet this standard, we did not explicitly include this requirement.

In the CY 2019 PFS proposed rule, we proposed to modify § 414.1415(b)(3) to explicitly require that an outcome measure must be evidence-based, reliable, and valid (unless, as specified in the current regulation, there is no available or applicable outcome measure), so that at least one outcome measure used for purposes of § 414.1415(b)(1) must also be:

- Finalized on the MIPS final list of measures, as described in § 414.1330;
- Endorsed by a consensus-based entity; or
- Determined by CMS to be evidence-based, reliable, and valid.

We proposed that this change would have an effective date of January 1, 2020, and would specifically require that at least one outcome measure for which measure results are included as a factor when determining payment to participants under the terms of the APM must also be a MIPS-comparable quality measure. This is intended to align with our parallel proposal for the Other Payer Advanced APM criteria that we discuss in section III.I.4.e.(3)(d)(iii) of this final rule.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Commenters supported the proposal to explicitly require that an outcome measure must be finalized on the MIPS final list of measures; be endorsed by a consensus-based entity; or otherwise determined by CMS to be evidenced-based, reliable, and valid. One commenter noted that this proposal is reasonable given the general growth in the use of outcome measures.

Response: We appreciate the commenters' support, but note that our proposal does not eliminate the exception for models where there are no available or applicable outcome measures at the performance start date of the model.

Comment: One commenter expressed concerns with the proposal to explicitly require that an outcome measure must be finalized on the MIPS final list of measures; be endorsed by a consensus-based entity; or otherwise determined by CMS to be evidenced-based, reliable, and valid. The commenter noted that there is little variation in outcomes for many surgical procedures as judged by existing outcome measures, and that outcome measures alone are not sufficient to verify that the highest quality care is made available to patients. The commenter suggested CMS implement a framework that could provide a much clearer picture of the quality of care provided to the patient and includes elements such as: Standards-based facility-level verification programs; patient reported experience and outcomes measures; and traditional quality measures including registry and claims-based measures.

Response: We acknowledge the commenter's concerns regarding this use of outcomes measures and appreciate the commenter's suggestions. The Advanced APM requirement for inclusion of one MIPS-comparable measure that is also an outcome measure does not represent a quality measure strategy for Advanced APMs. Rather, the statute identifies outcome measures as a priority measure type, and we wanted to encourage the use of outcome measures for quality performance assessment in APMs. The quality strategy for most Advanced APMs typically includes quality and/or utilization measures that correspond with the key payment and practice transformation activities being tested in the APM. This is why the majority of APMs include more than just one quality measure and many different types of quality performance measures (for example, process, clinical outcome, patient experience of care or patient reported outcome measures) to assess the clinical care provided by eligible clinicians under the APM. Our goal in developing APMs is to ensure that all patients realize better care, improved clinical outcomes and more efficient cost-effective care. We believe our requirement that at least one outcome measure for which measure results are included as a factor when determining payment to participants under the terms of the APM must also be a MIPS-

comparable quality measure further reinforces these goals.

Comment: One commenter expressed concern that CMS is placing too much emphasis on outcome measures. Specifically, the commenter suggested that CMS continue to support the use of process measures until meaningful outcome measures are available in more specialty areas.

Response: We note that we require only one of the quality measures to be an outcome measure, and have established an exception for models where there is no available or applicable outcome measure at the performance start date of the model. As such, we do not agree that we are emphasizing outcome measures over process measures.

After considering public comments, we are finalizing our proposal to revise § 414.1415(b)(3), effective January 1, 2020, to require that at least one outcome measure, for which measure results are included as a factor when determining payment to participants under the terms of the APM, must either be finalized on the MIPS final list of measures as described in § 414.1330, endorsed by a consensus-based entity; or determined by CMS to be evidence-based, reliable, and valid. As specified in the current regulation, this requirement does not apply if CMS determines that there are no available or applicable outcome measures included in the MIPS quality measures list for the Advanced APM's first QP Performance Period.

(5) Bearing Financial Risk for Monetary Losses

(a) Overview

In the CY 2017 Quality Payment Program final rule, we finalized the amount of the generally applicable revenue-based nominal amount standard at 8 percent for the first two QP Performance Periods only, and we sought comment on what the revenue-based nominal amount standard should be for the third and subsequent QP Performance Periods. Specifically, we sought comment on: (1) Setting the revenue-based standard for 2019 and later at up to 15 percent of revenue; or (2) setting the revenue-based standard at 10 percent so long as risk is at least equal to 1.5 percent of expected expenditures for which an APM Entity is responsible under an APM (81 FR 77427).

In the CY 2018 Quality Payment Program final rule, we finalized our proposal to maintain the generally applicable revenue-based nominal amount standard at 8 percent for the 2019 and 2020 QP Performance Periods at § 414.1415(c)(3)(i)(A). We also specified that the standard is based on the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities. We stated that we will address the nominal amount standard for QP Performance Periods after 2020 in future rulemaking (82 FR 53838).

(b) Generally Applicable Nominal Amount Standard

We proposed to amend § 414.1415(c)(3)(i)(A) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Many commenters supported our proposal to maintain the 8 percent generally applicable revenue-based standard for QP performance periods 2021–2024. Commenters noted that maintaining the 8 percent revenue-based standard through the 2024 QP performance period will promote consistency for participants across performance periods and further support CMS' efforts to transition clinicians into Advanced APMs.

Response: We appreciate the commenters' support of our proposal to maintain the 8 percent generally applicable revenue-based standard for QP performance periods 2021–2024.

Comment: Two commenters suggested that we limit the generally applicable revenue-based nominal amount standard to only include the average estimated total Part B revenue of participating providers and suppliers in APM Entities, rather than the average estimated total Part A and Part B revenues of providers and suppliers in APM Entities. The commenters stated that by including Part A revenue, CMS significantly disadvantages APM Entities, such as ACOs, that have hospital participants. The commenters noted that the APM Incentive Payment is based on payments for Part B covered professional services under the Medicare PFS, and as such, recommends that we revise the generally applicable revenue-based nominal amount standard to only consider Part B revenue under the Medicare PFS.

Response: We note that we did not propose to make changes to the types of revenue that are included in the generally applicable revenue-based nominal amount standard. However, we note that we disagree that the generally applicable revenue-based nominal amount standard should only include Part B revenues, as many APM Entities participating in Advanced APMs often include hospitals and other types of institutional providers or suppliers that may receive both Part A and B revenues. Additionally, the generally applicable revenue-based nominal amount standard is inclusive only of the Medicare Part A and B revenues of providers and suppliers in participating APM Entities; therefore, if the providers and suppliers in a given APM Entity have only Medicare Part B revenues, only such revenues will be considered.

Comment: Some commenters suggested we reconsider establishing a separate, lower nominal amount standard for small and rural practices. The commenters stated that a lower revenue-based nominal amount standard is necessary to ensure that the challenging operational risks and expenses, which put such practices at greater financial risk when compared to larger practices, do not prevent participation in Advanced APMs. The commenters suggested establishing a nominal amount standard for small and rural practices that would be aligned with the Medical Home Model nominal amount standard or set equal to the percentage of the APM incentive payment that an eligible clinician might attain based on their participation in an Advanced APM. The commenters noted that a lower revenue-base nominal amount standard may encourage greater participation in APMs by small and rural practices.

Response: We will continue to monitor the impact of the generally applicable revenue-based nominal amount standard and Medical Home Model nominal amount standard on small practices and those in rural areas. We did not include any proposals in the CY 2019 PFS proposed rule regarding a separate standard for small or rural practices, but may consider revisiting establishing a lower revenue-based nominal amount standard for small practices and those in rural areas in future rulemaking.

Comment: Some commenters requested CMS consider the financial and administrative risk that non-physician practitioners face when joining Advanced APMs. Specifically, the commenters suggested that CMS should adopt a more inclusive interpretation of financial risk for monetary losses by including any losses incurred in the operation of the APM

Entity rather than limiting financial risk only to losses or increased spending in the Medicare program. The commenters stated that the magnitude of risk CMS currently requires for participation in an Advanced APM may prevent many eligible clinicians from considering participation in the limited Advanced APMs available.

Response: As we stated in the CY 2018 Quality Payment Program final rule, we recognize the substantial investments that many APM Entities make to become successful APM participants, and also the financial and administrative burden that eligible clinicians of all types face when deciding to join an APM Entity. Nonetheless, as we discussed in the CY 2017 Quality Payment Program final rule, we continue to believe that there would be significant complexity involved in creating an objective and enforceable standard for determining whether an entity's business risk exceeds a nominal amount. We also reiterate that business risk is generally a cost that is unrelated to performance-based payment under an APM. No matter how well or poorly an APM Entity performs when assessed for purposes of the APM, costs associated with business risk are not reduced or increased correspondingly. Therefore, we maintain our view that business risk is not analogous to performance risk in the APM context because the costs of those activities and investments are not incorporated into the performance-based financial calculations of an APM, and are therefore not appropriate for consideration for purposes of the Advanced APM financial risk criterion (81 FR 77420).

After considering public comments, we are finalizing our proposal to revise § 414.1415(c)(3)(i)(A) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024. We continue to believe that 8 percent of Medicare Parts A and B revenues of all providers and suppliers in participating APM Entities generally represents an appropriate standard for more than a nominal amount of financial risk at this time. We also believe that maintaining a consistent standard for several more years will help APM Entities to plan for multi-year Advanced APM participation. We further believe that maintaining a consistent standard will allow us to evaluate how APM Entities succeed within these parameters over the applicable timeframe.

We also sought comment on whether, as APM entities and participating eligible clinicians grow more comfortable with assuming risk, we should consider increasing the nominal amount standard. Specifically, we requested comments on whether we should consider raising the revenue-based nominal amount standard to 10 percent, and the expenditure-based nominal amount standard to 4 percent starting for QP Performance Periods in 2025 and later.

Several comments stated we should consider raising the revenue-based nominal amount standard to 10 percent, and the expenditure-based nominal amount standard to 4 percent starting for QP Performance Periods in 2025 and later. We thank commenters for their feedback and will take this input into consideration for future years.

(6) Summary of Final Policies

Use of CEHRT

- We are finalizing revisions to § 414.1415(a)(i) to specify that an Advanced APM must require at least 75 percent of eligible clinicians in each APM Entity, or, for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT as defined at § 414.1305 to document and communicate clinical care with patients and other health care professionals.

MIPS-Comparable Quality Measures

- We are finalizing revisions to clarify at § 414.1415(b)(2), effective January 1, 2020, that at least one of the quality measures upon which an Advanced APM bases the payment in paragraph (b)(1) of this section must either be finalized on the MIPS final list of measures, as described in § 414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid.
- We are finalizing revisions at § 414.1415(b)(3), effective January 1, 2020, to provide that at least one outcome measure, for which measure results are included as a factor when determining payment to participants under the terms of the APM must either be finalized on the MIPS final list of measures as described in § 414.1330, endorsed by a consensus-based entity; or determined by CMS to be evidence-based, reliable, and valid.

Bearing Financial Risk for Monetary Losses

- We are finalizing revisions at § 414.1415(c)(3)(i)(A) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

d. Qualifying APM Participant (QP) and Partial QP Determinations

(1) Overview

We finalized policies relating to QP and Partial QP determinations in the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77450).

(2) Summary of Proposals

In the CY 2019 PFS proposed rule (83 FR 3599 through 35994), we included the following proposals, each of which is discussed in further detail below:

QP Performance Period

- We proposed that for each of the three QP determinations, we will allow for claims run-out for 60 days (approximately 2 months), before calculating the Threshold Scores so that the three QP determinations can be completed approximately 3 months after the end of that determination time period.

Partial QP Election To Report to MIPS

- We proposed that when an eligible clinician is determined to be a Partial QP for a year at the individual eligible clinician level, the individual eligible clinician will make an election whether to report to MIPS. If the eligible clinician elects to report to MIPS, they will be subject to the MIPS reporting requirements and payment adjustment. If the eligible clinician elects not to report, they will be excluded from the MIPS reporting requirements and payment adjustment. In the absence of an explicit election to report to MIPS, the eligible clinician will be excluded from the MIPS reporting requirements and payment adjustment. This means that no actions other than the eligible clinician's affirmative election to participate in MIPS will result in that eligible clinician becoming subject to the MIPS reporting requirements and payment adjustment.

(3) QP Performance Period

In the CY 2017 Quality Payment Program final rule, we finalized for the timing of QP determinations that a QP Performance Period runs from January 1 through August 31 of the calendar year that is 2 years prior to the payment year (81 FR 77446–77447). During that QP Performance Period, we will make QP determinations at three separate snapshot dates (March 31, June 30, and August 31), each of which will be a final determination for the eligible clinicians who are determined to be QPs. The QP Performance Period and the three

separate QP determinations apply similarly for both the group of eligible clinicians on a Participation List and the individual eligible clinicians on an Affiliated Practitioner List.

We also finalized that for each of the three QP determinations, we will allow for claims run-out for 3 months, or 90 days, before calculating the Threshold Scores so that QP determinations will be completed approximately 4 months after each snapshot date. As a result, the last of these three QP determinations is complete on or around January 1 of the subsequent calendar year, which is the year immediately prior to the MIPS payment year. For most MIPS data submission types, January 1 of the subsequent calendar year is also the beginning of the MIPS data submission period. This way, eligible clinicians know of their QP status prior to or near the beginning of the MIPS data submission period and know whether they should report any performance period data to MIPS for the applicable MIPS payment year.

Upon further consideration and based on our experience implementing the program to date, we believe providing eligible clinicians notification of their QP status more quickly after each of the three QP determination snapshot dates, and prior to the beginning of the MIPS data submission period after the last determination, will potentially reduce burden for eligible clinicians and APM Entities while improving their overall experience participating in the program.

We proposed that beginning in 2019 for each of the three QP determination dates, we will allow for claims run-out for 60 days (approximately 2 months), before calculating the Threshold Scores so that the three QP determinations will be completed approximately 3 months after the end of that determination time period. We note that this proposal does not affect the QP Performance Period per se, but rather the date by which claims for services furnished during the QP Performance Period will need to be processed for those services to be included in calculating the Threshold Scores. To the extent that claims are used for calculating the Threshold Scores, such claims will have to be processed by no later than 60 days after each of the three QP determination dates, for information on the claims to be included in our calculations.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Many commenters supported the proposal to allow for claims run-out of 60 days (approximately 2 months), before calculating the QP threshold scores so that the three QP determinations can be completed approximately 3 months after the end of that determination time period. Commenters noted the importance for APM Entities to have information about their QP status as soon as possible after each snapshot to determine if they will need to take any additional action to report to MIPS or seek a QP determination under the All-Payer Combination Option should they fall short of the QP thresholds under the Medicare Option.

Response: We appreciate the commenters' support of our proposal to allow for a claims run-out of 60 days before calculating the QP threshold scores so that the three QP determinations can be completed approximately 3 months after the end of that determination time period.

After considering public comments, we are finalizing our proposal that for each of the three QP determinations, we will allow for claims run-out for 60 days (approximately 2 months), before calculating the Threshold Scores so that the three QP determinations can be completed approximately 3 months after the end of that determination time period.

(4) Partial QP Election To Report to MIPS

(a) Overview

Section 1848(q)(1)(C)(ii)(II) of the Act excludes from the definition of MIPS eligible clinician an eligible clinician who is a Partial QP for a year and who does not report on applicable measures and activities as required under MIPS for the year. However, under section 1848(q)(1)(C)(vii) of the Act, an eligible clinician who is a Partial QP for a year and reports on applicable measures and activities as required under the MIPS is considered to be a MIPS eligible clinician for the year.

In the CY 2017 Quality Payment Program final rule, we finalized that following a determination that eligible clinicians in an APM Entity group in an Advanced APM are Partial QPs for a year, the APM Entity will make an election whether to report on applicable measures and activities as required under MIPS. If the APM Entity elects to report to MIPS, all eligible clinicians in the APM Entity will be subject to the MIPS reporting requirements and payment adjustments for the relevant year. If the APM Entity elects not to report, all eligible clinicians in the APM Entity group will be excluded from the MIPS reporting requirements and payment adjustments for the relevant year (81 FR 77449).

We also finalized that in cases where the Partial QP determination is made at the individual eligible clinician level, if the individual eligible clinician is determined to be a Partial QP, the eligible clinician will make the election whether to report on applicable measures and activities as required under MIPS and, as a result, be subject to the MIPS reporting requirements and payment adjustment (81 FR 77449). If the individual eligible clinician elects to report to MIPS, he or she will be subject to the MIPS reporting requirements and payment adjustments for the relevant year. If the individual eligible elects not to report to MIPS, he or she will be excluded from the MIPS reporting requirements and payment adjustments for the relevant year. We note that QP determinations are made at the individual eligible clinician level when the clinician is identified as participating in an Advanced APM on an Affiliated Practitioner List rather than a Participation List, or when an eligible clinician is in more than one APM Entity group in one or more Advanced APMs, and does not achieve QP status as part of any single APM Entity group (see § 414.1425(b)(2) and (c)(4) our regulations).

We also clarified how we consider the absence of an explicit election to report to MIPS or to be excluded from MIPS. We finalized that for situations in which the APM Entity is responsible for making the decision on behalf of all eligible clinicians in the APM Entity group, the group of Partial QPs will not be considered MIPS eligible clinicians unless the APM Entity opts the group into MIPS participation, so that no actions other than the APM Entity's election for the group to participate in MIPS will result in MIPS participation (81 FR 77449).

For eligible clinicians who are determined to be Partial QPs individually, we finalized that we will use the eligible clinician's actual MIPS reporting activity to determine whether to exclude the Partial QP from MIPS in the absence of an explicit election. Therefore, if an eligible clinician who is individually determined to be a Partial QP submits information to MIPS (not including information automatically populated or calculated by CMS on the Partial QP's behalf), we will consider the Partial QP to have reported, and thus to be participating in MIPS. Likewise, if such an individual does not take any action to submit information to MIPS, we will consider the Partial QP to have elected to be excluded from MIPS (81 FR 77449).

(b) Alignment of Partial QP Election Policies

We proposed that when an eligible clinician is determined to be a Partial QP for a year at the individual eligible clinician level, the individual eligible clinician will make an election whether to report to MIPS. If the eligible clinician elects to report to MIPS, they will be subject to MIPS reporting requirements and payment adjustments. If the eligible clinician elects to not report to MIPS, they will not be subject to the MIPS reporting requirements and payment adjustment. If the eligible clinician does not make any election, they will not be subject to the MIPS reporting requirements and payment adjustment.

We note that this proposed policy change would affect only situations where the Partial QP makes no election to either report to MIPS or to be excluded from the MIPS reporting requirements and payment adjustment. Under our proposed policy, all Partial QPs retain the full right to affirmatively decide through the election process whether or not to be subject to the MIPS reporting requirements and payment adjustment; whereas, if the Partial QP does not make any election, they will not be subject to the MIPS reporting requirements and payment adjustment.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Some commenters supported our proposal. Specifically, the commenters supported our proposal to exclude eligible clinicians determined to be a Partial QP for a year at the individual eligible clinician level from the MIPS reporting requirements and payment adjustment, in the absence of an explicit election to report to MIPS. Commenters noted this proposal will help to avoid confusion and prevent inadvertently subjecting eligible clinicians to MIPS reporting requirements and payment adjustments when information has been reported on their behalf.

Response: We appreciate the commenters' support of our proposal to align the Partial QP election policy for eligible clinicians who are determined to be Partial QPs individually and for eligible clinicians who are determined to be Partial QPs at the APM Entity level.

Comment: One commenter expressed concern that our proposal may create additional confusion for eligible clinicians. Specifically, the commenter noted that many eligible clinicians may not be aware that they attained Partial QP status, and that an affirmative election is required to participate in MIPS. The commenter also noted that such clinicians may assume that their MIPS data is being reported on their behalf by their practice or TIN, and as a result may inadvertently forego a potential positive MIPS payment adjustment.

The commenter suggested an alternative approach where CMS would apply the policy which yields the most advantageous MIPS final score and subsequently the most advantageous MIPS payment adjustment. The commenter noted that this alternative approach would work in such a manner that in cases where data is submitted by a Partial QP, or on their behalf, that would earn the Partial QP a MIPS final score resulting in a positive MIPS payment adjustment, CMS would use that data to provide them a MIPS final score, regardless of whether they made an election to participate in MIPS. In cases where data is submitted by a Partial QP, or on their behalf, that would earn the Partial QP a MIPS final score resulting in a negative MIPS payment adjustment, CMS would not use that data to provide them a MIPS final score, and they would be exempt from MIPS based on the Partial QP status.

The commenter noted this alternative approach would eliminate all potential unintended consequences and would be consistent with other CMS policies to use data that yields the most advantageous result. The commenter also noted the alternative approach may further incentivize participation in APMs and reduce burden on both eligible clinicians and CMS because eligible clinicians would no longer have to make an election to affirmatively opt-in or opt-out of MIPS.

Response: We acknowledge that our proposal could, in certain limited instances, create additional confusion for eligible clinicians, particularly eligible clinicians who may not be aware that they attained Partial QP status and an affirmative election is required for them to participate in MIPS. However, we note that clinicians' QP status, including Partial QP status, is accessible via the QPP Participation Status Tool via the Quality Payment Program website at *https://qpp.cms.gov/participation-lookup*. We also continue to believe our proposed approach will allow for greater operational simplicity while minimizing the possibility of unexpected participation in MIPS. We reiterate that all Partial QPs retain the full right to affirmatively decide through the election process whether or not to be subject to the MIPS reporting requirements and payment adjustment.

After considering public comments, we are finalizing our proposal that when an eligible clinician is determined to be a Partial QP for a year at the individual eligible clinician level, the individual eligible clinician will make an election whether to report to MIPS. If the eligible clinician elects to report to MIPS, they will be subject to the MIPS reporting requirements and payment adjustment. If the eligible clinician elects not to report, they will be excluded from the MIPS reporting requirements and payment adjustment. In the absence of an explicit election to report to MIPS, the eligible clinician will be excluded from the MIPS reporting requirements and payment adjustment. This means that no actions other than the eligible clinician's affirmative election to participate in MIPS would result in that eligible clinician becoming subject to the MIPS reporting requirements and payment adjustment.

(5) Summary of Final Policies

In this section, we are finalizing the following policies:

QP Performance Period

- We are finalizing our proposal that for each of the three QP determinations, we will allow for claims run-out for 60 days (approximately 2 months), before calculating the Threshold Scores so that the three QP determinations can be completed approximately 3 months after the end of that determination time period.

Partial QP Election To Report to MIPS

- We are finalizing our proposal that when an eligible clinician is determined to be a Partial QP for a year at the individual eligible clinician level, the individual eligible clinician will make an election whether to report to MIPS. If the eligible clinician elects to report to MIPS, they will be subject to the MIPS reporting requirements and payment adjustment. If the eligible clinician elects not to report, they will be excluded from the MIPS reporting requirements and payment adjustment. In the absence of an explicit election to report to MIPS, the eligible clinician will be excluded from the MIPS reporting requirements and payment adjustment. This means that no actions other than the eligible clinician's affirmative election to participate in MIPS would result in that eligible clinician becoming subject to the MIPS reporting requirements and payment adjustment.

e. All-Payer Combination Option

(1) Overview

Section 1833(z)(2)(B)(ii) of the Act requires that beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the Combination All-Payer and Medicare Payment Threshold Option, which we refer to as the All-Payer Combination Option. In the CY 2017 Quality Payment Program final rule, we finalized our overall approach to the All-Payer Combination Option (81 FR 77459). The Medicare Option focuses on participation in Advanced APMs, and we make QP determinations under this option based on Medicare Part B covered professional services attributable to services furnished through an APM Entity. The All-Payer Combination Option does not replace or supersede the Medicare Option; instead, it will allow eligible clinicians to become QPs by meeting the QP thresholds through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished through Advanced APMs and services furnished through Other Payer Advanced APMs. We finalized that beginning in payment year 2021, we will conduct QP determinations sequentially so that the Medicare Option is applied before the All-Payer Combination Option (81 FR 77438). The All-Payer Combination Option encourages eligible clinicians to participate in payment arrangements that satisfy the Other Payer Advanced APM criteria with payers other than Medicare. It also encourages sustained participation in Advanced APMs across multiple payers.

We finalized that the QP determinations under the All-Payer Combination Option are based on payment amounts or patient counts as illustrated in Tables 36 and 37, and Figures 1 and 2 of the CY 2017 Quality Payment Program final rule (81 FR 77460 through 77461). We also finalized that, in making QP determinations with respect to an eligible clinician, we will use the Threshold Score that is most advantageous to the eligible clinician toward achieving QP status, or if QP status is not achieved, Partial QP status, for the year (81 FR 77475).

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TABLE 57: QP Payment Amount Thresholds – All-Payer Combination Option

Payment Year	2019	2020	2021	2022	2023 and later
QP Payment Amount Threshold					
Medicare Minimum	N/A	N/A	25%	25%	25%
Total			50%	50%	75%
Partial QP Payment Amount Threshold					
Medicare Minimum	N/A	N/A	20%	20%	20%
Total			40%	40%	50%

TABLE 58: QP Patient Count Thresholds – All-Payer Combination Option

Payment Year	2019	2020	2021	2022	2023 and later
QP Patient Count Threshold					
Medicare Minimum	N/A	N/A	20%	20%	20%
Total			35%	35%	50%
Partial QP Patient Count Threshold					
Medicare Minimum	N/A	N/A	10%	10%	10%
Total			25%	25%	35%

FIGURE 4: QP Determination Tree, Payment Years 2021-2022

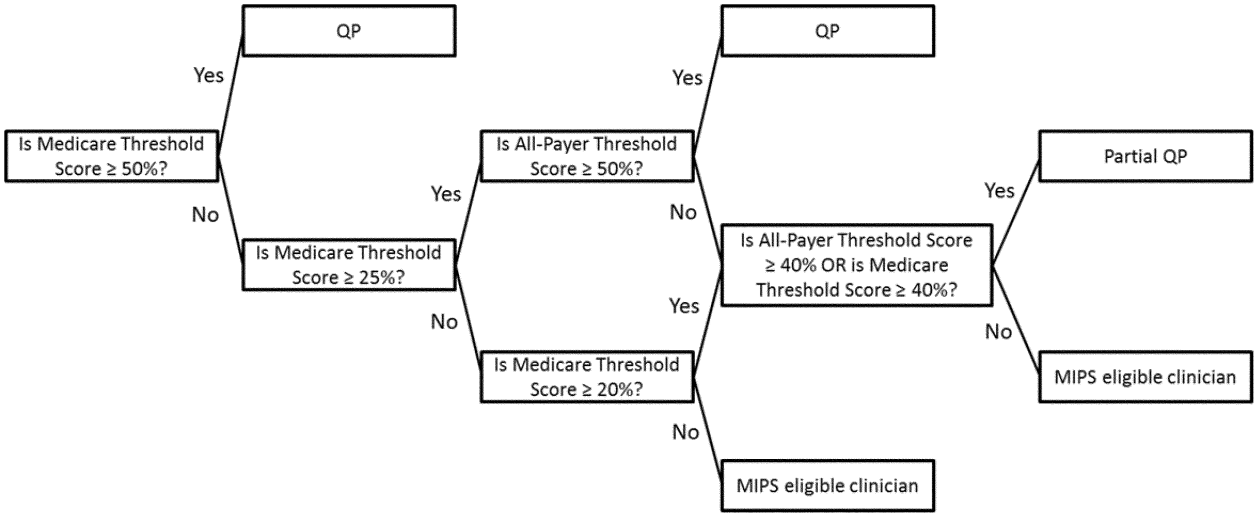
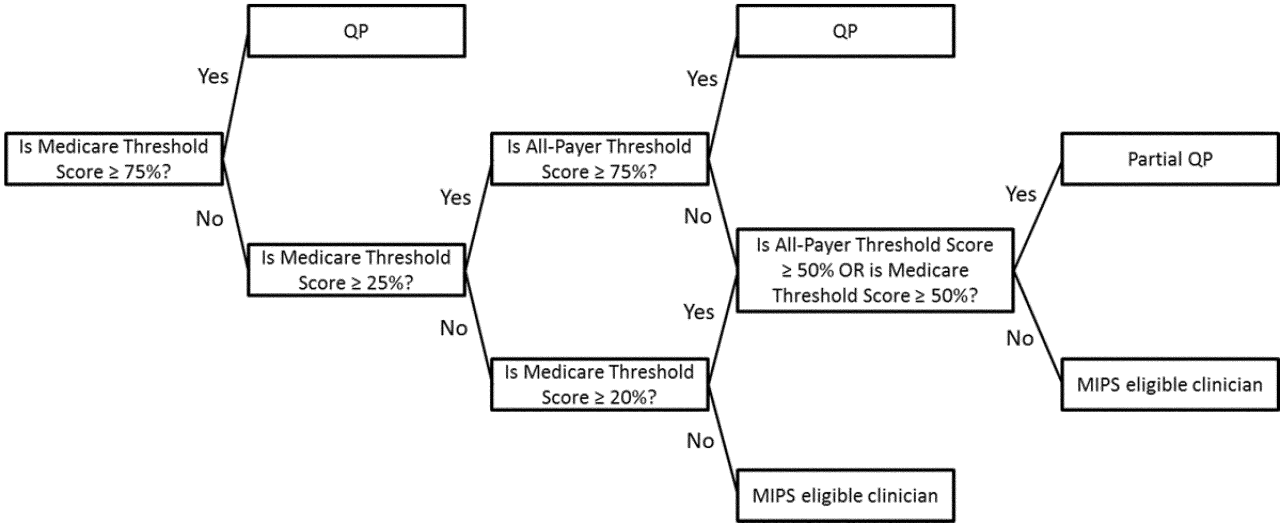


FIGURE 5: QP Determination Tree, Payment Years 2023 and Later



Unlike the Medicare Option, where we have access to all of the information necessary to determine whether an APM meets the criteria to be an Advanced APM, we cannot determine whether an other payer arrangement meets the criteria to be an Other Payer Advanced APM without receiving information about the payment arrangement from an external source. Similarly, we do not have the necessary payment amount and patient count information to determine under the All-Payer Combination Option whether an eligible clinician meets the payment amount or patient count threshold to be a QP without receiving certain information from an external source.

In the CY 2018 Quality Payment Program final rule, we established additional policies to implement the All-Payer Combination Option and finalized certain modifications to our previously finalized policies (82 FR 53844 through 53890). A detailed summary of those policies can be found at 82 FR 53874 through 53876 and 53890 through 53891. In relevant part, we finalized the following:

Payer Initiated Process

- We finalized at § 414.1445(a) and (b)(1) that certain other payers, including payers with payment arrangements authorized under Title XIX (the Medicaid statute), Medicare Health Plan payment arrangements, and payers with payment arrangements aligned with a CMS Multi-Payer Model, can request that we determine whether their other payer arrangements are Other Payer Advanced APMs starting prior to the 2019 QP Performance Period and each year thereafter. We finalized that Remaining Other Payers, including

commercial and other private payers, could request that we determine whether other payer arrangements are Other Payer Advanced APMs starting in 2019 prior to the 2020 QP Performance Period, and annually each year thereafter. We generally refer to this process as the Payer Initiated Other Payer Advanced APM Determination Process (Payer Initiated Process), and we finalized that the Payer Initiated Process would generally involve the same steps for each payer type for each QP Performance Period. If a payer uses the same other payer arrangement in other commercial lines of business, we finalized our proposal to allow the payer to concurrently request that we determine whether those other payer arrangements are Other Payer Advanced APMs as well. This policy is relevant only to the initial year of Payer Initiated Other Payer Advanced APM determinations for which these submissions can be made only by payers with arrangements under Title XIX, Medicare Health Plans, or arrangements aligned with CMS multi-payer models.

Eligible Clinician Initiated Process

- We finalized at § 414.1445(a) and (b)(2) that, through the Eligible Clinician Initiated Process, APM Entities and eligible clinicians participating in other payer arrangements would have an opportunity to request that we determine for the year whether those other payer arrangements are Other Payer Advanced APMs. The Eligible Clinician Initiated Process can be used to submit requests for determinations before the beginning of a QP Performance Period for other payer arrangements authorized under Title XIX. The Eligible Clinician Initiated Process is available for the 2019 QP Performance Period and each year thereafter.

Submission of Information for Other Payer Advanced APM Determinations

- We finalized that, for each other payer arrangement for which a payer requests us to make an Other Payer Advanced APM determination, the payer must complete and submit the Payer Initiated Submission Form by the relevant Submission Deadline.
- We finalized that, for each other payer arrangement for which an APM Entity or eligible clinician requests us to make an Other Payer Advanced APM determination, the APM Entity or eligible clinician must complete and submit the Eligible Clinician Initiated Submission Form by the relevant Submission Deadline.
- We removed the requirement, previously established at § 414.1445(b)(3), that payers must attest to the accuracy of information submitted by eligible clinicians, and we also removed the related attestation requirement at § 414.1460(c). Instead, we finalized an additional requirement at § 414.1445(d) that an APM Entity or eligible clinician that submits information under § 414.1445(c) must certify that, to the best of its knowledge, the information it submits to us is true, accurate, and complete.

QP Determinations Under the All-Payer Combination Option

- We finalized at § 414.1440(e) that eligible clinicians may request that we make QP determinations at the individual eligible clinician level and that APM Entities may request that we make QP determinations at the APM Entity level.
- We finalized at § 414.1440(d)(1) that we will make QP determinations under the All-Payer Combination Option based on eligible clinicians' participation in Advanced APMs and Other Payer Advanced APMs for three time periods of the QP Performance Period: January 1 through March 31; January 1 through June 30; and January 1 through August 31. We finalized that we will use patient or payment data for the same time periods to calculate both the Medicare and the other payer portion of the Threshold Score calculation under the All-Payer Cominbation Option.
- We finalized at § 414.1440(e)(4) that, to request a QP determination under the All-Payer Combination Option, APM Entities or eligible clinicians must submit all of the payment amount and patient count information sufficient for us to make QP determinations by December 1 of the calendar year that is 2 years to prior to the payment year, which we refer to as the QP Determination Submission Deadline.

In this section of the final rule, we address policies within the following topics: Other Payer Advanced APM Criteria; Other Payer Advanced APM determinations; and Calculation of the All-Payer Combination Option Threshold Scores and QP Determinations.

(2) Summary of Proposals

In the CY 2019 PFS proposed rule (83 FR 35999–36006), we included the following proposals, each of which is discussed below:

Other Payer Advanced APM Criteria

- We proposed to change the CEHRT use criterion so that in order to qualify as an Other Payer Advanced APM as of January 1, 2020, the other payer arrangement must require at least 75 percent of participating eligible clinicians in each APM Entity use CEHRT.
- We proposed to allow payers and eligible clinicians to submit evidence as part of their request for an Other Payer Advanced APM determination that CEHRT is used by the requisite percentage of eligible clinicians participating in the payment arrangement (50 percent for 2019, and 75 percent for 2020 and beyond) to document and communicate clinical care, whether or not CEHRT use is explicitly required under the terms of the payment arrangement.
- We proposed the following clarification to § 414.1420(c)(2), effective January 1, 2020, to provide that at least one of the quality measures used in the payment arrangement in paragraph (c)(1) of this regulation must be:

++ Finalized on the MIPS final list of measures, as described in § 414.1330;

++ Endorsed by a consensus-based entity; or

++ Determined by CMS to be evidenced-based, reliable, and valid.

- We proposed to revise § 414.1420(c)(3) to require that, effective January 1, 2020, unless there is no applicable outcome measure on the MIPS quality measure list, an Other Payer Advanced APM must use an outcome measure, that must be:

++ Finalized on the MIPS final list of measures, as described in § 414.1330;

++ Endorsed by a consensus-based entity; or

++ Determined by CMS to be evidenced-based, reliable, and valid.

- We also proposed to revise our regulation at § 414.1420(c)(3)(i) to provide that, for payment arrangements determined to be Other Payer Advanced APMs for the 2019 performance year that did not include an outcome measure that is evidence-based, reliable, and valid, and that are resubmitted for an Other Payer Advanced APM determination for the 2020 performance year (whether for a single year, or for a multi-year determination as proposed in section III.I.4.e.(4)(b) of this final rule), we would continue to apply the current regulation for purposes of those determinations. This proposed revision also applies to payment arrangements in existence prior to the 2020 performance year that are submitted for determination to be Other Payer Advanced APMs for the 2020 performance year and later.

Determination of Other Payer Advanced APMs

- We proposed details regarding the Payer Initiated Process for Remaining Other Payers. To the extent possible, we aligned the Payer Initiated Process for Remaining Other Payers with the previously finalized Payer Initiated Process for Medicaid, Medicare Health Plans, and CMS Multi-Payer Models.
- We proposed to eliminate the Payer Initiated Process that is specifically for CMS Multi-Payer Models. We believe that payers aligned with CMS Multi-Payer Models can submit their arrangements through the Payer Initiated Process for Remaining Other Payers proposed in section III.I.4.e.(4)(c) of this final rule, or through the Medicaid or Medicare Health Plan payment arrangement submission processes.

Calculation of All-Payer Combination Option Threshold Scores and QP Determinations

- We proposed to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who reassigned billing rights under the TIN participate in a single APM Entity. We proposed to modify our regulation at § 414.1440(d) by adding this third alternative to allow QP determinations at the TIN level in instances where all clinicians who have reassigned billing under the TIN participate in a single APM Entity, as well as to assess QP status at the most advantageous level for each eligible clinician.
- We also clarified that, in making QP determinations using the All-Payer Combination Option, eligible clinicians may meet the minimum Medicare threshold using one method, and the All-Payer threshold using the same or a different method. We proposed to codify this clarification by adding § 414.1440(d)(4).
- We proposed to extend the weighting methodology that is used to ensure that an eligible clinician does not receive a lower score on the Medicare portion of their all-payer calculation under the All-Payer Combination Option than the Medicare Threshold Score they received at the APM Entity level in order to apply a similar policy to the proposed TIN level Medicare Threshold Scores.

(3) Other Payer Advanced APM Criteria

(a) Overview

In general, our goal is to align the Advanced APM criteria under the Medicare Option and the Other Payer Advanced APM criteria under the All-Payer Combination Option as permitted by statute and as feasible and appropriate. We believe this alignment helps simplify the Quality Payment Program and encourage participation in Other Payer Advanced APMs (82 FR 53847).

(b) Investment Payments

Some stakeholders have requested that we take into account ''business risk'' costs such as IT, personnel, and other administrative costs associated with APM Entities' participation in Other Payer Advanced APMs when implementing the financial risk standard. We did not propose to modify our financial risk standard in response to this suggestion, and note that financial risk in the context of Other Payer Advanced APMs is defined both in the Act (at section 1833(z)(2)(B)(iii)(II)(cc) for payment years 2021 and 2022, and section 1833(z)(3)(B)(iii)(II)(cc) for subsequent years) and our regulations at § 414.1420(d) so as to require that APM Entities in the payment arrangement must assume financial risk when actual expenditures exceed expected expenditures. However, we note that a payment arrangement with an other payer, like some APMs, can be structured so that the APM provides an investment payment to the participating APM Entities to assist with the practice transformation that may be required for participation in the payment arrangement. This investment payment could be structured in various ways; for example, it could be structured similarly to the Medicare ACO Investment Model under, which expected shared savings payment were pre-paid to encourage new ACOs to form in rural and underserved areas and to assist existing ACOs in meeting certain criteria; or it could be structured so that the payment is made specifically to encourage participating APM Entities to continue to make staffing, infrastructure, and operations investments as a means of practice transformation; or it could have a different structure entirely.

Although CMS did not solicit comments regarding our statement on investment payments, the following is a summary of the public comments we received:

Comment: Many commenters expressed concern that CMS will continue the current policy that does not include investment payments in the definition and calculation of risk. The commenters stated that this approach fails to recognize the significant investment that APM Entities and eligible clinicians make in start-up and overhead costs in the development and operations of APMs. Some commenters suggested that CMS should develop a method to capture and quantify such risk.

Response: We reiterate that our policy has not changed. As we discussed in the CY 2017 Quality Payment Program final rule, we continue to believe that there would be significant complexity involved in creating an objective and enforceable standard for determining whether an entity's investment risk or business risk exceeds a nominal amount (81 FR 77420). Therefore, we maintain our view that investment risk or business risk is not analogous to performance risk in the APM context because the costs of those activities and investments are not incorporated into the performance-based financial calculations of an APM, and therefore, are not appropriate for consideration for purposes of the Advanced APM financial risk criterion (81 FR 77420). Other Payer Advanced APMs, like Advanced APMs, can be designed so that they include investment payments for participants, but those investment payments will not be considered financial risk when assessing whether a payment arrangement meets the Other Payer Advanced APM financial risk criterion.

(c) Use of CEHRT

(i) Overview

In the CY 2017 Quality Payment Program final rule, we finalized that to be an Other Payer Advanced APM, the other payer arrangement must require at least 50 percent of participating eligible clinicians in each APM Entity, or each hospital if hospitals are the APM Entities, to use CEHRT to document and communicate clinical care (81 FR 77465). This CEHRT use criterion directly paralleled the criterion established for Advanced APMs in § 414.1415(a)(1)(i).

In the CY 2018 Quality Payment Program final rule, we finalized that we would presume that an other payer arrangement meets the 50 percent CEHRT use criterion if we receive information and documentation from the eligible clinician through the Eligible Clinician Initiated Process showing that the other payer arrangement requires the requesting eligible clinician to use CEHRT to document and communicate clinical care (see § 414.1445(c)(2)).

(ii) Increasing the CEHRT Use Criterion for Other Payer Advanced APMs

We proposed to change the current CEHRT use criterion for Other Payer

Advanced APMs so that in order to qualify as an Other Payer Advanced APM as of January 1, 2020, the other payer arrangement must require at least 75 percent of participating eligible clinicians in each APM Entity to use CEHRT; this aligns with our proposals for the CEHRT use criterion for Advanced APMs.

According to data collected by ONC, since the CY 2017 Quality Payment Program final rule was published, EHR adoption has been widespread, and we want to encourage continued adoption. Additionally, in response to the CY 2017 Quality Payment Program proposed rule stakeholders encouraged us to raise the CEHRT use criterion to 75 percent (see 81 FR 77411). We believe that this proposed change aligns with the increased adoption of CEHRT among providers and suppliers that is already happening, and will encourage further CEHRT adoption. (83 FR 35990).

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: A few commenters supported increasing the CEHRT use criterion as of January 1, 2020, to 75 percent of participating eligible clinicians in each APM Entity.

Response: We appreciate the support for our proposal to change the Other Payer Advanced APM CEHRT use criterion to 75 percent.

Comment: Many commenters expressed concern with the proposed change to the current CEHRT use criterion stating that raising it to 75 percent of participating eligible clinicians in each APM Entity may be too burdensome. A few commenters noted that the CEHRT use criterion should not be increased by any amount. One commenter stated that the CEHRT use criterion should remain at 50 percent and allow APM entities to attest that APM participants are using health IT. Some commenters stated the increase is premature as the All-Payer Combination Option is beginning in 2019. Some commenters suggested that the increase in the threshold should occur over a longer period of time to accommodate multi-year cycles of APM contracts.

Response: We do not believe that such an increase in the Other Payer Advanced APM minimum CEHRT use threshold will be burdensome for APM participants. According to data collected by ONC, certified EHR adoption has been widespread with over 3 in 4 office-based physicians adopted a certified EHR in CY 2015, and we want to continue to encourage such adoption and use of CEHRT. Further, regarding the comments that the increase in the threshold should occur over a longer period of time to accommodate multi-year cycles of APM contracts, we remind the commenters that, although we proposed the same increase in the Advanced APM minimum CEHRT use threshold beginning January 1, 2019, the proposed increase for Other Payer Advanced APMs would not apply until January 1, 2020. We believe this is a sufficient amount of lead time, especially given the widespread adoption of EHRs.

After considering public comments, we are finalizing our proposal to change the current CEHRT use criterion for Other Payer Advanced APMs so that in order to qualify as an Other Payer Advanced APM as of January 1, 2020, the other payer arrangement must require at least 75 percent of participating eligible clinicians in each APM Entity to use CEHRT.

(iii) Evidence of CEHRT Use

In the CY 2017 Quality Payment Program final rule, we adopted a CEHRT use criterion for Other Payer Advanced APMs that directly paralleled the CEHRT use criterion for Advanced APMs wherein Other Payer Advanced APMs must require at least 50 percent of eligible clinicians in each participating APM Entity, or each hospital if hospitals are the APM Entities, to use CEHRT to document and communicate clinical care.

We have since heard from payers and other stakeholders that CEHRT is often used under other payer arrangements even if it is not expressly required under the payment arrangement. Because CEHRT use is increasingly common among eligible clinicians, payers may not believe it is necessary to specifically require the use of CEHRT under the terms of an Other Payer payment arrangement.

Given this, we believe our current policy may needlessly exclude certain existing payment arrangements that could meet the statutory requirements for Other Payer Advanced APMs—including some where the majority of eligible clinicians use CEHRT, even if they are not explicitly required to do so under the terms of their payment arrangements.

We proposed that a payer or eligible clinician must provide documentation to CMS that CEHRT is used to document and communicate clinical care under the payment arrangement by at least 50 percent of eligible clinicians in 2019, and 75 percent of the eligible clinicians in 2020 and beyond, whether or not such CEHRT use is explicitly required under the terms of the payment arrangement. We specifically proposed to modify the regulation at § 414.1420(b) to specify that to be an Other Payer Advanced APM, CEHRT must be used by at least 50 percent of eligible clinicians participating in the arrangement in 2019 (or, beginning in 2020, 75 percent) of such eligible clinicians).

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Many commenters expressed support for CMS' proposal that a payer or eligible clinician must provide documentation to CMS that CEHRT is used by at least 50 percent of eligible clinicians in 2019, and 75 percent of eligible clinicians in 2020 and beyond, whether or not such CEHRT use is explicitly required under the terms of the payment arrangement.

Response: We appreciate the support for our proposal to allow for documentation that CEHRT is used at required levels by eligible clinicians.

After considering public comments, we are finalizing our proposal that a payer or eligible clinician must provide documentation to CMS that CEHRT is used to document and communicate clinical care under the payment arrangement by at least 50 percent of eligible clinicians in 2019, and 75 percent of the eligible clinicians in 2020 and beyond, whether or not such CEHRT use is explicitly required under the terms of the payment arrangement. Specifically, we are finalizing our proposal to modify the regulation at § 414.1420(b) to specify that to be an Other Payer Advanced APM, CEHRT must be used by at least 50 percent of eligible clinicians participating in the arrangement in 2019 (or, beginning in 2020, 75 percent) of such eligible clinicians.

(d) MIPS Comparable Quality Measures

(i) Overview

In the CY 2017 Quality Payment Program final rule, we explained that one of the criteria for a payment arrangement to be an Other Payer Advanced APM is that it must apply quality measures comparable to those under the MIPS quality performance category (81 FR 77465).

In the CY 2017 Quality Payment Program proposed rule, we proposed that to be an Other Payer Advanced APM, a payment arrangement must have quality measures that are evidence-

based, reliable, and valid; and that at least one measure must be an outcome measure if there is an applicable outcome measure on the MIPS quality measure list. We generally refer to these measures in the remainder of this discussion as ''MIPS-comparable quality measures.'' We did not specify in our regulation that the outcome measure is required to be evidence-based, reliable, and valid (81 FR 77466). We finalized these policies in the CY 2017 Quality Payment Program final rule and codified them in the regulation at § 414.1420(c).

(ii) General Quality Measures: Evidence-Based, Reliable, and Valid

In the CY 2017 Quality Payment Program final rule, we codified at § 414.1420(c)(2) that at least one of the quality measures used in the payment arrangement with an APM Entity must have an evidence-based focus, be reliable, and valid, and meet at least one of the following criteria:

- Used in the MIPS quality performance category as described in § 414.1330;
- Endorsed by a consensus-based entity;
- Developed under section 1848(s) of the Act;
- Submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or
- Any other quality measures that CMS determines to have an evidence-based focus and to be reliable and valid.

It has come to our attention that, as with the comparable policy for Advanced APMs as discussed at 81 FR 28302, some have read the regulation at § 414.1420(c)(2) to mean that measures on the MIPS final list or submitted in response to the MIPS Call for Quality Measures necessarily are MIPS–comparable quality measures, even if they have not been determined to be evidence-based, reliable, and valid. We did not intend to imply that any measure that was merely submitted in response to the annual call for quality measures or developed using Quality Payment Program funding would automatically qualify as MIPS-comparable regardless of whether the measure was endorsed by a consensus-based entity, adopted under MIPS, or otherwise determined to be evidence-based, reliable, and valid. While we believe such measures may be evidence-based, reliable, and valid, we did not intend to consider them so for purposes of § 414.1420(c)(2) without independent verification by a consensus-based entity or based on our own assessment and determination that they are evidence-based, reliable, and valid. We further believe the same principle applies to QCDR measures. If QCDR measures are endorsed by a consensus-based entity they are presumptively considered MIPS-comparable quality measures for purposes of § 414.1420(c)(2); otherwise we would have needed independent verification, or to make our own assessment and determination, that the measures are evidence-based, reliable, and valid before considering them to be MIPS-comparable (see 81 FR 77415 through 77417).

Because of the potential ambiguity in the existing definition and out of an abundance of caution in order to avoid any adverse impact on APM entities, eligible clinicians or other stakeholders, we have used the more permissive interpretation of the text, wherein measures developed under section 1848(s) of the Act and submitted in response to the MIPS Call for Quality Measures will meet the quality criterion in implementing the program thus far, and intend to use this interpretation for the 2019 QP Performance Period. Recognizing that APMs and other payer arrangements that we might consider for Advanced APM and Other Payer Advanced APM determinations are well into development for 2019, we proposed to use this interpretation until our new proposal described below is effective on January 1, 2020.

Therefore, at § 414.1420(c)(2), we proposed, effective January 1, 2020, that at least one of the quality measures used in the payment arrangement with an APM Entity must meet at least one of the following criteria:

- Finalized on the MIPS final list of measures, as described in § 414.1330;
- Endorsed by a consensus-based entity; or
- Otherwise determined by CMS to be evidenced-based, reliable, and valid.

That is, for QP Performance Period 2020 and all future QP Performance Periods, we would treat any measure that is either included in the MIPS final list of measures or has been endorsed by a consensus-based entity as presumptively evidence-based, reliable, and valid. All other measures would need to be independently determined by CMS to be evidence-based, reliable, and valid, in order to be considered MIPS-comparable quality measures.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: A few commenters supported the proposal that at least one of the quality measures used in the payment arrangement with and APM Entity must meet at least one of the three proposed criteria to assure that it is evidence-based, reliable, and valid.

Response: We appreciate the support for our proposal.

Comment: One commenter urged CMS to include a fourth way to determine a quality measure is ''MIPS-like'' by clarifying that all Medicare Advantage Star Rating measures are determined to be evidence-based, reliable, and valid by CMS. The commenter stated that these metrics were determined by CMS to be valid and reliable enough to use as a basis of MA plan payment.

Response: We believe that all active Medicare Advantage Star Rating quality measures (*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html*) are evidenced-based, reliable, and valid when used at the health plan level. However, if a payer has changed the unit of analysis from applying it at the health plan level to using it at the provider level, as would likely be necessary in this context, this may have affected the reliability and validity of the measure. As such, we believe it is important that all such measures be independently determined by CMS to be evidenced-based, reliable, and valid in the context of their use in the payment arrangement in order to satisfy the Other Payer Advanced APM criterion. We would note that this determination that a quality measure is MIPS-comparable would be made using the information collected by CMS as part of the data submission process for Other Payer Advanced APM determinations.

After considering public comments, we are finalizing our proposal to revise § 414.1420(c)(2) to clarify, effective as of January 1, 2020, that at least one of the quality measures used in the payment arrangement with an APM Entity must either be finalized on the MIPS final list of measures, as described in § 414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid.

(iii) Outcome Measures: Evidence-Based, Reliable, and Valid

In § 414.1420(c)(3), we generally require that, to be an Other Payer Advanced APM, the payment arrangement must use an outcome measure if there is an applicable outcome measure on the MIPS quality measure list. We note that the current regulation does not require that the outcome measure be evidence-based, reliable, and valid.

We proposed to revise § 414.1420(c)(3), to explicitly require that, unless there is no applicable

outcome measure on the MIPS quality measure list, at least one outcome measure that is used in the payment arrangement must be evidence-based, reliable, and valid. This proposal would have an effective date of January 1, 2020, and would specifically require that an outcome measure must also be MIPS-comparable. This proposal aligns with the similar proposal for Advanced APMs discussed at section III.I.4.e.(3)(d)(ii) of this final rule, so that an outcome measure used in the payment arrangement must also be:

- Finalized on the MIPS final list of measures, as described in § 414.1330;
- Endorsed by a consensus-based entity; or
- Determined by CMS to be evidence-based, reliable, and valid.

The proposal would have an effective date of January 1, 2020. This proposed effective date is intended to provide stakeholders sufficient notice of, and opportunity to respond to, this change in our regulation because the current regulation does not explicitly require that an outcomes measures must be evidence-based, reliable, and valid and, as a result some Other Payer Advanced APMs that were submitted for determination in CY 2018 for the CY 2019 performance year may not include outcomes measures that are evidence-based, reliable, and valid.

We also proposed that, for such payment arrangements that are determined to be Other Payer Advanced APMs for the 2019 performance year and did not include an outcome measure that is evidence-based, reliable, and valid, and that are resubmitted for an Other Payer Advanced APM determination for the 2020 performance year (whether for a single year, or for a multi-year determination as proposed in section III.I.4.e.(4)(b) of this final rule), we will continue to apply the current regulation for purposes of those determinations. Additionally, payment arrangements in existence prior to the 2020 performance year that are submitted for determination to be Other Payer Advanced APMs for the 2020 performance year and later, will be assessed under the rules of the current regulation meaning they do not need to include an outcome measure that is evidence-based, reliable, and valid to be an Other Payer Advanced APM. For all other payment arrangements the proposed revised regulation would apply beginning in CY 2020.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: One commenter supported the proposal that at least one outcome measure must be among the quality measures used in the payment arrangement with an APM Entity, and that the outcome measure must meet at least one of the three proposed criteria to assure that it is evidence-based, reliable, and valid.

Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal to revise § 414.1420(c)(3), effective January 1, 2020, to explicitly require that, unless there is no applicable outcome measure on the MIPS quality measure list, at least one outcome measure that applies in the payment arrangement must either be finalized on the MIPS final list of measures as described in § 414.1330, endorsed by a consensus-based entity, or determined by CMS to be evidence-based, reliable, and valid.

(e) Financial Risk for Monetary Losses

(i) Overview

In the CY 2018 Quality Payment Program final rule, we finalized our proposal to add a revenue-based nominal amount standard to the generally applicable nominal amount standard for Other Payer Advanced APMs that is parallel to the generally applicable revenue-based nominal amount standard for Advanced APMs. Specifically, we finalized that an other payer arrangement would meet the total risk component of the proposed nominal risk standard if, under the terms of the other payer arrangement, the total amount that an APM Entity potentially owes the payer or foregoes is equal to at least: For the 2019 and 2020 QP Performance Periods, 8 percent of the total combined revenues from the payer of providers and suppliers in participating APM Entities. This standard is in addition to the previously finalized expenditure-based standard. We explained that a payment arrangement would only need to meet one of the two standards. We would use this standard only for other payer arrangements where financial risk is expressly defined in terms of revenue in the payment arrangement.

(ii) Generally Applicable Nominal Amount Standard

We proposed to amend § 414.1420(d)(3)(i) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the total combined revenues from the payer of providers and suppliers in participating APM Entities for QP Performance Periods 2019 through 2024. This change is consistent with the proposed amendment to our regulation to maintain the generally applicable revenue-based nominal standard at 8 percent for Advanced APMs during the same timeframe.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Commenters expressed support for the proposal to maintain the general applicable revenue-based nominal amount standard at 8 percent for QP Performance Periods 2021 through 2024.

Response: We appreciate the support for our proposal to maintain the generally applicable revenue-based nominal amount standard.

After considering public comments, we are finalizing our proposal to revise § 414.1420(d)(3)(i) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the total combined revenues from the payer of providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

(4) Determination of Other Payer Advanced APMs

(a) Overview

In the CY 2017 Quality Payment Program final rule, we specified that an APM Entity or eligible clinician must submit, by a date and in a manner determined by us, information necessary to identify whether a given payment arrangement satisfies the Other Payer Advanced APM criteria (81 FR 77480).

In the CY 2018 Quality Payment Program final rule, we codified at § 414.1445 the Payer Initiated Other Payer Advanced APM Determination Process and the Eligible Clinician Initiated Other Payer Advanced APM Determination Process pertaining to the determination of Other Payer Advanced APMs, as well as specifying the information required for Other Payer Advanced APM determinations (82 FR 53814 through 53873).

(b) Multi-Year Other Payer Advanced APM Determinations

In the CY 2018 Quality Payment Program final rule, we finalized that Other Payer Advanced APM determinations made in response to requests submitted either through the Payer Initiated Other Payer Advanced APM Determination Process (Payer Initiated Process) or the Eligible Clinician Initiated Other Payer

Advanced APM Determination Process (Eligible Clinician Initiated Process) would be in effect for only one year at a time. We sought additional comment regarding the current duration of payment arrangements and whether creating a multi-year determination process would encourage the creation of more multi-year payment arrangements as opposed to payment arrangements that are for one year only. We also sought comment on what kind of information should be submitted annually after the first year to update an Other Payer Advanced APM determination (82 FR 53869 through 53870).

After consideration of this feedback, we proposed to maintain the annual submission process with the modifications outlined below for both the Payer Initiated Process and the Eligible Clinician Initiated Process. We proposed that beginning with the 2019 and 2020 submission periods for Other Payer Advanced APM determinations for performance year 2020, after the first year that a payer, APM Entity, or eligible clinician (which we refer to as the ''requester'' in the remainder of this discussion) submits a multi-year payment arrangement that we determine to be an Other Payer Advanced APM for that year, the requester would need to submit information only on changes to the payment arrangement that are relevant to the Other Payer Advanced APM criteria for each successive year for the remaining duration of the payment arrangement. In the initial submission, the requester would certify as usual that the information provided about the payment arrangement using the Payer Initiated Process or Eligible Clinician Initiated Process, as applicable, is true, accurate, and complete; would authorize CMS to verify the information; and would certify that they would submit revised information in the event of a material change to the payment arrangement. For multi-year payment arrangements, we proposed to require as part of the submission that the certifying official for the requester must agree to review the submission at least once annually, to assess whether there have been any changes to the information since it was submitted, and to submit updated information notifying us of any changes to the payment arrangement that would be relevant to the Other Payer Advanced APM criteria, and thus, to our determination of the arrangement to be an Other Payer Advanced APM, for each successive year of the arrangement. Absent the submission by the requester of updated information to reflect changes to the payment arrangement, we would continue to apply the original Other Payer Advanced APM determination for each successive year through the earlier of the end of that multi-year payment arrangement or 5 years.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Many commenters supported the proposal that the requester would need to submit information only on any changes to the payment arrangement that are relevant to the Other Payer Advanced APM criteria for each successive year for the remaining duration of the payment arrangement.

Response: We appreciate the support for our proposal to allow for multi-year submissions of payment arrangements.

After considering public comments, we are finalizing our proposal to maintain the annual submission process with the modifications outlined above for both the Payer Initiated Process and the Eligible Clinician Initiated Process.

For multi-year payment arrangements, we proposed to require as part of the submission that the certifying official for the requester must agree to review the submission at least once annually, to assess whether there have been any changes to the information since it was submitted, and to submit updated information notifying us of any changes to the payment arrangement that would be relevant to the Other Payer Advanced APM criteria, and thus, to our determination of the arrangement to be an Other Payer Advanced APM, for each successive year of the arrangement. Absent the submission by the requester of updated information to reflect changes to the payment arrangement, we would continue to apply the original Other Payer Advanced APM determination for each successive year through the earlier of the end of that multi-year payment arrangement or 5 years.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Many commenters supported our proposal to require as part of the submission that the certifying official for the requester must agree to review the submission at least once annually, to assess whether there have been any changes to the information since it was submitted, and to submit updated information notifying us of any changes to the payment arrangement that would be relevant to the Other Payer Advanced APM criteria, and thus, to our determination of the arrangement to be an Other Payer Advanced APM, for each successive year of the arrangement. Commenters supported the proposal that this process remain in place through the earlier of the end of the multi-payment arrangement or 5 years.

Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal to require as part of the submission that the certifying official for the requester must agree to review the submission at least once annually, to assess whether there have been any changes to the information since it was submitted, and to submit updated information notifying us of any changes to the payment arrangement that would be relevant to the Other Payer Advanced APM criteria, and thus, to our determination of the arrangement to be an Other Payer Advanced APM, for each successive year of the arrangement. Absent the submission by the requester of updated information to reflect changes to the payment arrangement, we will continue to apply the original Other Payer Advanced APM determination for each successive year through the earlier of the end of that multi-year payment arrangement or 5 years.

(c) Payer Initiated Other Payer Advanced APM Determination Process (Payer Initiated Process)—Remaining Other Payers

In the CY 2018 Quality Payment Program final rule, we finalized that we will allow certain other payers, including payers with payment arrangements authorized under Title XIX, Medicare Health Plan payment arrangements (Medicare Advantage plans, section 1876 cost plans PACE organization operated under section 1894 of the Act, and similar plans, other than an APM under section 1833(z)(3)(C) of the Act, that provide Medicare benefits under demonstration or waiver authority), and payers with payment arrangements aligned with a CMS Multi-Payer Model to use the Payer Initiated Process to request that we determine whether their other payer arrangements are Other Payer Advanced APMs starting prior to the 2019 QP Performance Period and each year thereafter (82 FR 53854). We codified this policy at § 414.1445(b)(1).

We also finalized that the Remaining Other Payers, including commercial and other private payers, may request that

we determine whether other payer arrangements are Other Payer Advanced APMs starting prior to the 2020 QP Performance Period and each year thereafter (82 FR 53867).

In the CY 2019 PFS proposed rule, we proposed details regarding the Payer Initiated Process for the Remaining Other Payers that were not among those other payers permitted to use the Payer Initiated Process to submit their arrangements for Other Payer Advanced APM Determinations in 2018 (Remaining Other Payers). To the extent possible, we are aligning the Payer Initiated Process for Remaining Other Payers with the previously finalized Payer Initiated Process for Medicaid, Medicare Health Plans, and CMS Multi-Payer Models.

In the CY 2018 Quality Payment Program final rule, we finalized that the Payer Initiated Process will be voluntary for all payers (82 FR 53855). We note that the Payer Initiated Process will be similarly voluntary for payers that were permitted to submit payment arrangements in 2018 and for Remaining Other Payers starting in 2019.

Guidance and Submission Form: As we have for the other payers included in the Payer Initiated Process (82 FR 53874), we intend to make guidance available regarding the Payer Initiated Process for Remaining Other Payers prior to their first Submission Period, which will occur during 2019. We intend to modify the submission form (which we refer to as the Payer Initiated Submission Form) for use by Remaining Other Payers to request Other Payer Advanced APM determinations, and to make this Payer Initiated Submission Form available to Remaining Other Payers prior to the first Submission Period. We proposed that a Remaining Other Payer will be required to use the Payer Initiated Submission Form to request that we make an Other Payer Advanced APM determination. We intend for the Payer Initiated Submission Form to include questions that are applicable to all payment arrangements and some questions that are specific to a particular type of payment arrangement, and we intend for it to include a way for payers to attach supporting documentation.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Commenters supported the proposal to require Remaining Other Payers to use the Payer Initiated Submission Form to request that CMS make an Other Payer Advanced APM determination.

Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal that Remaining Other Payers will use the Payer Initiated Submission Form to request that CMS make an Other Payer Advanced APM determination.

We proposed that Remaining Other Payers may submit requests for review of multiple other payer arrangements through the Payer Initiated Process, though we would make separate determinations as to each other payer arrangement and a payer would be required to use a separate Payer Initiated Submission Form for each other payer arrangement. Remaining Other Payers may submit other payer arrangements with different tracks within that arrangement as one request along with information specific to each track.

We solicited comment on this proposal.

We did not receive any comment in response to this proposal.

We are finalizing our proposal that Remaining Other Payers may submit requests for review of multiple other payer arrangements through the Payer Initiated Process, though we would make separate determinations as to each other payer arrangement and a payer would be required to use a separate Payer Initiated Submission Form for each other payer arrangement.

Submission Period: We proposed that the Submission Period for the Payer Initiated Process for use by Remaining Other Payers to request Other Payer Advanced APM determinations will open on January 1 of the calendar year prior to the relevant QP Performance Period for which we would make Other Payer Advanced APM determinations.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: One commenter supported the CMS proposal that the Payer Initiated Process for use by Remaining Other Payers to request Other Payer Advanced APM determinations would open on January 1.

Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal that the Payer Initiated Process for use by Remaining Other Payers to request Other Payer Advanced APM determinations would open on January 1.

The finalized timeline for the Payer Initiated Process for Remaining Other Payers as well as the previously finalized timeline for the Payer Initiated Process for Medicaid and Medicare Health Plans, is summarized in Table 59 alongside the final timeline for the Eligible Clinician Initiated Process.

TABLE 59: Finalized Other Payer Advanced APM Determination Process for Medicaid, Medicare Health Plans, and Remaining Other Payers for QP Performance Period 2020

	Payer Initiated Process	Date	Eligible Clinician (EC) Initiated Process*	Date
Medicaid	Guidance sent to states, then Submission Period Opens	January 2019	Guidance made available to ECs, then Submission Period Opens	September 2019
	Submission Period Closes	April 2019	Submission Period Closes	November 2019
	CMS contacts states and posts Other Payer Advanced APM List	September 2019	CMS contacts ECs and states and posts Other Payer Advanced APM List	December 2019
Medicare Health Plans	Guidance made available to Medicare Health Plans, then Submission Period Opens	April 2019	Guidance made available to ECs, then Submission Period Opens	September 2020
	Submission Period Closes	June 2019	Submission Period Closes	November 2020
	CMS contacts Medicare Health Plans and posts Other Payer Advanced APM List	September 2019	CMS contacts ECs and Medicare Health Plans and posts Other Payer Advanced APM List	December 2020
Remaining Other Payers	Guidance made available to Remaining Other Payers, then Submission Period Opens	January 2019	Guidance made available to ECs, then Submission Period Opens	September 2020
	Submission Period Closes	June 2019	Submission Period Closes	November 2020
	CMS contacts Remaining Other Payers and posts Other Payer Advanced APM List	September 2019	CMS contacts ECs and Remaining Other Payers and posts Other Payer Advanced APM List	December 2020

*Note that APM Entities or eligible clinicians may use the Eligible Clinician Initiated Process.

CMS Determination: Upon the timely receipt of a Payer Initiated Submission Form, we will use the information submitted to determine whether the other payer arrangement meets the Other Payer Advanced APM criteria. We proposed that if we find that the Remaining Other Payer has submitted incomplete or inadequate information, we will inform the payer and allow them to submit additional information no later than 15 business days from the date we inform the payer of the need for additional information. For each other payer arrangement for which the Remaining Other Payer does not submit sufficient information in a timely fashion, we will not make a determination in response to that request submitted via the Payer Initiated Submission Form. As a result, the other payer arrangement will not be considered an Other Payer Advanced APM for the year. These determinations are final and not subject to reconsideration.

We solicited comment on this proposal.

We did not receive any comments in response to this proposal.

We are finalizing our proposal that if we find that the Remaining Other Payer has submitted incomplete or inadequate information, we would inform the payer and allow them to submit additional information no later than 15 business days from the date we inform the payer of the need for additional information.

CMS Notification: We intend to notify Remaining Other Payers of our determination for each request as soon as practicable after the relevant Submission Deadline. We note that Remaining Other Payers may submit information regarding an other payer arrangement for a subsequent QP Performance Period even if we have determined that the other payer arrangement is not an Other Payer Advanced APM for a prior year.

CMS Posting of Other Payer Advanced APMs: We intend to post on the CMS website a list (which we refer to as the Other Payer Advanced APM List) of all other payer arrangements that we determine to be Other Payer Advanced APMs. Prior to the start of the relevant QP Performance Period, we intend to post a list of the payment arrangements that we determine to be Other Payer Advanced APMs through the Payer Initiated Process, and Other Payer Advanced APMs under Title XIX through the Eligible Clinician Initiated Process. After the QP Performance Period, we will update this list to include payment arrangements that we determine to be Other Payer Advanced APMs based on other requests through the Eligible Clinician Initiated Process. We intend to post the list of other payer arrangements that we determine to be Other Payer Advanced APMs through the Payer Initiated Process prior to the start of the relevant QP Performance Period, and then to update the list to include payment arrangements that we determine to be Other Payer Advanced APMs based on requests received through the Eligible Clinician Initiated Process.

(d) Payer Initiated Process—CMS Multi-Payer Models

In the CY 2018 Quality Payment Program final rule, we finalized that beginning for the first QP Performance Period under the All-Payer Combination Option, payers with a payment arrangement aligned with a CMS Multi-Payer Model may request that we determine whether that aligned payment arrangement is an Other Payer Advanced APM.

In the CY 2019 PFS proposed rule, we proposed to eliminate the Payer Initiated Process and submission form that are specifically for CMS Multi-Payer Models. We believe that payers aligned with CMS Multi-Payer Models can submit their arrangements through the Payer Initiated Process for

Remaining Other Payers we have proposed in section III.I.4.g.(3)(c) of this final rule, or through the existing Medicaid or Medicare Health Plan payment arrangement submission process, as applicable.

We solicited comment on this proposal.

We did not receive any comment in response to this proposal.

We are finalizing our proposal to eliminate the Payer Initiated Process and submission form that are specifically for CMS Multi-Payer Models.

(5) Calculation of All-Payer Combination Option Threshold Scores and QP Determinations

(a) Overview

In the CY 2017 Quality Payment Program final rule, we finalized our overall approach to the All-Payer Combination Option (81 FR 77463). Beginning in 2021, in addition to the Medicare Option, an eligible clinician may alternatively become a QP through the All-Payer Combination Option, and an eligible clinician need only meet the QP threshold under one of the two options to be a QP for the payment year (81 FR 77459). We finalized that we will conduct the QP determination sequentially so that the Medicare Option is applied before the All-Payer Combination Option (81 FR 77459).

In the CY 2017 Quality Payment Program final rule, we finalized that we will calculate Threshold Scores under the Medicare Option through both the payment amount and the patient count methods, compare each Threshold Score to the relevant QP and Partial QP Thresholds, and use the most advantageous scores to make QP determinations (81 FR 77457). We finalized the same approach for the All-Payer Combination Option wherein we will use the most advantageous method for QP determinations with the data that has been provided (81 FR 77475).

(b) QP Determinations Under the All-Payer Combination Option

In the CY 2018 Quality Payment Program final rule, we finalized that an eligible clinician may request a QP determination at the eligible clinician level, and that an APM Entity may request a QP determination at the APM Entity Level (82 FR 53880 through 53881). In the event that we receive a request for QP determination from an individual eligible clinician and also separately from that individual eligible clinician's APM Entity, we would make a determination at both levels. The eligible clinician could become a QP on the basis of either of the two determinations (82 FR 53881).

We proposed to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights under the TIN participate in a single (meaning the same) APM Entity. Therefore, this option would be available to all TINs participating in Full TIN APMs, such as the Medicare Shared Savings Program. It would also be available to any other TIN for which all clinicians who have reassigned their billing rights to the TIN are participating in the same APM Entity.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Many commenters supported the proposal to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights under the TIN participate in a single APM Entity.

Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights under the TIN participate in a single APM Entity.

We proposed that, similar to our existing policies for individual and APM Entity requests for QP determinations under the All-Payer Combination Option, we would assess QP status based on the most advantageous result for each individual eligible clinician. That is, if we receive any combination of QP determination requests (at the TIN-level, APM Entity level, or individual level) we will make QP assessments at all requested levels and determine QP status on the basis of the QP assessment that is most advantageous to the eligible clinician.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Many commenters supported the proposal to assess QP status based on the most advantageous result for each individual eligible clinician.

Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal to assess QP status based on the most advantageous result for each individual eligible clinician.

(c) Use of Individual or APM Entity Information for Medicare Payment Amount and Patient Count Calculation Under the All-Payer Combination Option

(i) Flexibility in the Medicare Option and All-Payer Combination Option Threshold Methods

In the CY 2018 Quality Payment Program final rule, we finalized that when we make QP determinations at the individual eligible clinician level, we would use the individual eligible clinician payment amounts and patient counts for the Medicare calculations in the All-Payer Combination Option. When we make QP determinations at the APM Entity level, we will use APM Entity level payment amounts and patient counts for the Medicare calculations in QP determinations under the All-Payer Combination Option. Eligible clinicians assessed at the individual eligible clinician level under the Medicare Option at § 414.1425(b)(2) will be assessed at the individual eligible clinician level only under the All-Payer Combination Option. We codified these policies at § 414.1440(d)(2) (82 FR 53881).

We noted in the CY 2019 PFS proposed rule that some may have read our regulation at § 414.1440(d)(2) to suggest that consistency is required across the two thresholds requiring eligible clinicians or APM Entities to meet the minimum Medicare threshold needed to qualify for the All-Payer Combination Option and the All-Payer threshold using the same method—either payment amounts or patient counts. Although we did not directly address this specific question in our current regulation or in prior rulemaking, we are clarifying that eligible clinicians or APM Entities can meet the minimum Medicare threshold for the All-Payer Combination option using one method (whichever is most favorable), and the All-Payer threshold for the All-Payer Combination Option using either the same, or the other method. All data submitted to us for Other Payer Advanced APM determinations and, when applicable, QP determinations using the All-Payer Combination Option will be considered and evaluated; and eligible clinicians (or APM Entities or TINs, as appropriate) may submit all data relating to both the payment amount and patient count methods. To avoid any potential ambiguity for the future, we proposed a change to § 414.1440(d)

to codify this clarification. We proposed to add a new § 414.1440(d)(4) to expressly allow eligible clinicians or APM Entities to meet the minimum Medicare threshold using the most favorable of the payment amount or patient count method, and then to meet the All-Payer threshold using either the same method or the other method. We note that, in the preamble in the CY 2019 PFS proposed rule, we indicated that we would codify this proposed policy by adding a new § 414.1440(d)(4) to our regulations. However, the corresponding proposed regulation text included the proposed policy as an amendment to the regulation text at § 414.1440(d)(1). We intended to propose the policy reflected in the propoed regulation text, and due to a clerical error, inadvertently neglected to revise the description of the proposal in the preamble. As such, rather than adding a new § 414.1440(d)(4), we intended to propose to amend the regulation at § 414.1440(d)(1) to expressly allow eligible clinicians or APM Entities to meet the minimum Medicare threshold using the most favorable of the payment amount or patient count method, and then to meet the All-Payer threshold using either the same method or the other method.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Some commenters supported the proposal to allow eligible clinicians or APM Entities to meet the minimum Medicare threshold using the most favorable of the payment amount or patient count method, and then to meet the All-Payer threshold using either the same method or the other method.

Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal with the correction noted above, that we are amending the text in our regulation at § 414.1440(d)(1) to expressly allow eligible clinicians or APM Entities to meet the minimum Medicare threshold using the most favorable of the payment amount or patient count method, and then to meet the All-Payer threshold using either the same method or the other method.

(ii) Extending the Medicare Threshold Score Weighting Methodology to TIN Level All-Payer Combination Option Threshold Score Calculations

In the CY 2018 Quality Payment Program final rule, we explained that we recognize that in many cases an individual eligible clinician's Medicare Threshold Scores would likely differ from the corresponding Threshold Scores calculated at the APM Entity group level, which would benefit those eligible clinicians whose individual Threshold Scores would be higher than the group Threshold Scores and disadvantage those eligible clinicians whose individual Threshold Scores are equal to or lower than the group Threshold Scores (82 FR 53881–53882). In situations where eligible clinicians are assessed under the Medicare Option as an APM Entity group, and receive a Medicare Threshold Score at the APM Entity group level, we believe that the Medicare portion of their All-Payer calculation under the All-Payer Combination Option should not be lower than the Medicare Threshold Score that they received by participating in an APM Entity group.

To accomplish this outcome, we finalized a modified weighting methodology. We finalized that when the eligible clinician's Medicare Threshold Score calculated at the individual level would be lower than the Medicare Threshold Score calculated at the APM Entity group level, we would apply a weighting methodology to calculate the Threshold Score for the eligible clinician. This methodology allows us to apply the APM Entity group level Medicare Threshold Score (if higher than the individual eligible clinician level Medicare Threshold Score), to the eligible clinician, under either the payment amount or patient count method, but weighted to reflect the individual eligible clinician's Medicare volume. We multiply the eligible clinician's APM Entity group Medicare Threshold Score by the total Medicare payments or patients made to that eligible clinician as follows:

$$\frac{[\textit{APM Entity Medicare Threshold Score} \times \textit{Clinician Medicare Payments or Patients}] + \textit{Individual Other Payer Advanced APM Payments or Patients}}{\textit{Individual Payments or Patients (All Payers except those excluded)}}$$

In the CY 2019 PFS proposed rule, we proposed to extend the same weighting methodology to TIN level Medicare Threshold Scores in situations where a TIN is assessed under the Medicare Option as part of an APM Entity group, and receives a Medicare Threshold Score at the APM Entity group level. In this scenario, we believe that the Medicare portion of the TIN's All-Payer Combination Option Threshold Score should not be lower than the Medicare Threshold Score that they received by participating in an APM Entity group (82 FR 53881–53882). We note this extension of the weighting methodology would only apply to a TIN when that TIN represents a subset of the eligible clinicians in the APM Entity, because when the TIN and the APM Entity are the same there is no need for this weighted methodology. We would multiply the TIN's APM Entity group Medicare Threshold Score by the total Medicare payments or patients for that TIN as follows:

$$\frac{[\textit{APM Entity Medicare Threshold Score X TIN Medicare Payments or Patients}] + \textit{TIN Other Payer Advanced APM Payments or Patients}}{\textit{TIN Payment or Patients (All Payers except those excluded)}}$$

We proposed to calculate the TIN's Threshold Scores both on its own and with this weighted methodology, and then use the most advantageous score when making a QP determination. We believe that, as it does for QP determinations made at the APM Entity level, this approach promotes consistency between the Medicare Option and the All-Payer Combination Option to the extent possible. Additionally, the proposed application of this weighting approach in the case of a TIN level QP determination would be consistent with our established policy.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Commenters supported the proposal to extend the same weighting

methodology to TIN level Medicare Threshold Scores in situations where a TIN is assessed under the Medicare Option as part of an APM Entity group, and receives a Medicare Threshold Score at the APM Entity group level.

Response: We appreciate support for our proposal.

After considering public comments, we are finalizing our proposal to extend the same weighting methodology to TIN level Medicare Threshold Scores in situations where a TIN is assessed under the Medicare Option as part of an APM Entity group, and receives a Medicare Threshold Score at the APM Entity group level.

(6) Summary of Final Policies

In this section, we are finalizing the following policies:

Other Payer Advanced APM Criteria:

• We are finalizing our proposal to change the CEHRT use criterion so that in order to qualify as an Other Payer Advanced APM as of January 1, 2020, the percentage of eligible clinicians participating in the other payer arrangement who are using CEHRT must be 75 percent.

• We are finalizing our proposal to allow payers and eligible clinicians to submit evidence as part of their request for an Other Payer Advanced APM determination that CEHRT is used by the requisite percentage of eligible clinicians participating in the payment arrangement (50 percent for 2019, and 75 percent for 2020 and beyond) to document and communicate clinical care, whether or not CEHRT use is explicitly required under the terms of the payment arrangement. We codifying this change at § 414.1420(b).

• We are finalizing the following clarification to § 414.1420(c)(2), effective January 1, 2020, to provide that at least one of the quality measures used in the payment arrangement in paragraph (c)(1) of this regulation must be:

++ Finalized on the MIPS final list of measures, as described in § 414.1330;

++ Endorsed by a consensus-based entity; or

++ Determined by CMS to be evidenced-based, reliable, and valid.

• We are finalizing our proposal to revise § 414.1420(c)(3) to require that, effective January 1, 2020, unless there is no applicable outcome measure on the MIPS quality measure list, an Other Payer Advanced APM must use an outcome measure, that meets the proposed criteria in paragraph (c)(2) of this regulation.

• We are also finalizing our proposal at § 414.1420(c)(3)(i) that, for payment arrangements determined to be Other Payer Advanced APMs for the 2019 performance year which did not include an outcome measure that is evidence-based, reliable, and valid, that are resubmitted for an Other Payer Advanced APM determination for the 2020 performance year (whether for a single year, or for a multi-year determination as proposed in section III.I.4.g.(3)(b) of this final rule), we would continue to apply the current regulation for purposes of those determinations. This revision also applies to payment arrangements in existence prior to the 2020 performance year that are submitted for determination to be Other Payer Advanced APMs for the 2020 performance year and later.

Determination of Other Payer Advanced APMs

• We are finalizing details regarding the Payer Initiated Process for Remaining Other Payers. To the extent possible, we are aligning the Payer Initiated Process for Remaining Other Payers with the previously finalized Payer Initiated Process for Medicaid, Medicare Health Plans, and CMS Multi-Payer Models.

• We are finalizing our proposal to eliminate the Payer Initiated Process that is specifically for CMS Multi-Payer Models. We believe that payers aligned with CMS Multi-Payer Models can submit their arrangements through the Payer Initiated Process for Remaining Other Payers that we are finalizing as described in section III.I.4.g.(3)(c) of this final rule, or through the Medicaid or Medicare Health Plan payment arrangement submission processes.

Calculation of All-Payer Combination Option Threshold Scores and QP Determinations

• We are finalizing our proposal to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who reassigned billing rights under the TIN participate in a single APM Entity. We are finalizing this proposal to revise § 414.1440(d), by adding this third alternative to allow QP determinations at the TIN level in instances where all clinicians who have reassigned billing under the TIN participate in a single APM Entity, as well as to assess QP status at the most advantageous level for each eligible clinician.

• We also are finalizing our clarification that, in making QP determinations using the All-Payer Combination Option, eligible clinicians may meet the minimum Medicare threshold using one method, and the All-Payer threshold using the same or a different method. We are finalizing our proposal with a correction to codify this clarification by amending § 414.1440(d)(1).

• We are finalizing our proposal to extend the same weighting methodology to TIN level Medicare Threshold Scores in situations where a TIN is assessed under the Medicare Option as part of an APM Entity group, and receives a Medicare Threshold Score at the APM Entity group level.

5. Quality Payment Program Technical Correction: Regulation Text Changes

a. Overview

We proposed certain technical revisions to our regulations in order to correct several technical errors and to reconcile the text of several of our regulations with the final policies we adopted through notice and comment rulemaking.

b. Regulation Text Changes

We proposed a technical correction to § 414.1415(b)(1) of our regulations to specify that an Advanced APM must require quality measure performance as a factor when determining payment to participants for covered professional services under the terms of the APM (83 FR 36005). The addition of the word ''quality'' better aligns with section 1833(z)(3)(D) of the Act and with the policy that was finalized in the CY 2017 Quality Payment Program final rule (81 FR 77406), and corrects a clerical error we made in the course of revising the text of § 414.1415(b)(1) for inclusion in the CY 2017 QPP final rule. This proposed revision would not change our current policy for this Advanced APM criterion.

We solicited comment on this proposal.

We did not receive any comments in response to this proposal.

We are finalizing the technical correction to § 414.1415(b)(1) to specify that an Advanced APM must require quality measure performance as a factor when determining payment to participants for covered professional services under the terms of the APM.

We also proposed technical corrections to § 414.1420(d)(3)(ii)(B) (83 FR 36005). These changes align with the generally applicable nominal amount standard for Other Payer Advanced APMs that was finalized in the CY 2017 Quality Payment Program final rule, and the change to the generally applicable nominal amount standard in the CY 2018 Quality Payment Program final rule where we established a revenue-based nominal amount standard as part of the Other Payer Advanced APM

criteria (82 FR 53849–53850). We finalized that a payment arrangement must require APM Entities to bear financial risk for at least 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement, and that a payment arrangement's level of marginal risk must be at least 30 percent of losses in excess of the expected expenditures, and the maximum allowable minimum loss rate must be 4 percent (81 FR 77471). Due to a clerical oversight, we inadvertently published two conflicting provisions in regulation text. At § 414.1420(d)(3)(i), we correctly finalized that a payment arrangement must require APM Entities to bear financial risk for at least 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement, and at § 414.1420(d)(3)(ii)(B) we incorrectly finalized that the risk arrangement must have a total potential risk of at least 4 percent of expected expenditures. We are effectuating this change by removing the Other Payer Advanced APM Criteria, Financial Risk, Generally Applicable Nominal Amount Standard provision at § 414.1420(d)(3)(ii)(B) and consolidating § 414.1420(d)(3)(ii)(A) into § 414.1420(d)(3)(ii).

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: One commenter thanked the agency for making the technical correction to clarify that an Other Payer payment arrangement must require APM Entities to bear financial risk for at least 3 percent, not 4 percent.

Response: We thank the commenter for their support of this technical correction.

After considering public comments, we are finalizing this technical correction by removing the Other Payer Advanced APM Criteria, Financial Risk, Generally Applicable Nominal Amount Standard provision at § 414.1420(d)(3)(ii)(B) and consolidating § 414.1420(d)(3)(ii)(A) into § 414.1420(d)(3)(ii).

In the CY 2017 Quality Payment Program final rule, we finalized a capitation standard for the financial risk criterion under the Advanced APM Criteria and the Other Payer Advanced APM Criteria, respectively. We finalized that full capitation arrangements would meet the Advanced APM financial risk criterion and Other Payer Advanced APM financial risk criterion, and would not separately need to meet the generally applicable financial risk standard and generally applicable nominal amount standard in order to satisfy the financial risk criterion for Advanced APMs and Other Payer Advanced APMs (81 FR 77431; 77472). We proposed to clarify the application of the capitation standard by revising § 414.1415(c) and § 414.1420(d) to refer to the full capitation exception that is expressed in paragraphs (c)(6) and (d)(7), respectively (83 FR 36006).

We solicited comment on this proposal.

We did not receive any comments in response to this proposal.

We are finalizing our proposal to clarify the application of the capitation standard by revising § 414.1415(c) and § 414.1420(d) to refer to the full capitation exception that is expressed in paragraphs (c)(6) and (d)(7), respectively.

In finalizing §§ 414.1415(c)(6) and 414.1420(d)(7), we specified that a capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services for which payment is made through the APM furnished to a population of beneficiaries, and no settlement is performed to reconcile or share losses incurred or savings earned by the APM Entity. This language does not completely reflect our definition of capitation risk arrangements as discussed in the preamble at 81 FR 77430 where we state that, ''capitation risk arrangements, as defined here, involve full risk for the population of beneficiaries covered by the arrangement, recognizing that it might require no services whatsoever or could require exponentially more services than were expected in calculating the capitation rate. . . . [a] capitation risk arrangement adheres to the idea of a global budget for all items and services to a population of beneficiaries during a fixed period of time.'' Therefore, we proposed to revise these regulations to align the Advanced APM Criteria, Financial Risk, Capitation provision at § 414.1415(c)(6), and the Other Payer Advanced APM Criteria, Financial Risk, Capitation provision at § 414.1420(d)(7) with the definition of capitation risk arrangements that we expressed in the preamble of the CY 2017 Quality Payment Program final rule at 81 FR 77430–77431 (83 FR 36006).

We solicited comment on this proposal.

We did not receive any comments in response to this proposal.

We are finalizing our proposal to revise the Advanced APM Criteria, Financial Risk, Capitation provision at § 414.1415(c)(6), and the Other Payer Advanced APM Criteria, Financial Risk, Capitation provision at § 414.1420(d)(7) to align with the definition of capitation risk arrangements that we expressed in the preamble of the CY 2017 Quality Payment Program final rule at 81 FR 77430–77431.

We also proposed a technical correction to remove the ''; or'' and replace it with a ''.'' at § 414.1420(d)(3)(i) because the paragraph that follows that section does not specify a standard that is necessarily an alternative to the standard under § 414.1420(d)(3)(i), but rather expresses a standard that is independent of the standard under § 414.1420(d)(3)(i) (83 FR 36006). As indicated in the CY 2018 Quality Payment Program final rule at 82 FR 53849–53850, where we established a revenue-based nominal amount standard for Other Payer Advanced APMs, in order to meet the generally applicable nominal amount standard under the Other Payer Advanced APM criteria, the total amount that an APM Entity potentially owes the payer or foregoes under a payment arrangement must be equal to at least: For the 2019 and 2020 QP Performance Periods, 8 percent of the total combined revenues from the payer to providers and other entities under the payment arrangement; or, 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement.

We solicited comment on this proposal.

We did not receive any comments in response to this proposal.

We are finalizing our proposal to remove the ''; or'' and replace it with a ''.'' at § 414.1420(d)(3)(i) because the paragraph that follows that section does not specify a standard that is necessarily an alternative to the standard under § 414.1420(d)(3)(i), but rather expresses a standard that is independent of the standard under § 414.1420(d)(3)(i).

We also proposed to revise § 414.1440(d)(3) to correct a typographical error by replacing the ''are'' with ''is'' in the third clause of the second sentence (83 FR 36006).

We solicited comment on this proposal.

We did not receive any comments in response to this proposal.

We are finalizing our proposal to revise § 414.1440(d)(3) to correct a typographical error by replacing the ''are'' with ''is'' in the third clause of the second sentence.

c. Summary of Final Policies

We are finalizing these technical corrections to our regulations at §§ 414.1415(b)(1), 414.1420(d)(3)(ii),

414.1415(c), 414.1420(d), 414.1415(c)(6), 414.1420(d)(7), 414.1420(d)(3)(i), and 414.1440(d)(3) as proposed.

IV. Requests for Information

This section addressed two requests for information (RFI).

A. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

In the CY 2019 PFS proposed rule (83 FR 35704 through 36368), we included an RFI related to promoting interoperability and electronic health care information exchange (83 FR 36006 through 36009). We received approximately 79 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

B. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

In the CY 2019 PFS proposed rule (83 FR 35704 through 36368), we included an RFI related to price transparency and improving beneficiary access to provider and supplier charge information (83 FR 36009 through 36010). We received approximately 94 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

V. Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success

A. Statutory and Regulatory Background

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of the Patient Protection and Affordable Care Act (hereinafter collectively referred to as ''the Affordable Care Act''). Section 3022 of the Affordable Care Act amended Title XVIII of the Act (42 U.S.C. 1395 *et seq.*) by adding section 1899 to the Act to establish the Shared Savings Program to facilitate coordination and cooperation among health care providers to improve the quality of care for Medicare FFS beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. See 42 U.S.C. 1395jjj.

The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). We viewed this final rule as a starting point for the program, and because of the scope and scale of the program and our limited experience with shared savings initiatives under FFS Medicare, we built a great deal of flexibility into the program rules.

Through subsequent rulemaking, we have revisited and amended Shared Savings Program policies in light of the additional experience we gained during the initial years of program implementation as well as from testing through the Pioneer ACO Model, the Next Generation ACO Model and other initiatives conducted by the Center for Medicare and Medicaid Innovation (Innovation Center) under section 1115A of the Act. A major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). A final rule addressing changes related to the program's financial benchmark methodology appeared in the June 10, 2016 **Federal Register** (Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule'')). We have also made use of the annual calendar year (CY) Physician Fee Schedule (PFS) rules to address updates to the Shared Savings Program quality measures, scoring, and quality performance standard, the program's beneficiary assignment methodology and certain other issues.[34]

Policies applicable to Shared Savings Program ACOs have continued to evolve based on changes in the law. The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) (MACRA) established the Quality Payment Program. In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), CMS established regulations for the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) and related policies applicable to eligible clinicians who participate in the Shared Savings Program.

The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (Pub. L. 114–255). Accordingly, we revised the program's regulations in the CY 2018 PFS final rule to reflect these new requirements.

On February 9, 2018, the Bipartisan Budget Act of 2018 was enacted (Pub. L. 115–123), amending section 1899 of the Act to provide for the following: Expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to a prospectively assigned beneficiary, greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period, permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and mandating that any such voluntary identification will supersede claims-based assignment, and allowing ACOs under certain two-sided models to establish CMS-approved beneficiary incentive programs.

On August 17, 2018 a proposed rule, titled ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success'' (hereinafter referred to as the ''August 2018 proposed rule''), appeared in the **Federal Register** (83 FR 41786). This proposed rule would provide a new direction for the Shared Savings Program by establishing pathways to success through redesigning the participation options available under the program to encourage ACOs to transition to two-sided models (in which they may share in savings and are also accountable for repaying any shared losses). As part of the proposed redesign of the program, we proposed to

[34] See for example: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014; Final Rule (78 FR 74230, Dec. 10, 2013). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2015; Final Rule (79 FR 67548, Nov. 13, 2014). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2016; Final Rule (80 FR 70886, Nov. 16, 2015). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2017; Final Rule (81 FR 80170, Nov. 15, 2016). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2018; Final Rule (82 FR 52976, Nov. 15, 2017).

establish two tracks under the program—the BASIC track and the ENHANCED track. These new participation options were designed to increase savings for the Trust Funds and mitigate losses, reduce gaming opportunities, and promote regulatory flexibility and free-market principles. The August 2018 proposed rule would also provide new tools to support coordination of care across settings and strengthen beneficiary engagement; ensure rigorous benchmarking; and promote the use of interoperable electronic health record technology among ACO providers/suppliers. We received 470 timely pieces of correspondence in response to the August 2018 proposed rule. In the following sections of this final rule, we address a subset of the proposals described in the August 2018 proposed rule. We summarize and respond to the significant public comments on these proposals and discuss our final policies with respect to these issues after taking into consideration the public comments we received on this subset of proposals. We are not addressing the other topics included in the August 2018 proposed rule at this time. We will summarize and respond to public comments on these other proposed policies in a forthcoming final rule. We also received comments that are outside the scope of the August 2018 proposed rule. We may consider these comments when evaluating current Shared Savings Program policies and contemplating future refinements to the program.

B. Finalization of Certain Provisions of the Shared Savings Program August 2018 Proposed Rule

In this section of the final rule, we discuss the proposal, the comments received, and the final action that we are taking for the following proposals in the August 2018 proposed rule:

- A voluntary 6-month extension for existing ACOs whose participation agreements expire on December 31, 2018, and the methodology for determining financial and quality performance for this 6-month performance year from January 1, 2019 through June 30, 2019. We believe it is necessary to finalize the extension before these ACOs' participation agreements expire on December 31, 2018, so that they can continue their participation in the program without interruption. It is also necessary to finalize the methodology for determining ACO quality and financial performance for the extension period in advance of the 6-month performance year beginning on January 1, 2019.
- Implementation of the provisions of section 50331 of the Bipartisan Budget Act of 2018 on voluntary alignment. The Bipartisan Budget Act was enacted earlier this year, and we believe it is most consistent with the requirements of the statute to revise our voluntary alignment policies effective with assignment for performance years starting on January 1, 2019, to reflect the additional flexibility given to beneficiaries in selecting their primary care provider.
- A modification to the definition of primary care services used in assigning beneficiaries to ACOs to reflect recent code changes. Including these codes in the definition of primary care services will improve the accuracy of the assignment methodology and help to ensure that beneficiaries are assigned to the ACO that is responsible for coordinating their overall care.
- Relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in performance year 2018 and subsequent years. We believe it is necessary to finalize the changes to the extreme and uncontrollable circumstances policies for the Shared Savings Program as quickly as possible to ensure that relief is available for ACOs affected by the recent hurricanes in North Carolina and Florida and other disasters during 2018.
- Revisions to program requirements to further promote interoperability among ACO providers and suppliers. We believe it is necessary to finalize changes to our CEHRT use requirements to align with the Quality Payment Program.

We are also making technical changes to update the authority citation for 42 CFR part 425 to conform with OFR requirements.

The changes will be effective on December 31, 2018. Applicability or implementation dates may vary, depending on the policy, and the timing specified in this final rule. By indicating that a provision is applicable to a performance year (PY) or agreement period, activities related to implementation of the policy may precede the start of the performance year or agreement period.

1. Participation Options for Agreement Periods Beginning in 2019

In this final rule, we are addressing a subset of the proposals in the August 2018 proposed rule for participation options for agreement periods beginning in 2019. In the August 2018 proposed rule, we stated that we would forgo an application cycle for a January 1, 2019 agreement start date and proposed to allow for a July 1, 2019 agreement start date. We proposed an approach for determining financial and quality performance for two 6-month performance years during 2019, with the first from January 1, 2019 through June 30, 2019, for ACOs with participation agreements expiring on December 31, 2018, that elect a voluntary 6-month extension, and the second from July 1, 2019 through December 31, 2019, for ACOs entering a new agreement period beginning July 1, 2019. We also proposed an approach for determining financial and quality performance for the performance period from January 1, 2019 through June 30, 2019 for an ACO starting a 12-month performance year on January 1, 2019, that terminates its participation agreement with an effective date of termination of June 30, 2019, and enters a new agreement period beginning on July 1, 2019, referred to as ''early renewals.''

In this final rule, we are addressing our proposals to allow for a voluntary 6-month extension for ACOs whose agreement periods expire on December 31, 2018, and to establish a methodology for determining financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019. These proposals were necessary to prevent some ACOs from experiencing an involuntary gap in participation as a result of our decision to forgo an application cycle in 2018 for a January 1, 2019 agreement start date. Therefore, in this section of the final rule, we summarize and respond to comments and address final actions specific to our proposals regarding the 6-month extension and the methodology for determining financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019. As we describe in this section, some modifications to our proposals are necessary because of the limited scope of this final rule.

In a forthcoming final rule, we anticipate summarizing and responding to public comments on the other proposed policies related to determining financial and quality performance in 2019 for the following: (1) The performance period from January 1, 2019 through June 30, 2019, for ACOs starting a 12-month performance year on January 1, 2019, that terminate their participation agreement with an effective date of termination of June 30, 2019, and enter a new agreement period beginning on July 1, 2019; and (2) the 6-month performance year from July 1, 2019 through December 31, 2019, for ACOs entering an agreement period beginning on July 1, 2019.

a. Voluntary Extension for a 6-Month Performance Year From January 1, 2019 Through June 30, 2019, for ACOs Whose Current Agreement Period Expires on December 31, 2018

In section II.A.7. of the August 2018 proposed rule (83 FR 41847), we explained that we were forgoing the application cycle that otherwise would take place during CY 2018 for a January 1, 2019 start date for new Shared Savings Program participation agreements, initial use of the Skilled Nursing Facility (SNF) 3-day rule waiver, and entry into the Track 1+ Model, and we proposed to offer a July 1, 2019 start date as the initial opportunity for ACOs to enter an agreement period under the proposed BASIC track or ENHANCED track, which would be offered under the proposed redesign of the program's participation options. We proposed the July 1, 2019 start date as a one-time opportunity, and thereafter we would resume our typical process of offering an annual application cycle that allows for review and approval of applications in advance of a January 1 agreement start date.

We proposed that ACOs that entered a first or second agreement period with a start date of January 1, 2016 could elect to extend their agreement period for an optional fourth performance year, defined as the 6-month period from January 1, 2019 through June 30, 2019. This election to extend the agreement period would be voluntary and an ACO could choose not to extend its agreement period, in which case it would conclude its participation in the program with the expiration of its current agreement period on December 31, 2018.

We proposed that the ACO's voluntary election to extend its agreement period must be made in the form and manner and according to the timeframe established by CMS, and that an ACO executive who has the authority to legally bind the ACO must certify the election. We explained our expectation that this election process, if finalized, would begin in 2018 following the publication of the final rule, as part of the annual certification process in advance of 2019 (described in section II.A.7.c.(2) of the August 2018 proposed rule (83 FR 41855)). We noted that this optional 6-month agreement period extension would be a one-time exception for ACOs with agreements expiring on December 31, 2018, and would not be available to other ACOs that are currently participating in a 3-year agreement in the program, or to future program entrants.

In the August 2018 proposed rule, we noted that under the existing provision at § 425.210, the ACO must provide a copy of its participation agreement with CMS to all ACO participants, ACO providers/suppliers, and other individuals and entities involved in ACO governance. Further, all contracts or arrangements between or among the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities must require compliance with the requirements and conditions of the program's regulations, including, but not limited to, those specified in the participation agreement with CMS. We proposed that an ACO that elects to extend its participation agreement by 6 months must notify its ACO participants, ACO providers/suppliers and other individuals or entities performing functions or services related to ACO activities of this continuation of participation and must require their continued compliance with the program's requirements for the 6-month performance year from January 1, 2019 through June 30, 2019.

As discussed in section II.A.2. of the August 2018 proposed rule (83 FR 41799 through 41800), we proposed modifications to the definition of ''agreement period'' in § 425.20 to broaden the definition to generally refer to the term of the participation agreement. We also proposed to add a provision at § 425.200(b)(2) specifying that the term of the participation agreement is 3 years and 6 months for an ACO that entered an agreement period starting on January 1, 2016, that elects to extend its agreement period until June 30, 2019, and this election is made in the form and manner and according to the timeframe established by CMS, and certified by an ACO executive who has the authority to legally bind the ACO (83 FR 41849). For consistency, we also proposed minor formatting changes to the existing provision at § 425.200(b)(2) and (b)(3) to italicize the header text.

We also proposed to revise the definition of ''performance year'' in § 425.20 to mean the 12-month period beginning on January 1 of each year during the agreement period, unless otherwise specified in § 425.200(c) or noted in the participation agreement. We also proposed revisions to § 425.200(c) to make necessary formatting changes and specify additional exceptions to the definition of performance year as a 12-month period. Specifically, we proposed to add a provision specifying that for an ACO that entered a first or second agreement period with a start date of January 1, 2016, and that elects to extend its agreement period by a 6-month period, the ACO's fourth performance year is the 6-month period between January 1, 2019, and June 30, 2019. Similarly, we proposed to add a provision specifying that for an ACO that entered an agreement period with a start date of July 1, 2019, the ACO's first performance year of the agreement period is defined as the 6-month period between July 1, 2019, and December 31, 2019 (83 FR 41849).

In light of the proposed modifications to § 425.200(c) to establish two 6-month performance years during CY 2019, we proposed revisions to the regulation at § 425.200(d), which reiterates an ACO's obligation to submit quality measures in the form and manner required by CMS for each performance year of the agreement period, to address the quality reporting requirements for ACOs participating in a 6-month performance year during CY 2019 (83 FR 41849).

We also considered forgoing an application cycle for a 2019 start date altogether and allowing ACOs to enter agreement periods under the proposed BASIC track and ENHANCED track for the first time beginning on January 1, 2020. This approach would allow ACOs additional time to consider the redesign of the program, make organizational and operational plans, and implement business and investment decisions, and would avoid the complexity of needing to determine performance based on 6-month performance years during CY 2019. However, we noted that our proposed approach of offering an application cycle during 2019 for an agreement period start date of July 1, 2019 would allow for a more rapid progression of ACOs to the redesigned participation options, starting in mid-2019. We further noted that, under this alternative, we would also want to offer ACOs that started a first or second agreement period on January 1, 2016, a means to continue their participation between the conclusion of their current 3-year agreement period (December 31, 2018) and the start of their next agreement period (January 1, 2020), should the ACO wish to continue in the program. We indicated that under that alternative, which would postpone the start date for the new participation options to January 1, 2020, we would allow ACOs that started a first or second agreement period on January 1, 2016, to elect a 12-month extension of their current agreement period to cover the duration of CY 2019.

We sought comment on these proposals and the related considerations, as well as the alternatives considered.

Comment: Regarding the program's application cycles, most commenters generally supported CMS' decision to forgo an application cycle during CY 2018 for a January 1, 2019 agreement start date. Several commenters explained their support for this decision was due to the significant revisions to program policies contained in the proposed rule.

Response: We thank commenters for their support of our decision to forgo the application cycle that otherwise would take place during CY 2018 for a January 1, 2019 start date for new Shared Savings Program participation agreements.

Comment: Of the comments addressing the length of the extension for ACOs with agreement periods expiring December 31, 2018, a few commenters generally supported the proposed participation options for agreement periods beginning in 2019, including the proposed 6-month extension. Several commenters stated their support for CMS' proposal to allow ACOs with agreement periods ending December 31, 2018, to extend their agreements through June 30, 2019. Several commenters suggested that CMS allow ACOs whose agreement periods expire on December 31, 2018, an option to extend their current participation agreement by either 6 months or 12 months. In addition, many commenters supported allowing these ACOs the opportunity to elect a voluntary 12-month extension of their current agreement period, for a fourth performance year from January 1, 2019 through December 31, 2019. One commenter, whose comment was primarily focused on the applicability of policies to Track 1 ACOs, specifically recommended that this 12-month extension option should be offered for Track 1 ACOs. One commenter suggested that CMS permit Track 3 ACOs a 12-month extension for the performance year from January 1, 2019 through December 31, 2019, and that CMS apply certain aspects of the proposed program redesign, including the use of factors based on regional FFS expenditures in establishing, updating and adjusting the ACO's historical benchmark and the availability of beneficiary incentive programs, during this optional fourth 12-month performance year, enabling these Track 3 ACOs to gain experience with these policies before deciding whether to continue their participation in the Shared Savings Program in the ENHANCED track.

Some commenters explained that providing a 12-month extension option would give ACOs additional time to analyze program changes and prepare for the application process. One commenter expressed concern that a 6-month extension would provide a limited and inadequate amount of time for ACOs to consider participation options under a redesigned program, if a final rule establishing a July 1, 2019 start date is not issued until later in 2018. This commenter expressed the belief that this limited time to consider participation options in advance of a July 1, 2019 start date (if finalized) and general uncertainty about program policies would result in program attrition, due to ACOs and ACO participants electing not to continue in the program at the end of their current agreement. One commenter explained a 12-month extension would give ACOs additional time to evaluate whether they have the appropriate structure in place, implement processes to comply with new regulations, and make necessary changes to their ACO participant and ACO provider/supplier networks.

One commenter explained a 12-month extension would provide current ACOs with additional time and experience under their current agreement periods. Some commenters explained that providing a 12-month extension could avoid the complexity and increased burden on providers, practices, ACOs, and CMS that could potentially result from ACOs' participation in two, 6-month performance years in CY 2019. Other commenters raised concerns about making ACO participant list changes, and modifying agreements with their ACO participants, to allow for participation in two, 6-month performance years during CY 2019, with each performance year under a separate participation agreement: The first 6-month performance year under their current participation agreement (in an extension of their current agreement period); and the second 6-month performance year under a new participation agreement under one of the proposed redesigned participation options. Some commenters requesting a 12-month extension, or the choice between a 6-month or a 12-month extension, also raised concerns about the methodology for determining financial and quality performance for two, 6-month performance years during CY 2019. We summarize and respond to comments related to the methodology for determining performance for the 6-month performance year from January 1, 2019 through December 31, 2019, and other program policies applicable to ACOs participating in this 6-month performance year, in sections V.B.1.b. and V.B.1.c. of this final rule.

Response: We are not addressing in this final rule, comments on the timing for implementing the proposed redesign of the Shared Savings Program's participation options. However, we believe it is important to allow for continuity in participation for ACOs whose participation agreements expire December 31, 2018.

We appreciate commenters' concerns about preparing to enter a new agreement period in light of uncertainty around the participation options that may be available. However, we note that, based on the proposals in the August 2018 proposed rule, ACOs whose agreement periods expire on December 31, 2018, that were interested in continuing their participation in the program have had an opportunity to identify their likely ACO participants for the proposed 6-month performance year from January 1, 2019 through June 30, 2019, and have received preliminary feedback from CMS for ACO participant list additions for the performance year beginning on January 1, 2019. Moreover, we believe these ACOs generally have begun preparing the necessary revisions to their agreements with ACO participants and ACO providers/suppliers and, if under a two-sided model to extend their repayment mechanism in anticipation of the possibility that we would finalize the proposed 6-month extension period. We believe these ACOs have also been weighing their participation options in advance of applying to renew for a subsequent agreement period, and will have additional time to make these determinations during the 6-month extension (if elected). In particular, ACOs reaching the conclusion of their second agreement period under Track 1, would have been weighing their participation options under two-sided models, given the current requirement that ACOs transition to a two-sided model by the start of their third agreement period. In fact, the 6-month extension allows ACOs completing their second agreement period in Track 1 to continue participation under their current agreement period and thereby receive additional time under a one-sided model that otherwise would not have been available to these ACOs under the program's current regulations.

We also believe it is important to ensure we retain the flexibility to allow ACOs to more rapidly transition, starting as early as July 1, 2019, to the proposed new participation options, should they be finalized, including the participation options that would be Advanced APMs that would allow eligible clinicians participating in the ACO to qualify for incentive payments

under the Quality Payment Program. We believe that rapid transition to the new participation options would drive more meaningful systematic change in ACOs, which have the potential to control their assigned beneficiaries' Medicare Parts A and B FFS expenditures by coordinating care across care settings, and thus to achieve significant change in spending.

At this time, we believe the proposed 6-month extension for a 6-month performance year from January 1, 2019 through June 30, 2019, strikes an appropriate balance between these factors. To reduce the possibility for selective participation bias that could adversely affect the Trust Funds, we believe the same option for extending their current participation agreement should be made available to all eligible ACOs whose agreement periods expire December 31, 2018, as opposed to offering ACOs the option to choose between either a 6-month or a 12-month extension, or offering extensions of different lengths to ACOs based on their current participation track. For example, we believe that if we offered a choice regarding the length of the extension, only ACOs that would expect to benefit from being rebased under new program policies would elect a 6-month extension in order to allow the regional rebasing policies to apply sooner.

We also decline to adopt the commenter's suggestions that we finalize certain aspects of the proposed program redesign, such as the proposed modifications to the methodology for establishing, adjusting and updating an ACO's historical benchmark, and certain payment and program flexibilities for eligible ACOs participating under two-sided models, and apply these policies to a subset of the ACOs electing the voluntary extension. Continuing to apply the current benchmarking methodology during the optional fourth performance year maintains ACOs' existing historical benchmarks, allowing them to continue to build on their experience within their current agreement period and provides a more predictable and stable benchmark during the 6-month extension period. We also decline to allow only ACOs that are eligible for and elect the extension to have access to and make use of additional program and payment flexibilities (such as a SNF 3-day rule waiver, unless previously approved, or a beneficiary incentive program) as a way of allowing these organizations to gain experience with these policies in advance of their broader availability (if finalized) to eligible ACOs participating in the program. Our proposals to extend the availability of a SNF 3-day rule waiver and to give ACOs the opportunity to offer beneficiary incentive programs were developed in conjunction with our proposed changes to the participation options for ACOs participating in the Shared Savings Program. Therefore, we believe these proposals need to be considered together as part of a forthcoming final rule addressing our proposals for the overall redesign of the Shared Savings Program. Further, we believe it would be cumbersome to determine ACOs' eligibility for these flexibilities prior to the start of the performance year beginning January 1, 2019, particularly given the absence of a formal application cycle during CY 2018 during which ACOs could elect to apply for such opportunities.

Comment: One commenter pointed to the Regulatory Impact Analysis of the August 2018 proposed rule (83 FR 41926), and our estimate that a 12-month extension for ACOs whose participation agreements expire on December 31, 2018, would reduce overall Federal spending by approximately an additional $100 million, as further justification for allowing a 12-month rather than a 6-month extension.

Response: We believe it is important to allow for continuity in participation for ACOs whose agreement periods expire on December 31, 2018. We also believe it is important to ensure ACOs more rapidly transition to new participation options in the event we finalize a mid-year start date for those participation options in 2019. At this time, we believe the proposed 6-month extension for a 6-month performance year from January 1, 2019 through June 30, 2019, strikes an appropriate balance between these factors. The estimated impact of a 12-month extension for ACOs whose current agreement periods expire on December 31, 2018, is not comparable to the impact estimated for a 6-month extension for this same group of ACOs. To explain further, the impact estimate for a 12-month extension was estimated under a different hypothetical baseline. Differences in participation resulting from a 6-month or a 12-month extension were not a major factor in the impact estimate because under the proposed approach, a 12-month extension would not have changed the ultimate date that renewing ACOs would be required to transition to performance-based risk under the proposed redesign. For example, for Track 1 ACOs, a 12-month extension for performance year 2019 under Track 1 would result in the Track 1 ACO being eligible to participate in proposed BASIC track Level B during performance year 2020, whereas with a 6-month extension for a performance year from January 1, 2019 through June 30, 2019, under Track 1, would permit the ACO up to 1.5 years under proposed BASIC track Level B, because the ACO would not automatically transition from Level B to Level C at the start of performance year 2020 under the policies included in the proposed rule. In either event, however, the ACO would be required to participate in performance-based risk under Level C, D, or E of the BASIC track by performance year 2021. There were also a number of other competing factors working in different directions, such as the benchmark the ACO participates under, and the availability of Advanced APM incentive payments, which ultimately led to our projection that the 12-month extension would result in somewhat greater savings over 10 years when compared to the modeling of the proposed 6-month extension.

Comment: One commenter expressed confusion over whether the voluntary election for a 6-month performance year from January 1, 2019 through June 30, 2019, was an option for ACOs within an agreement period (such as an ACO that entered an agreement period on January 1, 2018) as part of the proposed early renewal process.

Response: The optional 6-month extension is only available for ACOs with agreements expiring on December 31, 2018, and would not be available to other ACOs that are currently participating in a 3-year agreement period in the program because their agreements are not expiring. Thus, these ACOs do not require the option of a 6-month extension because their current agreement periods will continue during 2019 and they will not experience a gap in participation as a result of our decision to forgo the application cycle in 2018 for an agreement start date of January 1, 2019.

Comment: One commenter suggested that all Track 3 ACOs should be offered an extension of their current agreement period, regardless of the ACO's agreement period start date.

Response: We proposed that the one-time, 6-month extension would only be available to ACOs whose agreement periods expire on December 31, 2018, in order to ensure that these ACOs would be able to continue participation in the Shared Savings Program without any gap. At this time, we decline the commenter's alternative suggestion that we offer a similar 6-month extension to ACOs whose agreement periods expire in subsequent years. These ACOs would not need a 6-month extension because we anticipate a typical, annual application cycle would be available in

future years so that these ACOs could renew their participation agreements and continue their participation in the program without interruption.

Comment: Some commenters urged CMS to provide additional guidance and education to ACOs on how ACOs should modify their agreements with their ACO participants for the 2019 performance periods. Several ACOs, with agreement periods expiring on December 31, 2018, submitted comments describing the burden of executing updated participation agreements with their ACO participants to account for the 6-month extension and the start of a new agreement period under one of the new participation options. These commenters explained that expecting the program would offer an application cycle in CY 2018 for a January 1, 2019 agreement start date, their newly executed ACO participant agreements were structured according to the program's current policies (under the program's regulations and, as applicable, the terms of the Track 1+ Model) and do not account for the 6-month extension or modified participation options under the proposed redesign of the program. One commenter expressed concern that the extension would cause some ACO participants to be operating under a different ACO participation agreement, depending on whether they started participating in the ACO prior to January 1, 2019, or after January 1, 2019, resulting in different sets of expectations, for example with respect to the distribution of shared savings. According to one commenter, the time and cost spent on revising agreements with their ACO participants would significantly burden the ACO and its participants, and delay the execution of many initiatives to reduce costs and improve the quality of care as the ACO would spend time executing revised agreements with its ACO participants rather than focusing on other aspects of its operations. One commenter requested that ACOs whose agreement periods expire on December 31, 2018, be given ample time to secure extensions to their agreements with ACO participants for 2019.

Response: To prepare for the extension period, ACOs electing to extend their participation agreement with CMS must update their ACO participant agreements and SNF affiliate agreements, as applicable, before the beginning of the next performance year to reflect the extension of their current agreement period. As part of the annual certification process in advance of 2019, ACOs electing the 6-month extension will be required to certify that they have notified their ACO participants and SNF affiliates, if applicable, of their continued participation in the Shared Savings Program in 2019, and that their ACO participant agreements and SNF affiliate agreements, if applicable, have been updated. However, ACOs will not be required to submit ACO participant agreement or SNF affiliate agreement extensions to CMS.

ACOs electing the extension would need to extend all current ACO participant and/or SNF affiliate agreements on or before December 31, 2018, so that entities will continue to be ACO participants or SNF affiliates, as applicable, for the performance year beginning on January 1, 2019. Additionally, the ACO will need to execute ACO participant agreements with any new ACO participants to be added to its ACO participant list effective January 1, 2019. We also note that these ACOs would have been required to revise their ACO participant and SNF affiliate agreements, as applicable, if they had been renewing their participation agreements for a new agreement period beginning January 1, 2019. We also note that we now allow ACOs, ACO participants and SNF affiliates to digitally sign their agreements, which should help to reduce any burden associated with extending agreements. We believe that the timing of the issuance of this final rule will permit sufficient time for ACOs electing to extend their participation agreements to take the necessary steps to extend their ACO participant and SNF affiliate agreements, as applicable, before the start of the 6-month performance year beginning January 1, 2019.

In response to the commenter's concern that the extension would cause some ACO participants to be operating under different sets of expectations (depending on whether they started participating in the ACO prior to January 1, 2019 or after January 1, 2019), we note that for ACOs that elect the 6-month extension, the payment methodology under the ACO's current track would be applicable to determining the ACO's shared savings or shared losses, if applicable, for the 6-month performance year from January 1, 2019 through June 30, 2019. This is the same payment methodology that has applied to the ACO for the duration of its agreement period, beginning on January 1, 2016.

Further, we note that with the exception of the requirements specified at § 425.116, the ACO and its ACO participants have significant flexibility to determine the contractual terms that would apply with respect to all ACO participant agreements, including with respect to the use/distribution of shared savings (and payment of shared losses).

Comment: One commenter explained that current and prospective ACOs and their leaders are evaluating their options with respect to not only the Shared Savings Program start date, but also to participation in other potential models such as the Direct Provider Contracting (DPC) models anticipated to be tested by CMS' Innovation Center. The commenter urged CMS to take the whole payment model landscape into account and to take any measures necessary to maximize the level of certainty for healthcare providers and to incentivize participation in higher-risk models over lower-risk models. For example, the commenter recommended that participants in the Shared Savings Program or current Innovation Center models should not be excluded from switching to a DPC model if and when such a model becomes available, regardless of where they are in their current agreement period or the lifecycle of their current model.

Response: We work to align and otherwise create synergies between the Shared Savings Program and the payment and service delivery models tested by the Innovation Center. We have policies in place to take into account overlap between the Shared Savings Program and Innovation Center models, which are designed to test new payment and service delivery models for the purpose of innovating in the areas of healthcare delivery and shared accountability for quality and financial performance, whenever possible. We continue to monitor these policies and make refinements as we gain experience and lessons learned from these interactions. When new models are announced, we encourage ACOs and their leaders to engage in dialogue with the Innovation Center and Shared Savings Program staff to inform their decision-making regarding the participation options.

After considering the comments received, we are finalizing our proposal to allow ACOs that entered a first or second agreement period beginning on January 1, 2016, to voluntarily elect a 6-month extension of their current agreement period for a fourth performance year from January 1, 2019 through June 30, 2019. For the reasons discussed, we believe this extension is necessary in order to avoid an involuntary gap in participation and to provide ACOs with an opportunity to prepare for a more rapid transition to the proposed new participation options, including new Advanced APMs that would allow eligible clinicians

participating in these ACOs to qualify for incentive payments under the Quality Payment Program.

We received no comments on the proposed modifications to the definitions of ''agreement period'' and ''performance year'' in § 425.20 or to the regulation at § 425.200 to establish the 6-month extension and to make certain technical and conforming changes. We are finalizing as proposed the modifications to the definition of ''agreement period'' in § 425.20 to broaden the definition to generally refer to the term of the participation agreement and the revisions to § 425.200(a) to allow for agreement periods greater than 3 years. We are also finalizing our proposal to add a provision at § 425.200(b)(2) specifying that the term of the participation agreement is 3 years and 6 months for an ACO that entered an agreement period starting on January 1, 2016, that elects to extend its agreement period until June 30, 2019, and this election is made in the form and manner and according to the timeframe established by CMS, and certified by an ACO executive who has the authority to legally bind the ACO. For consistency, we are also finalizing as proposed the minor formatting changes to the existing provisions at § 425.200(b)(2) and (b)(3) to italicize the header text.

We are also finalizing as proposed the revision to the definition of ''performance year'' in § 425.20 to mean the 12-month period beginning on January 1 of each year during the agreement period, unless otherwise specified in § 425.200(c) or noted in the participation agreement. Therefore, we are also finalizing the proposed revisions to § 425.200(c) to make necessary formatting changes and specify an additional exception to the definition of performance year as a 12-month period. Specifically, we are finalizing our proposal to add a provision specifying that for an ACO that entered a first or second agreement period with a start date of January 1, 2016, and that elects to extend its agreement period by a 6-month period, the ACO's fourth performance year is the 6-month period between January 1, 2019, and June 30, 2019.

In light of the modifications we are finalizing to § 425.200(c) to establish a 6-month performance year during CY 2019, we are also finalizing the proposed revisions to the regulation at § 425.200(d), which reiterates an ACO's obligation to submit quality measures in the form and manner required by CMS for each performance year of the agreement period, to address the quality reporting requirements for ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019. As described elsewhere in this final rule, ACOs electing the voluntary 6-month extension will be required to report quality measures for the 2019 reporting period, based on CY 2019, consistent with the existing quality reporting process and methodology.

b. Methodology for Determining Financial and Quality Performance for the 6-Month Performance Year From January 1, 2019 Through June 30, 2019

(1) Background and Description of Methodology

Under our proposed approach to determining performance for the 6-month performance year from January 1, 2019 through June 30, 2019, after the conclusion of CY 2019, CMS would reconcile the financial and quality performance of ACOs that participated in the Shared Savings Program during 2019. For ACOs that extended their agreement period for the 6-month performance year from January 1, 2019 through June 30, 2019, CMS would first reconcile the ACO based on its performance during the entire 12-month calendar year, and then pro-rate the calendar year shared savings or shared losses to reflect the ACO's participation for only half of the calendar year. In the August 2018 proposed rule, we explained this approach would avoid a more burdensome interim payment process that could accompany an alternative proposal to instead implement, for example, an 18-month performance year. Consistent with the 18- and 21-month performance years offered for the first cohorts of Shared Savings Program ACOs, such a policy could require ACOs to establish a repayment mechanism that otherwise might not be required, create uncertainty over whether the ACO may ultimately need to repay CMS based on final results for the extended performance year, and delay ACOs seeing a return on their investment in program participation if eligible for shared savings.

We explained our belief that the proposed approach would allow continuity in program operations, including operations that occur on a calendar year basis. Specifically, the proposed approach would allow payment reconciliation to remain on a calendar year basis, which would be most consistent with the calendar year-based methodology for calculating benchmark expenditures, trend and update factors, risk adjustment, county expenditures and regional adjustments. We explained that deviating from a 12-month reconciliation calculation by using fewer than 12 months of performance year expenditures could interject actuarial biases relative to the benchmark expenditures, which are based on 12-month benchmark years. As a result, we believed the proposed approach of reconciling ACOs based on a 12-month period would protect the actuarial soundness of the financial reconciliation methodology. We also explained our belief that the alignment of the proposed approach with the standard methodology used to perform the same calculations for 12-month performance years that correspond to a calendar year would make it easier for ACOs and other program stakeholders to understand the proposed methodology.

As is the case with typical calendar year reconciliations in the Shared Savings Program, we anticipated results with respect to participation during CY 2019 would be made available to ACOs in summer 2020. We explained that this would allow those ACOs that are eligible to share in savings as a result of their participation in the program during CY 2019 to receive payment of shared savings following the conclusion of the calendar year consistent with the standard process and timing for annual payment reconciliation under the program.

In section II.A.7.b.2 of the August 2018 proposed rule (83 FR 41851 through 41853), we described in detail our proposed approach to determining an ACO's performance for the 6-month performance year from January 1, 2019 through June 30, 2019. We also proposed that these policies would apply to ACOs that begin a 12-month performance year on January 1, 2019, but elect to terminate their participation agreement with an effective date of termination of June 30, 2019, in order to enter a new agreement period starting on July 1, 2019 (early renewals). Our proposed policies addressed the following: (1) The ACO participant list that will be used to determine beneficiary assignment; (2) the approach to assigning beneficiaries; (3) the quality reporting period; (4) the benchmark year assignment methodology and the methodology for calculating, adjusting and updating the ACO's historical benchmark; and (5) the methodology for determining shared savings and shared losses. We proposed to specify these policies for reconciling the 6-month period from January 1, 2019 through June 30, 2019, in paragraph (b) of a new section of the regulations at § 425.609.

We proposed to use the ACO participant list for the performance year beginning January 1, 2019, to determine

beneficiary assignment as specified in §§ 425.402 and 425.404, and according to the ACO's track as specified in § 425.400. As discussed in section II.A.7.c. of the August 2018 proposed rule (83 FR 41855 through 41856), we proposed to allow all ACOs, including ACOs entering a 6-month performance year, to make changes to their ACO participant list in advance of the performance year beginning January 1, 2019. Related considerations are discussed in section V.B.1.c.(2) of this final rule.

To determine beneficiary assignment, we proposed to consider the allowed charges for primary care services furnished to the beneficiary during a 12-month assignment window, allowing for a 3 month claims run out. For the 6-month performance year from January 1, 2019 through June 30, 2019, we proposed to determine the assigned population using the following assignment windows:

- For ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window would be CY 2019.
- For ACOs under prospective assignment, Medicare FFS beneficiaries would be prospectively assigned to the ACO based on the beneficiary's use of primary care services in the most recent 12 months for which data are available. For example, in determining prospective beneficiary assignment for the January 1, 2019 through June 30, 2019 performance year we could use an assignment window from October 1, 2017 through September 30, 2018, to align with the off-set assignment window typically used to determine prospective assignment prior to the start of a calendar year performance year. Beneficiaries would remain prospectively assigned to the ACO at the end of CY 2019 unless they meet any of the exclusion criteria under § 425.401(b) during the calendar year.

As discussed in section II.A.7.c.(4) of the August 2018 proposed rule (83 FR 41856), to determine ACO performance during a 6-month performance year, we proposed to use the ACO's quality performance for the 2019 reporting period, and to calculate the ACO's quality performance score as provided in § 425.502. We also proposed to use a different quality measure sampling methodology depending on whether an ACO participates in both a 6-month performance year (or performance period) beginning on January 1, 2019, and a 6-month performance year beginning on July 1, 2019, or only participates in a 6-month performance year from January 1, 2019 through June 30, 2019. As described in section V.B.1.c.(4) of this final rule, given the limited scope of this final rule, at this time, we are finalizing only our proposal to use the ACO's latest certified participant list (the ACO participant list effective on January 1, 2019) to determine the quality reporting samples for the 2019 reporting period for ACOs that extend their prior participation agreement for the 6-month performance year from January 1, 2019 to June 30, 2019.

Consistent with current program policy, we proposed to determine assignment for the benchmark years based on the most recent certified ACO participant list for the ACO effective for the performance year beginning January 1, 2019. This would be the participant list the ACO certified prior to the start of its agreement period unless the ACO has made changes to its ACO participant list during its agreement period as provided in § 425.118(b). If the ACO has made subsequent changes to its ACO participant list, we would adjust its historical benchmark to reflect the most recent certified ACO participant list. See the Medicare Shared Savings Program, ACO Participant List and Participant Agreement Guidance (July 2018, version 5), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO-Participant-List-Agreement.pdf*.

For the 6-month performance year from January 1, 2019 through June 30, 2019, we proposed to determine the benchmark and calculate performance year expenditures for assigned beneficiaries as though the performance year were the entire calendar year. The ACO's historical benchmark would be determined according to the methodology applicable to the ACO based on its agreement period in the program. We would apply the methodology for establishing, updating and adjusting the ACO's historical benchmark as specified in § 425.602 (for ACOs in a first agreement period) or § 425.603 (for ACOs in a second agreement period), except that data from CY 2019 would be used in place of data for the 6-month performance year in certain calculations, as follows:

- The benchmark would be adjusted for changes in severity and case mix between benchmark year 3 and CY 2019 using the methodology that accounts separately for newly and continuously assigned beneficiaries using prospective HCC risk scores and demographic factors as described under §§ 425.604(a)(1) through (3), 425.606(a)(1) through (3), and 425.610(a)(1) through (3).
- The benchmark would be updated to CY 2019 according to the methodology for using growth in national Medicare FFS expenditures for assignable beneficiaries described under §§ 425.602(b) (for ACOs in a first agreement period) and 425.603(b) (for ACOs in a second agreement period beginning January 1, 2016).

For determining financial performance during the 6-month performance year from January 1, 2019 through June 30, 2019, we would apply the methodology for determining shared savings and shared losses according to the approach specified for the ACO's track under the terms of the participation agreement that was in effect on January 1, 2019: § 425.604 (Track 1), § 425.606 (Track 2) or § 425.610 (Track 3) and, if applicable, the terms of the ACO's participation agreement for the Track 1+ Model authorized under section 1115A of the Act. (See discussion in section II.F. of the August 2018 proposed rule (83 FR 41912 through 41914) concerning applicability of proposed policies to Track 1+ Model ACOs.) However, some exceptions to the otherwise applicable methodology were needed because we proposed to calculate the expenditures for assigned beneficiaries over the full CY 2019 for purposes of determining shared savings and shared losses for the 6-month performance year from January 1, 2019 through June 30, 2019. We proposed to use the following steps to calculate shared savings and shared losses:

- Average per capita Medicare expenditures for Parts A and B services for CY 2019 would be calculated for the ACO's performance year assigned beneficiary population.
- We would compare these expenditures to the ACO's updated benchmark determined for the calendar year as previously described.
- We would apply the MSR and MLR (as applicable).

++ The ACO's assigned beneficiary population for the performance year starting on January 1, 2019, would be used to determine the MSR for Track 1 ACOs and the variable MSR/MLR for ACOs in a two-sided model that selected this option at the start of their agreement period. In the event a two-sided model ACO selected a fixed MSR/MLR at the start of its agreement period, and the ACO's performance year assigned population is below 5,000 beneficiaries, we proposed that the MSR/MLR would be determined based on the number of assigned beneficiaries as described in section II.A.6.b. of the August 2018 proposed rule (83 FR 41837 through 41839).

++ To qualify for shared savings, the ACO's average per capita Medicare expenditures for its performance year assigned beneficiaries during CY 2019 must be below its updated benchmark for the year by at least the MSR established for the ACO.

++ To be responsible for sharing losses with the Medicare program, the ACO's average per capita Medicare expenditures for its performance year assigned beneficiaries during CY 2019 must be above its updated benchmark for the year by at least the MLR established for the ACO.

• We would determine the shared savings amount if we determine the ACO met or exceeded the MSR, and if the ACO met the minimum quality performance standards established under § 425.502 as described in the August 2018 proposed rule and section V.B.1.c.(4) of this final rule, and otherwise maintained its eligibility to participate in the Shared Savings Program. We would determine the shared losses amount if we determine the ACO met or exceeded the MLR. To determine these amounts, we would do the following:

++ We would apply the final sharing rate or loss sharing rate to first dollar savings or losses.

++ For ACOs that generated savings that met or exceeded the MSR, we would multiply the difference between the updated benchmark expenditures and performance year assigned beneficiary expenditures by the applicable final sharing rate based on the ACO's track and its quality performance as calculated under § 425.502.

++ For ACOs that generated losses that met or exceeded the MLR, we would multiply the difference between the updated benchmark expenditures and performance year assigned beneficiary expenditures by the applicable shared loss rate based on the ACO's track and its quality performance as calculated under § 425.502 (for ACOs in tracks where the loss sharing rate is determined based on the ACO's quality performance).

• We would adjust the shared savings amount, if any, for sequestration by reducing by 2 percent and compare the sequestration-adjusted shared savings amount to the applicable performance payment limit based on the ACO's track.

• We would compare the shared losses amount, if any, to the applicable loss sharing limit based on the ACO's track.

• We would pro-rate any shared savings amount, as adjusted for sequestration and the performance payment limit, or any shared losses amount, as adjusted for the loss sharing limit, by multiplying by one half, which represents the fraction of the calendar year covered by the 6-month performance year. This pro-rated amount would be the final amount of shared savings that would be paid to the ACO for the 6-month performance year or the final amount of shared losses that would be owed by the ACO for the 6-month performance year.

We sought comment on these proposals.

Comment: In general, some commenters supported CMS' proposed policies governing how shared savings and shared losses would be calculated for the 6-month performance year from January 1, 2019 through June 30, 2019. Some commenters noted there is significant complexity with this approach and urged CMS to clarify and provide additional guidance and education to ACOs concerning how certain operational details will be addressed. Commenters raised concerns about certain aspects of the methodology for determining quality and financial performance for a 6-month performance year under the proposed approach, and other aspects of program participation affected by a 6-month performance year, which we summarize elsewhere within section V.B.1.b. and V.B.1.c. of this final rule, including (but not limited to) the approach to determining beneficiary assignment, flexibilities for making ACO participant list changes, quality reporting considerations, and interactions with the Quality Payment Program policies.

Response: We appreciate commenters' support for the proposed approach for determining financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019. As discussed in the August 2018 proposed rule, we continue to believe in the importance of using this approach to maintain alignment with program calculations made on a 12-month basis. This approach maintains alignment with the program's existing methodology by using 12 months of expenditure data (for CY 2019) in determining the ACO's financial performance and a 12-month period for quality measure assessment. In sections V.B.1.b. and V.B.1.c. of this final rule we respond to comments on the specific aspects of the methodology for determining financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, and other aspects of program participation affected by a 6-month performance year. We acknowledge that this approach will add complexity to program policies and certain operational processes. To assist ACOs in understanding the operational details of participation in a 6-month performance year from January 1, 2019 through June 30, 2019, we anticipate providing education and offering outreach to ACOs on these policies through the various methods available, including guidance documents, webinars, FAQs and a weekly newsletter.

Comment: A few commenters expressed support for the proposed approach to determining beneficiary assignment for the 6-month performance year from January 1, 2019 through June 30, 2019.

Response: In finalizing the 6-month agreement period extension for ACOs that started a first or second agreement period on January 1, 2016, we believe it is appropriate to finalize our proposed approach to determining beneficiary assignment for the performance year from January 1, 2019 through June 30, 2019. To determine beneficiary assignment for the 6-month performance year, we proposed to consider the allowed charges for primary care services furnished to beneficiaries during a 12-month assignment window, allowing for a 3-month claims run out. For ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window would be CY 2019. For ACOs under prospective assignment, Medicare FFS beneficiaries would be prospectively assigned to the ACO based on beneficiaries' use of primary care services in the most recent 12 months for which data are available. For example, in determining prospective beneficiary assignment for the January 1, 2019 through June 30, 2019 performance year, we could use an assignment window from October 1, 2017 through September 30, 2018, to align with the off-set assignment window typically used to determine prospective assignment prior to the start of a calendar year performance year. Beneficiaries would remain prospectively assigned to the ACO for the performance year unless they meet any of the exclusion criteria under § 425.401(b) during the calendar year. This approach would maintain alignment with our methodology for assigning beneficiaries to ACOs participating in a 12-month performance year, and allow us to use the same methodology to determine beneficiary assignment for all ACOs participating in a performance year beginning January 1, 2019. This approach would also be consistent with the methodology used to assign beneficiaries for the historical benchmark period.

Comment: One commenter noted that the proposal to pro-rate shared savings and shared losses to reflect the 6-month period of participation from January 1, 2019 through June 30, 2019, fails to account for habitual behavior of Medicare beneficiaries. The commenter explained that most annual wellness visits are performed in the 3rd and 4th quarters of the calendar year, and quarter 1 and quarter 2 of the calendar year typically show lower healthcare utilization. According to the commenter, Medicare beneficiaries tend to wait to visit the doctor until their deductible is met, which usually occurs towards the end of the calendar year. The commenter indicated that this delay occurs even for preventive services, like annual wellness visits, that are free at the point of delivery. The commenter also seems to have an incorrect understanding that we are using only quarter 1 and quarter 2 data to determine financial performance for the 6-month performance year from January 1, 2019 through June 30, 2019, suggesting that an approach that only accounts for 6 months of expenditures would result in quality and financial performance determinations that do not fairly reflect the ACO's quality of care and expenditures for assigned beneficiaries. Another commenter explained that Medicare expenditures demonstrate strong and well-known seasonality which would skew performance results when comparing performance from the first 6 months of the calendar year against a pro-rated benchmark which represents an annual average.

Response: Under the proposed approach to determining financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, as restated in this section of this final rule, we would continue to determine beneficiary assignment and expenditures on a 12-month basis. To determine beneficiary assignment, we would consider the allowed charges for primary care services furnished to the beneficiary during a 12-month assignment window, allowing for a 3-month claims run out. We would maintain the calendar year-based methodology for calculating benchmark expenditures, trend and update factors, and risk adjustment. To determine shared savings and shared losses, we would calculate average per capita Medicare expenditures for Parts A and B services for CY 2019 for the ACO's performance year assigned beneficiary population and compare this amount to the updated historical benchmark. We would then pro-rate any shared savings or shared losses by multiplying the amounts by one-half, which represents the fraction of the calendar year covered by the 6-month performance year. We believe this approach addresses the commenters' concerns, because we would capture assigned beneficiaries' expenditures for the entire CY 2019, which we would compare to a benchmark also based on 12 months of expenditures to maintain consistency and avoid any seasonality or other variation in expenditures that could result from the use of different timeframes. We continue to believe that this approach to reconciling ACOs for the 6-month performance year from January 1, 2019 through June 30, 2019, based on expenditures for the 12-month period corresponding to CY 2019 would protect the actuarial soundness of the financial reconciliation methodology.

Comment: A few commenters urged CMS to apply the regional benchmarking methodology in determining the historical benchmark for ACOs that first entered the program in 2013 or 2016 that elect a 6-month extension. One commenter stated that under the program's current policies, the regional rebasing methodology would apply to ACOs that renew for a second or third agreement period beginning January 1, 2019. This commenter also pointed to CMS' proposal in the August 2018 proposed rule to incorporate regional expenditures in benchmark calculations beginning with an ACO's first agreement period for agreement periods beginning on July 1, 2019, and in subsequent years to underscore the urgency for ACOs that may be entering their seventh performance year of program participation without any regional adjustment to be under a benchmarking approach that could help to sustain their accountable care programs and allow them to drive further cost reductions. Several other commenters suggested that CMS rebase the historical benchmark for ACOs electing the extension from January 1, 2019 through June 30, 2019, so that the ACO's historical benchmark years would be 2016, 2017, and 2018 (as opposed to 2013, 2014, and 2015 under the ACO's current agreement period), using a regional rebasing methodology. One commenter explained that rebasing these ACOs' benchmarks using regional factors would remove the drawback related to a delay in agreement period renewal for the organizations on the leading edge of the Shared Savings Program. This commenter also explained that benchmark rebasing would account for non-claims based payments during 2016, 2017, 2018 in the ACO's historical benchmark, and would eliminate the delay in aligning the benchmark with the full range of services included in calculating performance year expenditures.

Response: We appreciate the comments, but we decline to accept the commenters' suggestions to reset the benchmark for ACOs electing the 6-month extension to their current agreement period. As proposed, the 6-month extension allows for continued participation under the ACO's current agreement period, which would not meet the conditions for applying the program's methodology for rebasing the ACO's historical benchmark under § 425.603(a). Accordingly, we would continue to update and adjust the benchmarks for ACOs electing this extension using the methodology specified under §§ 425.602 and 425.603(b), as applicable. We also note that for ACOs with second agreement periods beginning on January 1, 2016, that elect the voluntary 6-month extension, the benchmark rebasing methodology that was used to determine their benchmark for their second agreement period accounts for a portion of the savings they generated in their prior agreement period as an adjustment to their historical benchmark. This adjustment coupled with the additional time they will be allowed to participate under their existing historical benchmark should continue to provide a strong incentive during the extension period.

(2) Use of Authority Under Section 1899(i)(3) of the Act

In the August 2018 proposed rule (83 FR 41851), we explained our belief that the proposal to determine shared savings and shared losses for the 6-month performance year starting on January 1, 2019, using expenditures for the entire CY 2019 and then pro-rating these amounts to reflect the shorter performance year, requires the use of our authority under section 1899(i)(3) of the Act to use other payment models. Section 1899(d)(1)(B)(i) of the Act specifies that, in each year of the agreement period, an ACO is eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark under section 1899(d)(1)(B)(ii) of the Act. We explained our belief that the proposed approach to calculating the expenditures for assigned beneficiaries

over the full calendar year, comparing this amount to the updated benchmark for 2019, and then pro-rating any shared savings (or shared losses, which already are implemented using our authority under section 1899(i)(3) of the Act) for the 6-month performance year involves an adjustment to the estimated average per capita Medicare Part A and Part B FFS expenditures determined under section 1899(d)(1)(B)(i) of the Act that is not based on beneficiary characteristics. Such an adjustment is not contemplated under the plain language of section 1899(d)(1)(B)(i) of the Act. As a result, we stated it would be necessary to use our authority under section 1899(i)(3) of the Act to calculate performance year expenditures and determine the final amount of any shared savings (or shared losses) for a 6-month performance year during 2019, in the proposed manner.

In order to use our authority under section 1899(i)(3) of the Act to adopt an alternative payment methodology to calculate shared savings and shared losses for the proposed 6-month performance year from January 1, 2019 through June 30, 2019, we must determine that the alternative payment methodology will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without additional program expenditures. We explained our belief that the proposed approach of allowing ACOs that started a first or second agreement period on January 1, 2016, to extend their agreement period for a 6-month performance year and of allowing entry into the program's redesigned participation options beginning on July 1, 2019, if finalized, would support continued participation by current ACOs that must renew their agreements to continue participating in the program, while also resulting in more rapid progression to two-sided risk by ACOs within current agreement periods and ACOs entering the program for an initial agreement period. As discussed in the Regulatory Impact Analysis of the August 2018 proposed rule (83 FR 41915 through 41928), we explained our belief that this approach would continue to allow for lower growth in Medicare FFS expenditures based on projected participation trends. Therefore, we did not believe that the proposed methodology for determining shared savings or shared losses for ACOs in a 6-month performance year during 2019 would result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) of the Act. Further, we noted that the proposed approach to measuring ACO quality performance for a 6-month performance year based on quality data reported for CY 2019 would maintain accountability for the quality of care ACOs provide to their assigned beneficiaries. Participating ACOs would also have an incentive to perform well on the quality measures in order to maximize the shared savings they may receive and minimize any shared losses they may be required to pay in tracks where the loss sharing rate is determined based on the ACO's quality performance. Therefore, we noted our expectation that this proposed approach to reconciling ACOs for a 6-month performance year during 2019 would continue to lead to improvement in the quality of care furnished to Medicare FFS beneficiaries.

As discussed in the Regulatory Impact Analysis section of this final rule (section VII.), we believe the approach to determining shared savings and shared losses for the 6-month performance year from January 1, 2019 through June 30, 2019, for ACOs that elect to voluntarily extend their agreement period meets the requirements for use of our authority under section 1899(i)(3) of the Act. The considerations we described in the August 2018 proposed rule were relevant in making this determination. Specifically, we do not believe that the methodology for determining shared savings or shared losses for ACOs in a 6-month performance year from January 1, 2019 through June 30, 2019, (as finalized in this section) will result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) of the Act. Finalizing the voluntary 6-month extension for ACOs whose agreement periods expire on December 31, 2018, will support continued participation by these ACOs, and therefore, also allow for lower growth in Medicare FFS expenditures based on projected participation trends. Further, we believe the approach we are finalizing for reconciling ACOs for a 6-month performance year from January 1, 2019 through June 30, 2019, will lead to continued improvement in the quality of care furnished to Medicare FFS beneficiaries. As described in section V.B.1.c.(4) of this final rule, the approach to measuring ACO quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, based on quality data reported for CY 2019, will maintain accountability for the quality of care ACOs provide to their assigned beneficiaries. Participating ACOs will have an incentive to perform well on the quality measures in order to maximize the shared savings they may receive and minimize any shared losses they may be required to pay in two-sided risk tracks where the loss sharing rate is determined based on the ACO's quality performance.

(3) Final Policies

After consideration of the public comments received, we are finalizing, with modifications, the proposed approach to determine financial and quality performance for ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019, as specified in paragraphs (a) and (b) of a new section of the regulations at § 425.609. These modifications are necessary because this final rule only addresses the 6-month extension period, and does not address our proposal to establish a July 1, 2019 agreement start date. In summary, we will do the following to determine an ACO's financial and quality performance during the 6-month performance year from January 1, 2019 through June 30, 2019: We will compare the ACO's historical benchmark updated to CY 2019 to the expenditures during CY 2019 for the ACO's performance year assigned beneficiaries. If the difference is positive and is greater than or equal to the MSR and the ACO has met the quality performance standard, the ACO will be eligible for shared savings. If the ACO is in a two-sided model and the difference between the updated benchmark and assigned beneficiary expenditures is negative and is greater than or equal to the MLR (in absolute value terms), the ACO will be liable for shared losses. ACOs will share in first dollar savings and losses. The amount of any shared savings will be determined using the applicable final sharing rate, which is determined based on the ACO's track for the applicable agreement period, and taking into account the ACO's quality performance for 2019.

We will adjust the amount of shared savings for sequestration, and then cap the amount of shared savings at the applicable performance payment limit for the ACO's track. Similarly, the amount of any shared losses will be determined using the loss sharing rate for the ACO's track and, as applicable, for ACOs in tracks with a loss sharing rate that depends upon quality performance, the ACO's quality performance for 2019.We will then cap the amount of shared losses at the applicable loss sharing limit for the ACO's track. We will then pro-rate any shared savings or shared losses by

multiplying by one-half, which represents the fraction of the calendar year covered by the 6-month performance year. This pro-rated amount will be the final amount of shared savings earned or shared losses owed by the ACO for the 6-month performance year.

Because we are not addressing the proposed July 1, 2019 agreement period start date for the proposed new BASIC track and ENHANCED track at this time, we note the following differences between our proposed approach (which contemplated that ACOs may be participating in both a 6-month performance year from January 1, 2019 through June 30, 2019, and a 6-month performance year from July 1, 2019 through December 31, 2019) and our final policies (which are limited to the 6-month performance year from January 1, 2019 through June 30, 2019, for eligible ACOs that elect to extend their agreement period, which would otherwise expire on December 31, 2018):

- We are omitting references that we proposed to include in § 425.609(b) in order to establish the applicability of these policies to ACOs that begin a 12-month performance year on January 1, 2019, but elect to terminate their participation agreement with an effective date of termination of June 30, 2019, in order to enter a new agreement period starting on July 1, 2019 (early renewals). We are also making clarifying revisions to the introductory text in § 425.609(b).
- As described in section V.B.1.c.(4) of this final rule we are finalizing a subset of our proposals for identifying the ACO participant list used in determining quality reporting samples for ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019. We are finalizing our proposal to use the ACO's latest certified ACO participant list (the ACO participant list effective on January 1, 2019) to determine the quality reporting samples for the 2019 reporting period.
- We are not addressing at this time the proposals for modifying the MSR/MLR to address small population sizes (83 FR 41837 through 41839). Therefore, the policies for determining shared savings and shared losses in the event the ACO's assigned population falls below 5,000, as specified under the program's current regulations at § 425.110, would apply to ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019. Therefore, we will specify in § 425.609(b)(3)(ii)(C)(*1*) that the ACO's performance year assigned beneficiary population is used to determine the MSR for Track 1 ACOs and the variable MSR/MLR for ACOs in a two-sided model that selected this option at the start of their agreement period. For two-sided model ACOs that selected a fixed MSR/MLR at the start of the ACO's agreement period, this fixed MSR/MLR is applied. In the event an ACO's performance year assigned population identified in § 425.609(b)(1) is below 5,000 beneficiaries, the MSR/MLR is determined according to § 425.110(b).
- We are also reserving paragraph (c) of § 425.609 in the event that we finalize policies for a second 6-month performance year during CY 2019 in the future.

In section V.B.1.c. of this final rule, we discuss our decision to finalize other provisions from the August 2018 proposed rule related to determining performance for the 6-month performance year, as specified in paragraphs (d) and (e) of § 425.609.

c. Applicability of Program Policies to ACOs Participating in a 6-Month Performance Year

In the August 2018 proposed rule (83 FR 41854), we proposed that program requirements under 42 CFR part 425 that are applicable to the ACO under the ACO's chosen participation track and based on the ACO's agreement start date would be applicable to an ACO participating in a 6-month performance year, unless otherwise stated. We received no comments on this general proposal and we are finalizing this general approach as proposed. As we explained in the August 2018 proposed rule, this approach will allow routine program operations to continue to apply for ACOs participating under a shorter performance year. Further, it will ensure consistency in the applicability and implementation of our requirements across all program participants, including ACOs participating in a 6-month performance year.

In section V.B.1.b. of this final rule, we describe limited exceptions to our general policies for determining financial and quality performance which are necessary to ensure calculations can continue to be performed on a calendar year basis and using the most relevant data.

In this section, we describe program participation options affected by our decision to forgo an application cycle in CY 2018 for a January 1, 2019 start date, and offer a voluntary extension to allow ACOs whose agreement periods expire on December 31, 2018, to continue their participation in the program for a 6-month performance year from January 1, 2019 through June 30, 2019. We discuss modifications to program policies to allow for the 6-month performance year and related revisions to the program's regulations. As discussed in section II.A.7.c. of the August 2018 proposed rule (83 FR 41854 through 41860), these proposals were developed, in part, based on our proposal to offer an application cycle in CY 2019 for a July 1, 2019 start date. Therefore, we considered that some ACOs would participate in the program for both the 6-month performance year (or performance period) from January 1, 2019 through June 30, 2019, and the 6-month performance year from July 1, 2019 through December 31, 2019, while other ACOs would only participate in one of these performance years. In this final rule, we do not address the considerations related to the proposed July 1, 2019 agreement period start date because we are not addressing the proposal to offer that start date at this time.

(1) Unavailability of an Application Cycle for Use of a SNF 3-Day Rule Waiver Beginning January 1, 2019

Eligible ACOs may apply for use of a SNF 3-day rule waiver at the time of application for an initial agreement or to renew their participation. Further, as described in sections II.B.2.a. and II.F. of the August 2018 proposed rule (83 FR 41860, 41912), ACOs within a current agreement period under Track 3, or the Track 1+ Model may apply for a SNF 3-day rule waiver, which, if approved, would begin at the start of their next performance year.

In light of our decision to forgo an application cycle in CY 2018 for a January 1, 2019 agreement period start date, we are also not offering an opportunity for ACOs to apply for a start date of January 1, 2019, for initial use of a SNF 3-day rule waiver. We proposed that, if finalized, the next available application cycle for a SNF 3-day rule waiver would occur in advance of a July 1, 2019 start date. Absent further rulemaking to establish participation options for a start date in 2019 that includes an opportunity for ACOs within existing agreement periods in Track 3 or the Track 1+ Model to apply for a SNF 3-day rule waiver, these ACOs would not have the opportunity to apply to begin use of the waiver until January 1, 2020.

(2) Annual Certifications and ACO Participant List Modifications

At the end of each performance year, ACOs complete an annual certification process. At the same time as this annual certification process, CMS also requires ACOs to review, certify and electronically sign official program

documents to support the ACO's participation for the upcoming performance year. As we stated in the August 2018 proposed rule (83 FR 41855), requirements for this annual certification, and other certifications that occur on an annual basis, continue to apply to all currently participating ACOs in advance of the performance year beginning on January 1, 2019.

Each ACO is required to certify its list of ACO participant TINs before the start of its agreement period, before every performance year thereafter, and at such other times as specified by CMS in accordance with § 425.118(a). A request to add ACO participants must be submitted prior to the start of the performance year in which these additions would become effective. An ACO must notify CMS no later than 30 days after termination of an ACO participant agreement, and the entity is deleted from the ACO participant list effective as of the termination date of the ACO participant agreement. Absent unusual circumstances, the ACO participant list that was certified prior to the start of the performance year is used to determine beneficiary assignment for the performance year and therefore also the ACO's quality reporting samples and financial performance. See § 425.118(b)(3) and see also Medicare Shared Savings Program ACO Participant List and Participant Agreement Guidance (July 2018, version 5), available at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/sharedsavingsprogram/downloads/aco-participant-list-agreement.pdf*. As we explained in the August 2018 proposed rule (83 FR 41855), these policies would apply for ACOs participating in a 6-month performance year consistent with the terms of the existing regulations.

As we explained in the August 2018 proposed rule (83 FR 41855), ACOs that started a first or second agreement period on January 1, 2016, that extend their agreement period for a 6-month performance year beginning on January 1, 2019, would have the opportunity during 2018 to make changes to their ACO participant list to be effective for the 6-month performance year from January 1, 2019, to June 30, 2019. To prepare for the possible implementation of this 6-month performance year, we allowed ACOs that started a first or second agreement period on January 1, 2016, to submit change requests in accordance with usual program procedures to indicate additions, updates, and deletions to their existing ACO participant lists, and if applicable, SNF affiliate lists.

The program's current regulations prevent duplication of shared savings payments; thus, under § 425.114, ACOs may not participate in the Shared Savings Program if they include an ACO participant that participates in another Medicare initiative that involves shared savings. In addition, under § 425.306(b)(2), each ACO participant that submits claims for services used to determine the ACO's assigned population must be exclusive to one Shared Savings Program ACO. If, during a benchmark or performance year (including the 3-month claims run out for such benchmark or performance year), an ACO participant that participates in more than one ACO submits claims for services used in assignment, then CMS will not consider any services billed through the TIN of the ACO participant when performing assignment for the benchmark or performance year; and the ACO may be subject to the pre-termination actions set forth in § 425.216, termination under § 425.218, or both.

Comment: Some commenters urged CMS to provide ACOs with opportunities to add and delete ACO participants throughout the performance years (or performance periods) during 2019 and to clarify when such opportunities would be available. These commenters urged CMS to provide additional guidance and education to ACOs on when participant list changes would be permitted. One commenter suggested that CMS should provide an additional opportunity for ACOs with agreement periods expiring on December 31, 2018, to add ACO participants and/or SNF affiliate TINs and CCNs for performance year 2019 because of the short period of time between the issuance of the proposed rule (August 9, 2018) and the final deadline for adding ACO participants for performance year 2019 (September 28, 2018). The commenter explained that the proposed rule caused confusion and uncertainty, and as a result, the commenter believes many ACO participants missed the deadline to be added to the ACO participant lists of other ACOs. The commenter suggested that we should offer an additional opportunity to add ACO participants, with the deadline set for 1 month after publication of a final rule.

Response: During 2018, we allowed ACOs that started a first or second agreement period on January 1, 2016, to submit ACO participant change requests in accordance with usual program procedures to indicate additions, updates, and deletions to their existing ACO participant lists and, if applicable, SNF affiliate lists. We noted that the final disposition of any change request submitted by an ACO that started a first or second agreement period on January 1, 2016, would be contingent upon issuance of a final rule establishing an opportunity for these ACOs to continue their participation during 2019 without a gap in participation. As discussed in section V.B.1. of this final rule, we are finalizing the proposed 6-month extension for ACOs whose current participation agreement expire on December 31, 2018.

As a result, all ACOs, including those ACOs that will be eligible to elect the voluntary 6-month extension that we are finalizing this final rule, had multiple opportunities to submit change requests to add ACO participants and/or SNF affiliates for performance years starting on January 1, 2019. We also launched a new ACO management system during 2018 that is more user friendly, provides faster feedback, and encourages ACOs to submit change requests to add ACO participants and SNF affiliates with fewer errors than the system that was available in previous years. We do not believe it is operationally feasible to extend the date for ACOs to submit change requests after September 28, 2018, the date we communicated to ACOs as being the deadline to add ACO participants to be effective for performance years beginning on January 1, 2019. Allowing change requests seeking to add new ACO participants to be submitted very close to the end of the calendar year would not provide sufficient time to review and screen providers/suppliers for program integrity issues and create 2019 assignment list reports, and may have other operational impacts (such as on timely production of certain other program reports). We note, however, ACO participants can be terminated and deleted from the ACO participant list at any time during a performance year. The ACO participant is no longer an ACO participant as of the termination effective date of the ACO participant agreement. Absent unusual circumstances, however, the ACO participant data will continue to be utilized for certain operational purposes.

(3) Repayment Mechanism Requirements

ACOs must demonstrate that they have in place an adequate repayment mechanism prior to entering a two-sided model. The repayment mechanism must be in effect for the duration of an ACO's participation in a two-sided model and for a sufficient period of time after the conclusion of the agreement period to permit CMS to calculate the amount of

shared losses owed and to collect this amount from the ACO (§ 425.204(f)(4)). We noted in our ''Repayment Mechanism Arrangements'' guidance document that we would consider this standard to be satisfied by a repayment mechanism arrangement that remains in effect for 24 months after the end of the agreement period. See Medicare Shared Savings Program & Medicare ACO Track 1+ Model, Repayment Mechanism Arrangements, Guidance Document (July 2017, version #6), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Repayment-Mechanism-Guidance.pdf (herein Repayment Mechanism Arrangements Guidance).*

In the August 2018 proposed rule (83 FR 41856), we noted that ACOs that started a first or second agreement period on January 1, 2016, in a two-sided model would have in place under current program policies a repayment mechanism arrangement that would cover the 3 years between January 1, 2016 and December 31, 2018, plus a 24-month tail period until December 31, 2020. We would expect an ACO with an agreement period ending December 31, 2018, that extends its agreement for the 6-month performance year from January 1, 2019 through June 30, 2019, to likewise extend the term of its repayment mechanism so that it will be in effect for the duration of the ACO's participation in a two-sided model plus 24 months following the conclusion of the agreement period (that is, until June 30, 2021). This would allow us sufficient time to perform financial calculations for the 6-month performance year from January 1, 2019 through June 30, 2019, and to use the arrangement to collect shared losses for that performance year, if necessary.

In a forthcoming final rule, we expect to summarize and respond to comments on our proposed changes to § 425.204(f) regarding repayment mechanism requirements for ACOs that are in a two-sided model.

Comment: One commenter expressed concern over the lack of current guidance on the required amount of a repayment mechanism arrangement (particularly for Track 1+ Model ACOs) and on how to execute changes to an existing repayment mechanism arrangement in order to support an ACO's participation during the 6-month performance year from January 1, 2019 through June 30, 2019. The commenter also indicated that changing repayment mechanism amounts mid-year would likely result in extra costs to an ACO.

Response: We appreciate the commenter's concern. We may require a Track 1+ Model ACO to adjust its repayment mechanism amount if, during the ACO's agreement period, changes in the ACO's participant composition occur that result in the application of a relatively higher or lower loss sharing limit. For example, if a Track 1+ Model ACO reports changes to its composition during the annual certification process in advance of the next performance year, and we determine that the ACO no longer qualifies for a revenue-based loss sharing limit, we may require the ACO to demonstrate that its repayment mechanism is sufficient to support losses for a higher amount under a benchmark-based loss sharing limit (83 FR 41841). We will notify an ACO if there is a significant change in its repayment mechanism amount warranting modification of its repayment mechanism arrangement and will specify the process for submitting to us revised repayment mechanism arrangement documentation for review. With regard to ACOs participating under Track 2 or Track 3, we clarify that, for the 6-month performance year from January 1, 2019 through June 30, 2019, we will not require any such ACO that elects to extend its participation agreement for such performance year to modify the amount we previously approved for the ACO's repayment mechanism arrangement.

In addition, we have notified ACOs participating under a two-sided model that if they elect the 6-month extension from January 1, 2019 through June 30, 2019 then we expect that they will extend their repayment mechanisms in accordance with § 425.204(f)(4). As we noted in our *Repayment Mechanism Arrangements Guidance,* we would consider § 425.204(f)(4) to be satisfied by a repayment mechanism arrangement that remains in effect for 24 months after the end of the agreement period. Accordingly, an ACO participating under a two-sided model that elects the 6-month extension from January 1, 2019 through June 30, 2019, should extend the term of its repayment mechanism until June 30, 2021.

We acknowledge that amending certain repayment mechanism arrangements could come at additional costs to ACOs. However, we believe it necessary that the repayment mechanism arrangements comply with Shared Savings Program and Track 1+ Model policy to ensure the ACO can repay losses for which it may be liable.

(4) Quality Reporting and Quality Measure Sampling

As described in the August 2018 proposed rule (83 FR 41856 through 41858), to determine an ACO's quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, we proposed to use the ACO's quality performance for the 2019 reporting period as determined under § 425.502. Under this proposed approach, we would account for the ACO's quality performance using quality measure data reported for the 12-month CY 2019.

As we explained in the August 2018 proposed rule, the following considerations support this proposed approach. For one, use of a 12-month period for quality measure assessment maintains alignment with the program's existing quality measurement approach, and aligns with the proposed use of 12 months of expenditure data (for CY 2019) in determining the ACO's financial performance. Also, this approach would continue to align the program's quality reporting period with policies under the Quality Payment Program. ACO professionals that are MIPS eligible clinicians (not QPs based on their participation in an Advanced APM or otherwise excluded from MIPS) would continue to be scored under MIPS using the APM scoring standard that covers all of 2019. Second, the measure specifications for the quality measures used under the program require 12 months of data. See for example, the Shared Savings Program ACO 2018 Quality Measures Narrative Specification Document (January 20, 2018), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/2018-reporting-year-narrative-specifications.pdf.* Third, in light of our proposal to use 12 months of expenditures (based on CY 2019) in determining shared savings and shared losses for a 6-month performance year, it would also be appropriate to hold ACOs accountable for the quality of the care furnished to their assigned beneficiaries during this same timeframe. Fourth, and lastly, using an annual quality reporting cycle for the 6-month performance year would avoid the need to introduce new reporting requirements, and therefore, potential additional burden on ACOs.

The ACO participant list is used to determine beneficiary assignment for purposes of generating the quality reporting samples. Beneficiary assignment is performed using the applicable assignment methodology under § 425.400, either preliminary prospective assignment or prospective assignment, with excluded beneficiaries removed under § 425.401(b), as applicable. The samples for claims-based measures are typically

determined based on the assignment list for calendar year quarter 4. The sample for quality measures reported through the CMS Web Interface is typically determined based on the beneficiary assignment list for calendar year quarter 3. The CAHPS for ACOs survey sample is typically determined based on the beneficiary assignment list for calendar year quarter 2.

For purposes of determining the quality reporting samples for the 2019 reporting period, we proposed to use the ACO's most recent certified ACO participant list available at the time the quality reporting samples are generated, and the assignment methodology most recently applicable to the ACO for a 2019 performance year. We explained our belief that the use of the ACO's most recent certified ACO participant list to assign beneficiaries according to the assignment methodology applicable based on the ACO's most recent participation in the program during 2019 would result in the most relevant beneficiary samples for 2019 quality reporting. Additionally, we believed this proposed approach to determining the ACO's quality reporting samples was also appropriate for an ACO that participated in only one 6-month performance year during 2019 because the most recent certified ACO participant list applicable for the performance year would also be the certified ACO participant list that is used to determine financial performance.

We proposed two approaches to determine the certified ACO participant list, assignment methodology, and assignment window that would be used to generate the quality reporting samples for measuring quality performance of ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019. One approach was applicable to ACOs that enter a new agreement period under the proposed July 1, 2019 agreement start date, including ACOs that extended their prior participation agreement for the 6-month performance year from January 1, 2019, to June 30, 2019. For ACOs that enter a new agreement period beginning on July 1, 2019, we proposed to use the certified ACO participant list for the performance year starting on July 1, 2019, to determine the quality reporting samples for the 2019 reporting period. This most recent certified ACO participant list would therefore be used to determine the quality reporting samples for the 2019 reporting year. A second approach was proposed for an ACO that extends its participation for the first 6 months of 2019, but does not enter a new agreement period beginning on the proposed July 1, 2019 agreement start date. This second approach is relevant to the policies we are finalizing in this final rule, for the 6-month performance year from January 1, 2019 through June 30, 2019, for ACOs whose current participation agreements expire on December 31, 2018, and that voluntarily elect to extend their agreement period for a fourth performance year. Under this approach, we proposed to use the ACO's latest certified participant list (the ACO participant list effective on January 1, 2019) to determine the quality reporting samples for the 2019 reporting period. Beneficiary assignment for purposes of generating the quality reporting samples would be based on the assignment methodology applicable to the ACO during its 6-month performance year from January 1, 2019 through June 30, 2019, under § 425.400, either preliminary prospective assignment or prospective assignment, with excluded beneficiaries removed under § 425.401(b), as applicable. We anticipated that the assignment windows for the quality reporting samples would be as follows, based on our operational experience: (1) Samples for claims-based measures would be determined based on the assignment list for calendar year quarter 4; (2) the sample for CMS Web Interface measures would be determined based on the assignment list for calendar year quarter 3; and (3) the sample for the CAHPS for ACOs survey would be determined based on the assignment list for calendar year quarter 2. We noted that this approach would maintain alignment with the assignment windows currently used for establishing quality reporting samples for these measures.

We proposed to specify the certified ACO participant list that would be used in determining the quality reporting samples for measuring quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, in a new section of the regulations at § 425.609(b).

Comment: Some commenters requested clarification about how quality reporting will take place for 6-month performance periods based on 12 months of data. Specifically, these commenters stated their assumption that all ACOs would only be responsible for reporting quality one time, during the typical January to March timeframe following the end of 2019. One commenter expressed concern that the proposed approach for two 6-month performance years and two financial reconciliations for performance years in CY 2019 would also require two separate quality reporting samples for measures reported through the CMS Web Interface. The commenter was concerned about the burden that would be imposed on ACOs by such a requirement, given that annual quality reporting requires a significant amount of ACO resources.

Response: We proposed to determine quality performance for the 6-month performance years during 2019 based on an ACO's quality performance during the 12-month CY 2019 in order to align with the program's existing quality reporting methodology, measure specifications which require 12-months of data, and the APM scoring standard under MIPS. In addition, because we proposed to use quality performance during all of CY 2019, we proposed that ACOs would only have to report quality once for CY 2019, regardless of whether they complete their participation in the program following the conclusion of the 6-month performance year from January 1, 2019 through June 30, 2019, or they renew for a new agreement period beginning on July 1, 2019 (if finalized as proposed). Therefore, ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019, and the 6-month performance year from July 1, 2019 through December 31, 2019 (if finalized as proposed), would report quality for one beneficiary sample for CY 2019.

We also note that for the 2019 reporting period, ACOs would be required to report quality data through the CMS Web Interface, according to the method and timing of submission established by CMS. The period for reporting quality data through the CMS Web Interface typically occurs for a 12-week period between January and March, following the conclusion of the calendar year. Thus, ACOs that participate in a 6-month performance year from January 1, 2019 through June 30, 2019, along with all other Shared Savings Program ACOs would be required to report for the 2019 reporting period, and would report quality data through the CMS Web Interface during the designated reporting period in early 2020. Further, ACOs participating in the 6-month performance year from January 1, 201 through June 30, 2019, would be required to contract with a CMS-approved vendor to administer the CAHPS for ACOs survey for the 2019 reporting period, consistent with program-wide policies applicable to all other ACOs. We would apply the program's sampling methodology, as we have described in the August 2018 proposed rule and this section of this final rule, to determine the beneficiaries eligible for the samples for claims-based measures (as calculated by CMS), CMS

Web Interface reporting, and the CAHPS for ACOs survey.

After consideration of the comments, we are finalizing without modification our proposal to determine an ACO's quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, using the ACO's quality performance for the 12-month CY 2019 (2019 reporting period) as determined under § 425.502. We are also finalizing a subset of our proposals for identifying the ACO participant list used in determining quality reporting samples for ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019. Given the limited scope of this final rule we are finalizing our proposal to use an ACO's latest certified ACO participant list for the performance year from January 1, 2019 through June 30, 2019, (the ACO participant list effective on January 1, 2019) to determine the quality reporting samples for the 2019 reporting period. We are not addressing at this time our proposals related to the proposed July 1, 2019 agreement start date, including the policies for determining the quality reporting samples for ACOs that extend their participation agreement for the 6-month performance year from January 1, 2019 through June 30, 2019, and continue their participation in the program in a new agreement period beginning on July 1, 2019. We anticipate summarizing and responding to comments received on these proposals in a forthcoming final rule.

(5) Applicability of Extreme and Uncontrollable Circumstances Policies

In section II.E.4 of the August 2018 proposed rule (83 FR 41899 through 41906), we proposed to extend the policies for addressing the impact of extreme and uncontrollable circumstances on ACO financial and quality performance results for performance year 2017 to performance year 2018 and subsequent years. As discussed in section V.B.2.d of this final rule, we are finalizing this proposal. In section II.E.4. of the August 2018 proposed rule, we indicated that if finalized, these policies would apply to ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019.

There were no comments directed specifically at our proposals with respect to the applicability of these policies for addressing the impact of extreme and uncontrollable circumstances on ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019. We direct readers to review section V.B.2.d. of this final rule, for a more comprehensive discussion of the modifications to the program's extreme and uncontrollable circumstances policies that we are finalizing with this final rule.

We are finalizing as proposed the policies for determining the financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, for ACOs affected by extreme and uncontrollable circumstances during CY 2019. In addition, we are also finalizing our proposal to specify, in a new section of the regulations at § 425.609(d), the following policies related to determining the financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, for an ACO affected by extreme and uncontrollable circumstances during CY 2019: (1) In calculating the amount of shared losses owed by the ACO, CMS makes adjustments to the amount determined under § 425.609(b), as specified in § 425.606(i) (Track 2) or § 425.610(i) (Track 3), as applicable; and (2) in determining the ACO's quality performance score for the 2019 quality reporting period, CMS uses the alternative scoring methodology specified in § 425.502(f).

(6) Payment and Recoupment for 6-Month Performance Years

In the August 2018 proposed rule (83 FR 41858), we proposed policies regarding CMS' notification to ACOs of shared savings and shared losses and the timing for ACOs' repayment of shared losses for both the 6-month performance year (or performance period) from January 1, 2019 through June 30, 2019, and the 6-month performance year from July 1, 2019 through December 31, 2019.

In this final rule, we are addressing the proposals specific to the 6-month performance year from January 1, 2019 through June 30, 2019. In a forthcoming final rule, we anticipate discussing comments received on the proposals related to payment and recoupment for the 6-month performance year from July 1, 2019 through December 31, 2019, and the performance period from January 1, 2019 through June 30, 2019, for ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019. We anticipate this final rule would include a discussion of our proposal to reduce the shared savings payment for one 6-month performance year (or performance period) by the amount of any shared losses owed for the other 6-month performance year (or performance period).

In the August 2018 proposed rule, we proposed that the following policies would be applicable to ACOs that elect a 6-month extension for the performance year from January 1, 2019 through June 30, 2019. Because we proposed to perform financial reconciliation for this 6-month performance year after the end of CY 2019, we anticipated that financial performance reports for the 6-month performance year would be available in Summer 2020, similar to the expected timeframe for issuing financial performance reports for the 12-month 2019 performance year (and for 12-month performance years generally).

We proposed to apply the same policies regarding notification of shared savings and shared losses and the timing of repayment of shared losses to ACOs in a 6-month performance year that apply under our current regulations to ACOs in 12-month performance years. For the 6-month performance year from January 1, 2019 through June 30, 2019, we proposed to specify in a new regulation at § 425.609 that CMS would notify the ACO of shared savings or shared losses, consistent with the notification requirements specified in § 425.604(f) (Track 1), § 425.606(h) (Track 2), and § 425.610(h) (Track 3). Specifically, we proposed that the following approach: (1) CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due; (2) CMS provides written notification to an ACO of the amount of shared losses, if any, that it must repay to the program; (3) if an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

We proposed to specify policies on payment and recoupment for ACOs in a 6-month performance year during CY 2019 in a new section of the regulations at § 425.609(e).

Comment: Some commenters urged CMS to provide additional guidance and education to ACOs on whether there will be any disruptions in providing performance results to ACOs participating in a 6-month performance year in CY 2019.

Response: We anticipate determining financial and quality performance for ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019, according to the typical annual projected timeline for making these determinations, and for issuing performance reports to ACOs. The ACO's annual financial reconciliation report, quality performance reports, and additional informational reports and files, are

typically made available in the summer following the conclusion of a 12-month performance year. We also plan to provide ACOs that participate in the 6-month performance year from January 1, 2019 through June 30, 2019, quarterly reports for the third and fourth quarter of CY 2019 (see discussion in section V.B.1.c.(8) of this final rule). We anticipate that we will make available to ACOs an annual schedule for report delivery for 2019. For example, see the 2018 Shared Savings Program report schedule included as Table 12 in the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (May 2018, version 6) available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-guidance-and-specifications.html*.

We are finalizing without modification our proposal to specify in a new section of the regulations at § 425.609(e) that CMS will notify the ACO of shared savings or shared losses for the 6-month performance year from January 1, 2019 through June 30, 2019, consistent with the notification requirements specified in §§ 425.604(f), 425.606(h), and 425.610(h), as applicable. Specifically, we will notify an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due. CMS will provide written notification to an ACO of the amount of shared losses, if any, that the ACO must repay to the program. If an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

(7) Interactions With the Quality Payment Program

In the August 2018 proposed rule (83 FR 41859), we took into consideration how the proposed July 1, 2019 start date could interact with other Medicare initiatives, particularly the Quality Payment Program timelines relating to participation in APMs. In the CY 2018 Quality Payment Program final rule with comment period, we finalized a policy for APMs that start or end during the QP Performance Period. Specifically, under § 414.1425(c)(7)(i), for Advanced APMs that start during the QP Performance Period and are actively tested for at least 60 continuous days during a QP Performance Period, CMS will make QP determinations and Partial QP determinations for eligible clinicians in the Advanced APM using claims data for services furnished during those dates on which the Advanced APM is actively tested. CMS performs QP determinations for eligible clinicians in an APM entity three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination dates: March 31, June 30, and August 31 (§ 414.1425(b)(1)). We explained that this meant that an APM (such as a two-sided model of the Shared Savings Program) would need to begin operations by July 1 of a given performance year in order to be actively tested for at least 60 continuous days before August 31—the last date on which QP determinations are made during a QP Performance Period (as specified in § 414.1425(b)(1)). Therefore, we believed that our proposed July 1, 2019 start date for the proposed new participation options under the Shared Savings Program would align with Quality Payment Program rules and requirements for participation in Advanced APMs. However, we did not address QP determinations for eligible clinicians participating in an ACO whose agreement period expires on December 31, 2018, that elects a voluntary extension for the 6-month performance year from January 1, 2019 through June 30, 2019, and does not continue in the program past June 30, 2019.

Further, as described in section II.A.7.c.(4) of the August 2018 proposed rule (83 FR 41856), our proposal to use a 12-month period for quality measure assessment for either 6-month performance year during 2019 would maintain alignment with the program's existing quality measurement approach, and align with the proposed use of 12 months of expenditure data (for CY 2019) in determining the ACO's financial performance for a 6-month performance year. Also, this approach would continue to align the program's quality reporting period with policies under the Quality Payment Program (83 FR 41856). We explained that ACO professionals that are MIPS eligible clinicians (not QPs based on their participation in an Advanced APM or otherwise excluded from MIPS) would continue to be scored under MIPS using the APM scoring standard that covers all of 2019.

Comment: One commenter indicated that, as proposed, it appears ACOs in a two-sided model may lose Advanced APM Entity status and sought clarity on the Advanced APM status for all participating ACOs. This commenter was specifically concerned about the Advanced APM status of the Track 1+ Model.

Response: We believe the comment reflects the need for clarification about whether eligible clinicians in an ACO that is participating in a track that meets the Advanced APM criteria and that elects to extend for the 6-month performance year from January 1, 2019 through June 30, 2019, but does not continue its participation in the Shared Savings Program past June 30, 2019, would be eligible to become QPs during the 2019 QP Performance Period. Eligible clinicians who become QPs will earn the Advanced APM incentive payment and will not be subject to the MIPS reporting requirements and payment adjustments for the applicable year. The commenter may have been concerned that an agreement period that ends prior to the end of the QP performance period (August 31, 2019) would be considered an early termination and that the ACO would therefore lose its status as participating in an Advanced APM, which is not the case under our previously-finalized policy for Advanced APMs that start or end during a performance period. For an ACO that is in a track that meets the Advanced APM criteria and elects to extend for the 6-month performance year from January 1, 2019 through June 30, 2019, the agreement period would end during the QP performance period. However, because the ACO would have been active for more than 60 days, it would continue to be an APM entity in an Advanced APM in 2019 (§ 414.1425(c)(7)). Therefore, clinicians who obtain QP status based on the March 31, 2019, or June 30, 2019 snapshot through participation in an ACO with a 6-month extension of its agreement period will: Maintain QP status, be exempt from MIPS, and receive the APM incentive payment, as long as their ACO completes its agreement period by remaining in the program through June 30, 2019.

We also believe there is a need to clarify what happens to an eligible clinician's QP status if they are participating in an ACO that is in a track that meets the Advanced APM criteria and elects to extend for the 6-month performance year from January 1, 2019 through June 30, 2019, and either voluntarily terminates or is involuntarily terminated prior to June 30, 2019. If their ACO terminates or is involuntarily terminated any time after March 31, 2019, and before August 31, 2019, then eligible clinicians previously determined to have had QP status would lose their status as a result of the termination, and would instead be scored under MIPS using the APM Scoring Standard (§ 414.1425(c)(5) and (6)). If their ACO terminates before March 31, 2019, then the eligible clinicians would not be scored under the APM Scoring Standard and will be

assessed under regular MIPS scoring rules (§§ 414.1370(e) and 414.1425(b)(1)).

Comment: Some commenters requested clarification on how quality reporting for a 6-month performance period based on 12-months of data for 2019 will satisfy the MIPS quality reporting requirements for MIPS eligible clinicians in ACOs that elect to extend their participation agreement for the 6-month performance year from January 1, 2019 through June 30, 2019. One commenter indicated there was no discussion of how the proposed 6-month extension period would impact scoring under the APM scoring standard.

Response: We believe the comments reflect the need for clarification about whether 2019 quality performance for a 6-month performance year under the Shared Savings Program will count the same as a full year of performance for purposes of the APM scoring standard if the ACO ends its current agreement period at the end of the 6-month extension and chooses to not renew its agreement with a July 1, 2019 start date (if finalized as proposed). That is, would the 2019 quality reporting for the 6-month performance year count toward the final MIPS score in the same way that it would for an ACO that is participating in a full 12-month performance year in the program.

As discussed in this section of this final rule, we are finalizing a policy of using a 12-month period for quality performance assessment for the 6-month performance year from January 1, 2019 through June 30, 2019, in order to maintain alignment with the program's existing quality measurement approach, and with policies under the Quality Payment Program. ACO professionals that are MIPS eligible clinicians (not QPs based on their participation in an Advanced APM or otherwise excluded from MIPS) participating in an ACO that completes a 6-month performance year from January 1, 2019 through June 30, 2019, would continue to be scored under MIPS using the APM Scoring Standard, based on quality data submitted for all of 2019 during the regular submission period in early 2020. Thus, for a Track 1 ACO in a 6-month performance year from January 1, 2019 through June 30, 2019, whose agreement period expires and the ACO does not renew to continue program participation, the ACO would be scored under the MIPS APM scoring rules for quality reporting based on the entire CY 2019.

(8) Sharing CY 2019 Aggregate Data With ACOs in 6-Month Performance Year From January 1, 2019 Through June 30, 2019

Under the program's current regulations at § 425.702, we share aggregate data with ACOs during the agreement period. This includes providing data at the beginning of each performance year, during each quarter, and in conjunction with the annual reconciliation. In the August 2018 proposed rule (83 FR 41859), for ACOs that started a first or second agreement period on January 1, 2016, that extend their agreement for an additional 6-month performance year from January 1, 2019 through June 30, 2019, we proposed to continue to deliver aggregate reports for all four quarters of CY 2019 based on the ACO participant list in effect for the 6-month performance year. This would give ACOs a more complete understanding of the Medicare FFS beneficiary population that is the basis for reconciliation for the 6-month performance year by allowing them to continue to receive data, including demographic characteristics and expenditure/utilization trends for their assigned population for the entire calendar year. We believed this proposed approach would allow us to maintain transparency by providing ACOs with data that relates to the entire period for which the expenditures for the beneficiaries assigned to the ACO for the 6-month performance year would be compared to the ACO's benchmark (before pro-rating any shared savings or shared losses to reflect the length of the performance year), and maintain consistency with the reports delivered to ACOs that participate in a 12-month performance year 2019. Otherwise, we could be limited to providing ACOs with aggregate reports only for the first and second quarters of 2019, even though under our proposed methodology for assessing the financial performance of ACOs in a 6-month performance year, the financial reconciliation for the 6-month performance year would involve consideration of expenditures from outside this period during 2019. We proposed to specify this policy in revisions to § 425.702.

Comment: Some commenters urged CMS to provide additional guidance and education to ACOs on whether there will be any disruptions in sharing claims files with ACOs participating in a 6-month performance year in CY 2019.

Response: In the August 2018 proposed rule, we did not describe in detail the applicability of the program's policies on sharing beneficiary-identifiable claims data with ACOs under § 425.704. We proposed, generally, that unless otherwise stated, program requirements under 42 CFR part 425 that are applicable to the ACO under the ACO's chosen participation track and based on the ACO's agreement start date would be applicable to an ACO participating in a 6-month performance year. Therefore, we would continue to provide beneficiary-identifiable claims data (referred to as claim and claim line feed files) to ACOs only during their participation in the program, including during the 6-month performance year from January 1, 2019 through June 30, 2019. ACOs would receive monthly Part A, B and D claim and claim line feed files during the 6-month performance year based on the ACO participant list they certify before the start of the performance year. Consistent with the program's current data sharing policies, we would discontinue delivery of beneficiary-identifiable data to ACOs when their participation agreement is no longer in effect.

After consideration of the comments received, we are finalizing our proposal to deliver to ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019, aggregate reports for all four quarters of CY 2019 based on the ACO participant list in effect for the performance year. This policy is specified in revisions to § 425.702.

(9) Technical or Conforming Changes To Allow for 6-Month Performance Years

In the August 2018 proposed rule (83 FR 41859 through 41860), we proposed to make certain technical, conforming changes to certain provisions of the regulations, including additional changes to provisions discussed elsewhere in the proposed rule, to reflect our proposal to add a new provision at § 425.609 to govern the calculation of the financial and quality results for the proposed 6-month performance years within CY 2019.

In this final rule, we are addressing only the proposals specific to the 6-month performance year from January 1, 2019 through June 30, 2019. In a forthcoming final rule, we anticipate discussing comments received on the proposed 6-month performance year from July 1, 2019 through December 31, 2019, and the proposed 6-month performance period from January 1, 2019 through June 30, 2019, for ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019.

The following proposals discussed in the August 2018 proposed rule would be applicable to ACOs that elect a 6-month extension for the performance year from January 1, 2019 through June 30, 2019.

Our proposal that the policies on reopening determinations of shared savings and shared losses to correct financial reconciliation calculations (§ 425.315) would apply with respect to applicable payment determinations for performance years within CY 2019. To clarify, we proposed to amend § 425.315 to incorporate a reference to the proposed provision for notification of shared savings and shared losses for ACOs in a 6-month performance year within CY 2019, as specified in § 425.609(e).

Our proposal to add a reference to § 425.609 in § 425.100 in order to include ACOs that participate in a 6-month performance year during 2019 in the general description of ACOs that are eligible to receive payments for shared savings under the program.

Our proposal to amend § 425.400(a)(1)(ii), which describes the step-wise process for determining beneficiary assignment for each performance year, to specify that this process would apply to ACOs participating in a 6-month performance year within CY 2019, and that assignment would be determined based on the beneficiary's utilization of primary care services during the entirety of CY 2019, as specified in § 425.609.

Our proposal to further revise § 425.400(c)(1)(iv), on the use of certain Current Procedural Terminology (CPT) codes and Healthcare Common Procedure Coding System (HCPCS) codes in determining beneficiary assignment, to specify that it would be used in determining assignment for performance years starting on January 1, 2019, and subsequent years. We note that we also proposed certain other revisions to this provision in section II.E.3. of the August 2018 proposed rule (83 FR 41896), as discussed in section V.B.2.c. of this final rule.

Our proposal to revise § 425.401(b), describing the exclusion of beneficiaries from an ACO's prospective assignment list at the end of a performance year or benchmark year and quarterly during each performance year, to specify that these exclusions would occur at the end of CY 2019 for purposes of determining assignment to an ACO in a 6-month performance year in accordance with §§ 425.400(a)(3)(ii) and 425.609.

Our proposal, as part of the proposed revisions to § 425.402(e)(2), which, as described in section II.E.2. of the August 2018 proposed rule (83 FR 41894), specifies that beneficiaries who have designated a provider or supplier outside the ACO as responsible for coordinating their overall care will not be added to the ACO's list of assigned beneficiaries for a performance year under the claims-based assignment methodology, to allow the same policy to apply to ACOs participating in a 6-month performance year during CY 2019. We are finalizing our proposed revisions to § 425.402(e)(2), as described in section V.B.2.b. of this final rule.

Our proposal to revise § 425.404(b), on the special assignment conditions for ACOs that include FQHCs and RHCs that provide services used in determining beneficiary assignment, to specify its applicability in determining assignment for performance years starting on January 1, 2019, and subsequent performance years.

We also proposed to incorporate references to § 425.609 in the regulations that govern establishing, adjusting, and updating the benchmark, including the existing provisions at §§ 425.602 and 425.603, to specify that the annual risk adjustment and update to the ACO's historical benchmark for the 6-month performance year from January 1, 2019 through June 30, 2019, would use factors based on the entirety of CY 2019. For clarity and simplicity, we proposed to add a paragraph to each of these sections to explain the following: (1) Regarding the annual risk adjustment applied to the historical benchmark, when CMS adjusts the benchmark for the 6-month performance year from January 1, 2019 through June 30, 2019, the adjustment will reflect the change in severity and case mix between benchmark year 3 and CY 2019; (2) Regarding the annual update to the historical benchmark, when CMS updates the benchmark for the 6-month performance year from January 1, 2019 through June 30, 2019, the update to the benchmark will be based on growth between benchmark year 3 and CY 2019.

We also proposed to incorporate references to § 425.609 in the following provisions regarding the calculation of shared savings and shared losses: §§ 425.604, 425.606, and 425.610. For clarity and simplicity, we proposed to add a paragraph to each of these sections explaining that shared savings or shared losses for the 6-month performance year from January 1, 2019 through June 30, 2019, are calculated as described in § 425.609. That is, all calculations will be performed using CY 2019 data in place of performance year data.

There were no comments directed specifically at our proposed technical and conforming changes to allow for 6-month performance years. We are finalizing as proposed the technical and conforming changes to the Shared Savings Program regulations as previously described in this section of this final rule, to allow them to apply to ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019.

(10) Payment Consequences of Early Termination

In the August 2018 proposed rule (83 FR 41845 through 41847), we proposed policies to govern the payment consequences of early termination for performance years beginning in 2019 and subsequent years, including for ACOs participating in 6-month performance years from January 1, 2019 through June 30, 2019, and July 1, 2019 through December 31, 2019, as well as for ACOs participating in 12-month performance years. We proposed to impose payment consequences for early termination by holding ACOs in two-sided models liable for pro-rated shared losses. This approach would apply to ACOs that voluntarily terminate their participation more than midway through a 12-month performance year and all ACOs that are involuntarily terminated by CMS. ACOs would be ineligible to share in savings for a performance year if the effective date of their termination from the program is prior to the last calendar day of the performance year; but, we would allow an exception for ACOs that are participating in a 12-month performance year under the program as of January 1, 2019, that terminate their agreement with an effective date of June 30, 2019, and enter a new agreement period under the proposed BASIC track or ENHANCED track beginning July 1, 2019. In these cases, we would perform separate reconciliations to determine shared savings and shared losses for the ACO's first 6 month period of participation in 2019 and for the ACO's 6-month performance year from July 1, 2019, to December 31, 2019, under the subsequent participation agreement.

In a forthcoming final rule we anticipate addressing comments received on proposals for the payment consequences of early termination from 12-month performance years and from 6-month performance years beginning on July 1, 2019, should we finalize the proposal to offer a July 1, 2019 start date for the new participation options. Therefore, in this section of this final rule we focus specifically on the proposals regarding the payment consequences of early termination as they relate to the 6-month performance

year from January 1, 2019 through June 30, 2019.

We proposed that an ACO would be eligible to receive shared savings for a 6-month performance year during 2019 if it completes the term of the performance year, regardless of whether the ACO chooses to continue its participation in the program. That is, we would reconcile ACOs that started a first or second agreement period January 1, 2016, that extend their agreement period for a fourth performance year, and complete this performance year (concluding on June 30, 2019).

For an ACO that participates for a portion of a 6-month performance year during 2019, we proposed the following: (1) If the ACO terminates its participation agreement effective before the end of the performance year, we would not reconcile the ACO for shared savings or shared losses (if a two-sided model ACO); (2) if CMS terminates a two-sided model ACO's participation agreement effective before the end of the performance year, the ACO would not be eligible for shared savings and we would reconcile the ACO for shared losses and pro-rate the amount reflecting the number of months during the performance year that the ACO was in the program. We proposed to specify these policies in amendments to § 425.221(b).

We also proposed to revise the regulation at § 425.221 to streamline and reorganize the provisions in paragraph (b), which we believed necessary to incorporate the proposed new requirements. We sought comment on these proposals.

We are not addressing our proposed modifications to program policies to impose payment consequences for early termination in this final rule. Accordingly, for ACOs participating in a performance year starting on January 1, 2019, we will continue to apply the program's current policies for payment consequences of early termination. We believe that continuing to use the current approach would be simpler, both from the standpoint of CMS as the regulatory entity and operator of the program, and for ACOs as regulated entities already familiar with the current policies. Under this approach, ACOs that terminate from a performance year starting on January 1, 2019, with an effective date of termination prior to the end of their performance year will not be eligible for shared savings or accountable for shared losses.

At this time, we are finalizing a subset of our proposed policies for determining payment consequences of early termination, to account for ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019. Specifically, we are finalizing without modification our proposal that an ACO participating in a 6-month performance year from January 1, 2019 through June 30, 2019, is eligible for shared savings if the following conditions are met: CMS has designated or approved an effective date of termination that is the last calendar day of the performance year (June 30, 2019); the ACO has completed all close-out procedures specified in § 425.221(a) by the deadline specified by CMS (if applicable); and the ACO has satisfied the criteria for sharing in savings for the performance year. Consistent with our existing policies, if the participation agreement is terminated at any time by CMS under § 425.218, the ACO will not be eligible to receive shared savings for the performance year during which the termination becomes effective, and will not be accountable for any shared losses. Further, for an ACO participating in a 6-month performance year from January 1, 2019 through June 30, 2019, that elects to terminate early, we will apply the payment consequences of early termination consistent with the current regulations, and the ACO will not be eligible to receive shared savings for the performance year and will not be accountable for any shared losses.

We are finalizing the proposed revisions to § 425.221 to allow us to consistently apply current program policies on the payment consequences of early termination or agreement expiration to ACOs in a 6-month performance year from January 1, 2019 through June 30, 2019. We are amending § 425.221(b) to remove references to December 31st of a performance year and instead to refer to the last calendar day of the performance year, so that the regulatory provisions will apply to ACOs regardless of whether they are participating in a 12-month or 6-month performance year. We are not addressing at this time the other proposed revisions to the regulation at § 425.221, including the proposals to streamline and reorganize the provisions in paragraph (b).

2. Updating Program Policies

a. Overview

This section addresses various proposed revisions described in the August 2018 proposed rule (83 FR 41894 through 41911) that are designed to update policies under the Shared Savings Program. We proposed to revise our regulations governing the assignment process in order to align our voluntary alignment policies with the requirements of section 50331 of the Bipartisan Budget Act of 2018 and to update the definition of primary care services. We also proposed to extend the policies that we recently adopted for ACOs impacted by extreme and uncontrollable circumstances during 2017 to 2018 and subsequent performance years. We also solicited comment on considerations related to supporting ACOs' activities to address the national opioid crisis and the agency's meaningful measures initiative. We proposed to discontinue use of the quality performance measure that assesses the level of adoption of CEHRT by the eligible clinicians in an ACO and proposed instead that ACOs be required to certify upon application to participate in the Shared Savings Program and annually thereafter that the percentage of eligible clinicians participating in the ACO using CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds certain thresholds.

b. Revisions to Policies on Voluntary Alignment

(1) Background

Section 50331 of the Bipartisan Budget Act of 2018 amended section 1899(c) of the Act (42 U.S.C. 1395jjj(c)) to add a new paragraph (2)(B) that requires the Secretary, for performance year 2018 and each subsequent performance year, to permit a Medicare FFS beneficiary to voluntarily identify an ACO professional as the primary care provider of the beneficiary for purposes of assigning such beneficiary to an ACO, if a system is available for electronic designation. A voluntary identification by a Medicare FFS beneficiary under this provision supersedes any claims-based assignment otherwise determined by the Secretary. Section 50331 also requires the Secretary to establish a process under which a Medicare FFS beneficiary is notified of his or her ability to designate a primary care provider or subsequently to change this designation. An ACO professional is defined under section 1899(h) of the Act as a physician as defined in section 1861(r)(1) of the Act and a practitioner described in section 1842(b)(18)(C)(i) of the Act.

As we stated in the August 2018 proposed rule (83 FR 41894), we believe that section 50331 requires certain revisions to our current beneficiary voluntary alignment policies in § 425.402(e). Prior to enactment of the Bipartisan Budget Act of 2018, section 1899(c) of the Act required that beneficiaries be assigned to an ACO based on their use of primary care services furnished by a physician as

defined in section 1861(r)(1) of the Act, and beginning January 1, 2019, services provided in RHCs/FQHCs. In order to satisfy this statutory requirement, we currently require that a beneficiary receive at least one primary care service during the beneficiary assignment window from an ACO professional in the ACO who is a physician with a specialty used in assignment in order to be assigned to the ACO (see § 425.402(b)(1)). As currently provided in § 425.404(b), for performance year 2019 and subsequent performance years, for purposes of the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim as a primary care service performed by a primary care physician. After identifying the beneficiaries who have received a primary care service from a physician in the ACO, we use a two-step, claims-based methodology to assign beneficiaries to a particular ACO for a calendar year (see § 425.402(b)(2) through (4)). In the CY 2017 PFS final rule (81 FR 80501 through 80510), we augmented this claims-based beneficiary assignment methodology by finalizing a policy under which beneficiaries, beginning in 2017 for assignment for performance year 2018, may voluntarily align with an ACO by designating a ''primary clinician'' they believe is responsible for coordinating their overall care using *MyMedicare.gov*, a secure online patient portal. *MyMedicare.gov* contains a list of all of the Medicare-enrolled practitioners who appear on the Physician Compare website and beneficiaries may choose any practitioner present on Physician Compare as their primary clinician.

Notwithstanding the assignment methodology in § 425.402(b), beneficiaries who designate an ACO professional whose services are used in assignment as responsible for their overall care will be prospectively assigned to the ACO in which that ACO professional participates, provided the beneficiary meets the eligibility criteria established at § 425.401(a) and is not excluded from assignment by the criteria in § 425.401(b), and has had at least one primary care service during the assignment window with an ACO professional in the ACO who is a primary care physician as defined under § 425.20 or a physician with one of the primary specialty designations included in § 425.402(c) (see § 425.402(e)). Such beneficiaries will be added prospectively to the ACO's list of assigned beneficiaries for the subsequent performance year, superseding any assignment that might have otherwise occurred under the claims-based methodology. Further, beneficiaries may change their designation at any time through *MyMedicare.gov*; the new choice will be incorporated when we perform assignment for the subsequent performance year. Beneficiaries who designate a provider or supplier outside an ACO, who is a primary care physician, a physician with a specialty designation that is considered in the assignment methodology, or a nurse practitioner, physician assistant, or clinical nurse specialist, as responsible for coordinating their overall care will not be added to an ACO's list of assigned beneficiaries, even if they would otherwise meet the criteria for claims-based assignment.

(2) Summary of Proposed Revisions

Section 1899(c) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, requires the Secretary to permit a Medicare FFS beneficiary to voluntarily identify an ACO professional as their primary care provider for purposes of assignment to an ACO. Under our current methodology, a beneficiary may select any practitioner who has a record on the Physician Compare website as their primary clinician; however, we will only assign the beneficiary to an ACO if they have chosen a practitioner who is a primary care physician (as defined at § 425.20), a physician with one of the primary specialty designations included in § 425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist. Therefore, we proposed to modify our current voluntary alignment policies at § 425.402(e)(2)(iii) to provide that we will assign a beneficiary to an ACO based upon their selection of any ACO professional, regardless of specialty, as their primary clinician. Under this proposal, a beneficiary may select a practitioner with any specialty designation, for example, a specialty of allergy/immunology or surgery, as their primary care provider and be eligible for assignment to the ACO in which the practitioner is an ACO professional. Specifically, we proposed to revise § 425.402(e)(2)(iii) to remove the requirement that the ACO professional designated by the beneficiary be a primary care physician as defined at § 425.20, a physician with a specialty designation included at § 425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist. In addition, the provision at § 425.402(e)(2)(iv) addresses beneficiary designations of clinicians outside the ACO as their primary clinician. The current policy at § 425.402(e)(2)(iv) provides that a beneficiary will not be assigned to an ACO for a performance year if the beneficiary has designated a provider or supplier outside the ACO who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at § 425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist as their primary clinician responsible for coordinating their overall care. Consistent with the proposed revisions to § 425.402(e)(2)(iii) to incorporate the requirements of section 50331 of the Bipartisan Budget Act, we proposed to revise § 425.402(e)(2)(iv) to indicate that if a beneficiary designates any provider or supplier outside the ACO as their primary clinician responsible for coordinating their overall care, the beneficiary will not be added to the ACO's list of assigned beneficiaries for a performance year.

Section 1899(c) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, requires the Secretary to allow a beneficiary to voluntarily align with an ACO, and does not impose any restriction with respect to whether the beneficiary has received any services from an ACO professional (see section 1899(c)(2)(B)(i) of the Act). As we explained in the August 2018 proposed rule (83 FR 41895), we believe the requirement in section 1899(c)(2)(B)(iii) of the Act that a beneficiary's voluntary identification shall supersede any claims-based alignment is also consistent with eliminating the requirement that the beneficiary have received a service from an ACO professional in order to be eligible to be assigned an ACO. Therefore, we proposed to remove the requirement at § 425.402(e)(2)(i) that a beneficiary must have received at least one primary care service from an ACO professional who is either a primary care physician or a physician with a specialty designation included in § 425.402(c) within the 12-month assignment window in order to be assigned to the ACO. Under this proposal, a beneficiary who selects a primary clinician who is an ACO professional, but who does not receive any services from an ACO participant during the assignment window, will remain eligible for assignment to the ACO. We stated that we believe this approach would reduce burden on beneficiaries and their practitioners by not requiring practitioners to provide unnecessary care during a specified period of time in order for a beneficiary to remain eligible for assignment to the ACO. Consistent with this proposal, we proposed to remove § 425.402(e)(2)(i) in its entirety.

We noted that, under this proposal, if a beneficiary does not change their primary clinician designation, the beneficiary will remain assigned to the ACO in which that practitioner participates during the ACO's entire agreement period and any subsequent agreement periods under the Shared Savings Program, even if the beneficiary no longer seeks care from any ACO professionals. Because a beneficiary who has voluntarily identified a Shared Savings Program ACO professional as their primary care provider will remain assigned to the ACO regardless of where they seek care, this proposed change could also impact assignment under certain Innovation Center models in which overlapping beneficiary assignment is not permitted. As we explained in the August 2018 proposed rule (83 FR 41895), we believe our proposed policy is consistent with the requirement under section 1899(c)(2)(B)(iii) of the Act that a voluntary identification by a beneficiary shall supersede any claims-based assignment. However, we also believe it could be appropriate, in limited circumstances, to align a beneficiary to an entity participating in certain specialty and disease-specific Innovation Center models, such as the Comprehensive ESRD Care (CEC) Model. CMS implemented the CEC Model to test a new system of payment and service delivery that CMS believes will lead to better health outcomes for Medicare beneficiaries living with ESRD, while lowering costs to Medicare Parts A and B. Under the model, CMS is working with groups of health care providers, dialysis facilities, and other suppliers involved in the care of ESRD beneficiaries to improve the coordination and quality of care that these individuals receive. We believe that an ESRD beneficiary, who is otherwise eligible for assignment to an entity participating in the CEC Model, could benefit from the focused attention on and increased care coordination for their ESRD available under the CEC Model. Such a beneficiary could be disadvantaged if they were unable to receive the type of specialized care for their ESRD that will be available from an entity participating in the CEC Model. Furthermore, we believe it could be difficult for the Innovation Center to conduct a viable test of a specialty or disease-specific model, if we were to require that beneficiaries who have previously designated an ACO professional as their primary clinician remain assigned to the Shared Savings Program ACO under all circumstances. Currently, the CEC Model completes its annual PY prospective assignment lists prior to the Shared Savings Program in order to identify the beneficiaries who may benefit from receiving specialized care from an entity participating in the CEC Model. Additionally, on a quarterly basis, a beneficiary may be assigned to the CEC Model who was previously assigned to a Track 1 or Track 2 ACO.

As a result, we believe that in some instances it may be necessary for the Innovation Center to use its authority under section 1115A(d)(1) of the Act to waive the requirements of section 1899(c)(2)(B) of the Act solely as necessary for purposes of testing a particular model. Therefore, we proposed to create an exception to the general policy that a beneficiary who has voluntarily identified a Shared Savings Program ACO professional as their primary care provider will remain assigned to the ACO regardless of where they seek care. Specifically, we proposed that we would not assign such a beneficiary to the ACO when the beneficiary is also eligible for assignment to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services and for which there has been a determination by the Secretary that a waiver under section 1115A(d)(1) of the Act of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model. Under this proposal, if a beneficiary selects a primary clinician who is a Shared Savings Program ACO professional and the beneficiary is also eligible for alignment to a specialty care or disease specific model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services and for which there has been a determination that a waiver of the requirement in section 1899(c)(2)(B) is necessary solely for purposes of testing the Model, the Innovation Center or its designee would notify the beneficiary of their alignment to an entity participating in the model. Additionally, although such a beneficiary may still voluntarily identify his or her primary clinician and may seek care from any clinician, the beneficiary would not be assigned to a Shared Savings Program ACO even if the designated primary clinician is an ACO professional in a Shared Savings Program ACO.

In the August 2019 proposed rule (83 FR 41896), we indicated that we would include a list of any models that meet these criteria on the Shared Savings Program website, to supplement the information already included in the beneficiary assignment reports we currently provide to ACOs (as described under § 425.702(c)), so that ACOs can know why certain beneficiaries, who may have designated an ACO professional as their primary clinician, are not assigned to them. Similar information would also be shared with 1–800–MEDICARE to ensure that Medicare customer service representatives are able to help beneficiaries who may be confused as to why they are not aligned to the ACO in which their primary clinician is participating.

Section 1899(c)(2)(B)(ii) of the Act, as amended by section 50331 of the Bipartisan Budget Act, requires the Secretary to establish a process under the Shared Savings Program through which each Medicare FFS beneficiary is notified of the ability to identify an ACO professional as his or her primary care provider and informed of the process that may be used to make and change such identification. In the August 2018 proposed rule (83 FR 41896), we stated our intent to implement section 1899(c)(2)(B)(ii) of the Act under the beneficiary notification process at § 425.312. We are not addressing this topic at this time. We will summarize and respond to public comments on this proposed policy in a forthcoming final rule.

We proposed to apply these modifications to our policies under the Shared Savings Program regarding voluntary alignment beginning for performance years starting on January 1, 2019, and subsequent performance years. We proposed to incorporate these new requirements in the regulations by redesignating § 425.402(e)(2)(i) through (iv) as § 425.402(e)(2)(i)(A) through (D), adding a paragraph heading for newly redesignated § 425.402(e)(2)(i), and including a new § 425.402(e)(2)(ii).

We noted that as specified in § 425.402(e)(2)(ii) a beneficiary who has designated an ACO professional as their primary clinician must still be eligible for assignment to an ACO by meeting the criteria specified in § 425.401(a). These criteria establish the minimum requirements for a beneficiary to be eligible to be assigned to an ACO under our existing assignment methodology, and we believe it is appropriate to impose the same basic limitations on the assignment of beneficiaries on the basis of voluntary alignment. We do not believe it would be appropriate, for example, to assign a beneficiary to an ACO if the beneficiary does not reside in the United States, or if the other eligibility requirements are not met.

We requested comments on our proposals to implement the new requirements governing voluntary alignment under section 50331 of the Bipartisan Budget Act of 2018. We also sought comment on our proposal to create a limited exception to our proposed policies on voluntary alignment to allow a beneficiary to be assigned to an entity participating in a model tested or expanded under section 1115A of the Act when certain criteria are met. In addition, we welcomed comments on how we might increase beneficiary awareness and further improve the electronic process through which a beneficiary may voluntarily identify an ACO professional as their primary care provider through *My.Medicare.gov* for purposes of assignment to an ACO.

Comment: Many commenters supported the proposed policies to implement the new requirements governing voluntary alignment under section 50331 of the Bipartisan Budget Act of 2018. In particular, many commenters supported the proposal to remove the requirement that a beneficiary must have received at least one primary care service from an ACO professional who is either a primary care physician or a physician with a specialty designation included in § 425.402(c) within the 12-month assignment window in order to be assigned to the ACO. Commenters were in favor of removing this requirement because it would allow a beneficiary to select a NP, PA, or CNS, who is participating in an ACO, as their primary clinician to voluntarily align to the ACO even if they do not receive care from any physicians participating in the ACO. Commenters suggested this more inclusive policy supports CMS' goals of improving patient access and quality of care, and is consistent with patient-centered health care delivery. Additionally, some commenters specifically supported the proposal to allow a beneficiary to voluntarily designate any ACO professional, regardless of specialty, as their primary care provider for purposes of assignment to an ACO. In particular, commenters representing neurologists and palliative care practitioners were supportive of this proposed change. In addition, one commenter agreed that the proposed policy would allow ''the opportunity for patients to choose and establish a medical home with their clinician.'' The commenter also supported voluntary alignment because it results in prospective beneficiary attribution, which the commenter preferred over the preliminary prospective assignment methodology with retrospective reconciliation.

Response: We appreciate the commenters' support for the proposed policies to implement the new requirements governing voluntary alignment under section 50331 of the Bipartisan Budget Act of 2018.

Comment: A few commenters proposed a change to section 1899(h)(1)(A) of the Act. Section 1899(c) of the Act requires the Secretary to determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of primary care services provided under this title by an ACO professional described in subsection (h)(1)(A). Section 1899(h)(1)(A) of the Act constitutes one element of the definition of the term ''ACO professional''. Specifically, this provision establishes that a physician (as defined in section 1861(r)(1)) is an ACO professional for purposes of the Shared Savings Program. Section 1861(r)(1) of the Act in turn defines the term physician as a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action. One commenter proposed a change to allow for ''private NP led practices and NP led clinics'' to be included as ACO professionals described in section 1899(h)(1)(A) of the Act. The commenter recommended this change in particular for rural areas, stating that NPs account for 1 in 4 medical providers in rural areas.

Response: Because commenters are requesting a change to the statute, these suggestions are outside the scope of this final rule. However, as many commenters noted above, the proposed changes to the voluntary alignment methodology will allow a beneficiary to align with a NP, PA, or CNS participating in an ACO and ultimately be assigned to the ACO regardless of whether they receive care from a physician in the ACO. Additionally, we agree these non-physician practitioners play an important role in coordinating patient care and providing primary care services, as such we have included primary care services furnished by NPs, PAs, and CNSs in step 1 of our two-step claims-based assignment methodology (see § 425.402(b)).

Comment: Some commenters opposed the proposed changes to the voluntary alignment methodology. One commenter expressed concern about beneficiary confusion if their practitioners participate in different ACOs or the beneficiary selects a practitioner outside of an ACO as their primary care provider. Similarly, one commenter expressed concern about an ACO's ability to maintain an assigned population of 5,000 beneficiaries if beneficiaries can select any ACO professional regardless of specialty as their primary care provider. A few commenters disagreed with including all practitioner specialties citing differences in training, education, knowledge, and experience. Another commenter expressed concern about whether specialists are willing to take on the role of a primary care physician and manage the overall care of beneficiaries assigned to the ACO through voluntary alignment. Some commenters disagreed with the proposal to remove the requirement that a beneficiary receive a primary care service from an ACO professional, with a physician specialty used in assignment, during the assignment window. One commenter stated that removing the requirement would exacerbate a ''leakage'' problem that they described as a scenario where assigned beneficiaries receive some or all of their care from providers and suppliers outside the ACO. One commenter suggested beneficiaries should be required to renew their selection of their primary care clinician one year following the beneficiary's entry into a long-term care setting. Another commenter suggested that beneficiaries who voluntarily align with an ACO be required to receive a minimum number of primary care services from ACO professionals within the same ACO in order to remain aligned to the ACO.

Response: We disagree with these comments. We believe that when a beneficiary selects a primary clinician, they are identifying their primary care provider, regardless of specialty or whether the beneficiary has received a recent primary care service. We believe they are informing CMS that they view the practitioner as their primary care provider and responsible for managing their overall care. We also believe all practitioners, regardless of specialty, play an important role in coordinating care for beneficiaries and if a beneficiary selects a practitioner as their primary clinician, the beneficiary should be treated as having made an informed election. Although we understand the concern that an ACO could lose assigned beneficiaries due to their voluntary alignment with another ACO, we note that our experience to date shows that the majority of beneficiaries who voluntarily align to an ACO would have been assigned to the same ACO via our two-step claims-based assignment methodology under § 425.402(b). We

also believe requiring beneficiaries to renew their primary clinician selection would create additional unnecessary burden on beneficiaries. Beneficiaries who have designated a primary clinician must have established a *MyMedicare.gov* account, which likely indicates that they are actively engaged in reviewing and managing their health information. We believe these engaged beneficiaries will also manage and update their primary clinician selections as necessary. We also disagree with establishing a requirement that a beneficiary receive a minimum number of primary care services from ACO providers/suppliers in the ACO in order to honor a beneficiary's voluntary alignment selection. We believe our proposed approach is in accordance with the requirement under section 1899(c) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, that primary care provider selections take precedence over any claims-based assignment.

Comment: A few commenters suggested CMS simplify the process by which a beneficiary selects their primary clinician. Commenters suggested that, in addition to the electronic means of voluntary alignment, CMS allow beneficiaries to voluntarily align with their primary clinician through the ACO, at the point of care, through 1–800 Medicare, a smart phone application, or Physician Compare. One commenter noted they had experienced difficulties with CMS' operationalization of the voluntary alignment policy through *MyMedicare.gov*.

Response: Currently, if beneficiaries need help in designating a primary clinician, they can call 1–800 Medicare to have a representative walk them through the process or use the ''Empowering Patients to Make Decisions About Their Healthcare: Register for *MyMedicare.gov* and Select Your Primary Clinician'' fact sheet available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/vol-alignment-bene-fact-sheet.pdf*. We plan to continue to make refinements to our implementation of voluntary alignment in order to improve the user experience for beneficiaries and will take the commenters' suggestions into consideration in developing future policies regarding voluntary alignment.

Comment: One commenter disagreed with allowing beneficiaries to voluntarily align with an ACO professional. The commenter cited difficulty tracking the cost of beneficiaries who are not assigned to an ACO through our two-step claims-based assignment methodology. Another commenter suggested we not hold an ACO accountable for a voluntarily aligned beneficiary for a performance year if the beneficiary does not receive any services from their primary clinician in the ACO during that performance year. Another commenter opposed voluntary alignment because they believe the costs for voluntarily aligned beneficiaries are not reflected in an ACO's historical benchmark.

Response: Consistent with section 1899(c)(2)(B)(i) of the Act, we are required to allow beneficiaries to voluntarily identify an ACO professional as their primary care provider for purposes of assignment to an ACO if a system is available for electronic designation. To aid ACOs in identifying and tracking costs and Medicare services for voluntarily aligned beneficiaries, we provide ACOs with quarterly aggregate reports (see § 425.702) that identify beneficiaries who have voluntarily aligned with the ACO, as well as monthly claim and claim line feed files (see § 425.704) to aid ACOs in their operations. Additionally, as previously stated, we have found the majority of beneficiaries who voluntarily align to an ACO would have been assigned to the same ACO in the applicable performance year based on our two-step assignment methodology. As required under section 1899(b)(2)(A) of the Act and the regulation at § 425.100(a), ACOs participating in the Shared Savings Program must agree to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO. Beneficiaries who voluntarily align to an ACO are prospectively assigned to the ACO for the performance year. Under the prospective assignment methodology, ACOs are accountable for their assigned beneficiary population regardless of where the beneficiaries receive the plurality of their primary care services during the performance year. We believe this is an appropriate approach when a beneficiary selects a practitioner as their primary clinician. As we stated earlier, we believe that when a beneficiary selects a primary clinician, the beneficiary is making an informed decision and identifying for CMS the provider or supplier whom they consider to be responsible for managing their overall care. The historical benchmark reflects the beneficiary population who received the plurality of their primary care services from the ACO during the three benchmark years and, in our experience, there is a high correlation between the beneficiaries who are assigned based on our two-step claims-based assignment methodology and voluntarily aligned beneficiaries. As a result, we believe our current benchmarking methodology provides for a population of assigned beneficiaries during the benchmark years that is comparable to the population assigned during the performance years. We also note, in the future, when an ACO renews for a new agreement period and its previous performance years become historical benchmark years, beneficiaries who were voluntarily aligned to the ACO for those years will then be included in the historical benchmark calculations for the ACO's new agreement period.

Comment: One commenter stated the current voluntary alignment process can be confusing and causes unnecessary delays in assigning beneficiaries to the ACO in which their primary clinician participates. The commenter suggested a rolling voluntary alignment process allowing beneficiaries who voluntarily align with an ACO to be added to the assignment list for that ACO during a performance year.

Response: We understand that our policy of performing beneficiary assignment annually can cause a delay between when a beneficiary selects their primary clinician and when the beneficiary is assigned to the ACO. However, we believe this approach reduces complexity and burden. For example, ACOs are able to clearly identify a date by which to communicate to their beneficiaries regarding the opportunity to designate a primary clinician if they would like to align with an ACO professional.

Comment: One commenter expressed concern that physicians with a specialty designation not used in assignment would become subject to the exclusivity requirements, which would limit an ACO participant to participation in a single ACO. The commenter opposed any policy that would require an ACO participant to be exclusive to a single Shared Savings Program ACO in the event that a beneficiary voluntarily aligns to a practitioner billing under the TIN of that ACO participant.

Response: We agree with the concerns raised by the commenter and believe it is important to clarify the operational process we will implement if a beneficiary designates a clinician billing under the TIN of an ACO participant that participates in more than one Shared Savings Program ACO (as permitted under certain circumstances under § 425.306(b)) as their primary clinician. ACO participants that do not bill for services that are considered in assignment will not be required to be

exclusive to a single Shared Savings Program ACO as a result of the changes to the voluntary alignment methodology. In the circumstance where a beneficiary aligns with a clinician billing under an ACO participant TIN that is participating in more than one Shared Savings Program ACO, we will determine where the beneficiary received the plurality of their primary care services under our claims-based assignment methodology under § 425.402(b). If the beneficiary did not receive the plurality of their primary care services from ACO professionals in either ACO, we will not assign the beneficiary to either of the ACOs. However, consistent with § 425.402(c)(2)(iv), we will honor the beneficiary's selection of a primary clinician and will not align the beneficiary to another ACO in which their primary clinician is not participating.

We did not receive any public comments on the proposal not to voluntarily align a beneficiary to the ACO in which their primary clinician participates when the beneficiary is also eligible for assignment to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services (for example, CEC).

After considering the comments received in response to the proposals to revise the voluntary alignment methodology, we are finalizing the policies as proposed. Specifically, we are finalizing the policy to assign a beneficiary to an ACO based upon their selection of any ACO professional, regardless of specialty, as their primary clinician. We are also finalizing our proposal to remove the requirement that a beneficiary must have received at least one primary care service from an ACO professional who is either a primary care physician or a physician with a specialty designation included in § 425.402(c) within the 12-month assignment window in order to be assigned to the ACO. Lastly, we are finalizing a policy not to voluntarily align a beneficiary to an ACO when the beneficiary is also eligible for assignment to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services. Accordingly, we are also finalizing the proposed revisions to § 425.402(e)(2) without modification.

c. Revisions to the Definition of Primary Care Services Used in Beneficiary Assignment

(1) Background

Section 1899(c)(1) of the Act, as amended by the 21st Century Cures Act and the Bipartisan Budget Act of 2018, provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by a physician and all services furnished by RHCs and FQHCs. However, the statute does not specify which kinds of services may be considered primary care services for purposes of beneficiary assignment. We established the initial list of services that we considered to be primary care services in the November 2011 final rule (76 FR 67853). In that final rule, we indicated that we intended to monitor this issue and would consider making changes to the definition of primary care services to add or delete codes used to identify primary care services, if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking to reflect additions or modifications to the codes that have been recognized for payment under the Medicare PFS, as summarized in the CY 2018 PFS proposed rule (82 FR 34109 and 34110). Subsequently, in the CY 2018 PFS final rule, we revised the definition of primary care services to include three additional chronic care management service codes, 99487, 99489, and G0506, and four behavioral health integration service codes, G0502, G0503, G0504 and G0507 (82 FR 53212 and 53213). These additions are effective for purposes of performing beneficiary assignment under § 425.402 for performance year 2019 and subsequent performance years.

Accounting for these recent changes, we define primary care services in § 425.400(c) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the following HCPCS/CPT codes:

CPT codes:

(1) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(2) 99304 through 99318 (codes for professional services furnished in a Nursing Facility, excluding services furnished in a SNF which are reported on claims with place of service code 31).

(3) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(4) 99341 through 99350 (codes for evaluation and management services furnished in a patients' home).

(5) 99487, 99489 and 99490 (codes for chronic care management).

(6) 99495 and 99496 (codes for transitional care management services).

HCPCS codes:

(1) G0402 (the code for the Welcome to Medicare visit).

(2) G0438 and G0439 (codes for the Annual Wellness Visits).

(3) G0463 (code for services furnished in electing teaching amendment hospitals).

(4) G0506 (code for chronic care management).

(5) G0502, G0503, G0504 and G0507 (codes for behavioral health integration).

As discussed in the CY 2018 PFS final rule (82 FR 53213), a commenter recommended that CMS consider including the advance care planning codes, CPT codes 99497 and 99498, in the definition of primary care services in future rulemaking. We indicated that we would consider whether CPT codes 99497 and 99498 or any additional existing HCPCS/CPT codes should be added to the definition of primary care services in future rulemaking for purposes of assignment of beneficiaries to ACOs under the Shared Savings Program. In addition, effective for CY 2018, the HCPCS codes for behavioral health integration G0502, G0503, G0504 and G0507 have been replaced by CPT codes 99492, 99493, 99494, 99484 (82 FR 53078).

CPT codes 99304 through 99318 are used for reporting evaluation and management (E&M) services furnished by physicians and other practitioners in a SNF (reported on claims with POS code 31) or a nursing facility (reported on claims with POS code 32). Based on stakeholder input, we finalized a policy in the CY 2016 PFS final rule (80 FR 71271 through 71272) effective for performance year 2017 and subsequent performance years, to exclude services identified by CPT codes 99304 through 99318 from the definition of primary care services for purposes of the beneficiary assignment methodology when the claim includes the POS code 31 modifier designating the services as having been furnished in a SNF. We established this policy to recognize that SNF patients are shorter stay patients who are generally receiving continued acute medical care and rehabilitative services. Although their care may be coordinated during their time in the SNF, they are then transitioned back into the community to the primary care professionals who are typically responsible for providing care to meet their true primary care needs. We

continue to believe that it is appropriate for SNF patients to be assigned to ACOs based on care received from primary care professionals in the community (including nursing facilities), who are typically responsible for providing care to meet the true primary care needs of these beneficiaries. As we discussed in the August 2019 proposed rule (83 FR 41897), ACOs serving special needs populations, including beneficiaries receiving long term care services, and other stakeholders have recently suggested that we consider an alternative method for determining operationally whether services identified by CPT codes 99304 through 99318 were furnished in a SNF. Instead of indirectly determining whether a beneficiary was a SNF patient when the services were furnished based on physician claims data, these stakeholders suggest we more directly determine whether a beneficiary was a SNF patient based on SNF facility claims data. These commenters recommended that CMS use contemporaneous SNF Medicare facility claims to determine whether a professional service identified by CPT codes 99304 through 99318 was furnished in a SNF, and therefore, should not be used for purposes of the beneficiary assignment methodology under § 425.402. Specifically, these commenters suggested that we determine whether services identified by CPT codes 99304 through 99318 were furnished in a SNF by determining whether the beneficiary also received SNF facility services on the same date of service.

In the August 2018 proposed rule (83 FR 41897 through 41899), we proposed to make changes to the definition of primary care services in § 425.400(c) to add new codes and to revise how we determine whether services identified by CPT codes 99304 through 99318 were furnished in a SNF.

(2) Proposed Revisions

Based on feedback from ACOs and our further review of the HCPCS and CPT codes currently recognized for payment under the PFS, we believe it would be appropriate to amend the definition of primary care services to include certain additional codes. Specifically, we proposed to revise the definition of primary care services in § 425.400(c) to include the following HCPCS and CPT codes: (1) Advance care planning service codes; CPT codes 99497 and 99498; (2) administration of health risk assessment service codes; CPT codes 96160 and 96161; (3) prolonged evaluation and management or psychotherapy service(s) beyond the typical service time of the primary procedure, CPT codes 99354 and 99355; (4) annual depression screening service code, HCPCS code G0444; (5) alcohol misuse screening service code, HCPCS code G0442; and (6) alcohol misuse counseling service code, HCPCS code G0443. In addition, in the CY 2019 PFS proposed rule (see 83 FR 35841 through 35844), CMS proposed to create three new HCPCS codes to reflect the additional resources involved in furnishing certain evaluation and management services: (1) GPC1X add-on code, for the visit complexity inherent to evaluation and management associated with certain primary care services, (2) GCG0X add-on code, for visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care, and (3) GPRO1, an additional add-on code for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure. As we explained in the August 2018 proposed rule (83 FR 41897), we believe it would be appropriate to include these codes in the definition of primary care services under the Shared Savings Program because these codes are used to bill for services that are similar to services that are already included in the list of primary care codes at § 425.400(c). We also expect that primary care physicians, nurse practitioners, physician assistants, and clinical nurse specialists frequently furnish these services as part of their overall management of a patient. As a result, we believe that including these codes would increase the accuracy of the assignment process by helping to ensure that beneficiaries are assigned to the ACO or other entity that is actually managing the beneficiary's care.

The following provides additional information about the HCPCS and CPT codes that we proposed to add to the definition of primary care services:

• *Advance care planning (CPT codes 99497 and 99498):* Effective January 1, 2016, CMS pays for voluntary advance care planning under the PFS (80 FR 70955 through 70959). See CMS, Medicare Learning Network, ''Advance Care Planning'' (ICN 909289, August 2016), available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AdvanceCarePlanning.pdf*. Advance care planning enables Medicare beneficiaries to make important decisions that give them control over the type of care they receive and when they receive it. Medicare pays for advance care planning either as a separate Part B service when it is medically necessary or as an optional element of a beneficiary's Annual Wellness Visit. We believe it would be appropriate to include both Advance Care Planning codes 99497 and 99498 in the definition of primary care services under the Shared Savings Program because the services provided as part of advance care planning include counseling and other evaluation and management services similar to the services included in Annual Wellness Visits and other evaluation and management service codes that are already included in the list of primary care codes.

• *Administration of health risk assessment (CPT codes 96160 and 96161):* In the CY 2017 PFS final rule (81 FR 80330 through 80331), we added two new CPT codes, 96160 and 96161, to the PFS, effective for CY 2017, to be used for payment for the administration of health risk assessment. These codes are ''add-on codes'' that describe additional resource components of a broader service furnished to the patient that are not accounted for in the valuation of the base code. For example, if a health risk assessment service were administered during a physician office visit, then the physician would bill for both the appropriate office visit code and the appropriate health risk assessment code. We believe it would be appropriate to include CPT codes 96160 and 96161 in the definition of primary care services because these add-on codes frequently represent additional practice expenses related to office visits for evaluation and management services that are already included in the definition of primary care services.

• *Prolonged evaluation and management or psychotherapy service(s) beyond the typical service time of the primary procedure (CPT codes 99354 and 99355):* These two codes are also ''add-on codes'' that describe additional resource components of a broader service furnished in the office or other outpatient setting that are not accounted for in the valuation of the base codes. Code 99354 is listed on a claim to report the first hour of additional face-to-face time with a patient and code 99355 is listed separately for each additional 30 minutes of face-to-face time with a patient beyond the time reported under code 99354. Codes 99354 and 99355 would be billed separately in addition to the base office or other outpatient evaluation and management or

psychotherapy service. (See Medicare Claims Processing Manual Chapter 12, Sections 30.6.15.1 Prolonged Services With Direct Face-to-Face Patient Contact Service (Codes 99354–99357) available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf*; also see CMS, MLN Matters, Prolonged Services (Codes 99354–99359) (Article Number MM5972, Revised March 7, 2017), available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm5972.pdf*.) Although we do not currently include prolonged services codes CPT codes 99354 and 99355 on our list of primary care services, based on further review we believe it would be appropriate to include them on our list of primary care services to more accurately assign beneficiaries to ACOs based on all the allowed charges for the primary care services furnished to beneficiaries. In the August 2018 proposed rule (83 FR 41898), we noted that the definitions of codes 99354 and 99355 also include prolonged services for certain psychotherapy services, which are not currently included on our list of primary care services. Therefore, we proposed to include the allowed charges for CPT codes 99354 and 99355, for purposes of assigning beneficiaries to ACOs, only when the base code is also on the list of primary care services.

• *Annual depression screening (HCPCS code G0444), alcohol misuse screening (HCPCS code G0442), and alcohol misuse counseling (HCPCS code G0443):* Effective October 14, 2011, all Medicare beneficiaries are eligible for annual depression screening and alcohol misuse screening. (See CMS Manual System, Screening for Depression in Adults (Transmittal 2359, November 23, 2011) available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2359CP.pdf*; and see CMS, MLN Matters, Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse (Article Number MM7633, Revised June 4, 2012), available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm7633.pdf*). Although these three codes have been in use since before the implementation of the Shared Savings Program in 2012, based on further review of these services, we believe that it would be appropriate to consider these services in beneficiary assignment. Annual depression screening may be covered if it is furnished in a primary care setting that has staff-assisted depression care supports in place to assure accurate diagnosis, effective treatment, and follow-up. Alcohol misuse screening and counseling are screening and behavioral counseling interventions in primary care to reduce alcohol misuse. All three of these codes include screening and counseling services similar to counseling and other evaluation and management services included in the codes already on the list of primary care codes.

In the CY 2019 PFS proposed rule (see 83 FR 35841 through 35844), we proposed to create three new HCPCS G-codes as part of a broader proposal to simplify the documentation requirements and to more accurately pay for services represented by CPT codes 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient). All three of these codes are ''add-on codes'' that describe additional resource components of a broader service furnished to the patient that are not accounted for in the valuation of the base codes.

HCPCS code GPC1X is intended to capture the additional resource costs, beyond those involved in the base evaluation and management codes, of providing face-to-face primary care services for established patients. HCPCS code GPC1X would be billed in addition to the base evaluation and management code for an established patient when the visit includes primary care services. In contrast, new HCPCS code GCG0X is an add-on code intended to reflect the complexity inherent to evaluation and management services associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, and interventional pain management-centered care. As we stated in the August 2018 proposed rule (83 FR 41899), we believe it would be appropriate to include both proposed new HCPCS codes GCG0X and GPC1X in our definition of primary care services because they represent services that are currently included in CPT codes 99201 through 99215, which are already included in the list of primary care codes in § 425.400(c).

Finally, proposed new HCPCS code GPRO1 (prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure, in the office or other outpatient setting requiring direct patient contact beyond the usual service; 30 minutes) is modeled on CPT code 99354, a prolonged services code discussed earlier in this section which we proposed to add to our list of primary care services. HCPCS code GPRO1 is intended to reflect prolonged evaluation and management or psychotherapy service(s) of 30 minutes duration beyond the typical service time of the primary or base service, whereas existing CPT code 99354 reflects prolonged services of 60 minutes duration. As is the case for code 99354, code GPRO1 would be billed separately in addition to the base office or other outpatient evaluation and management or psychotherapy service. We stated that we believe it would be appropriate to include proposed HCPCS code GPRO1 on our list of primary care services for the same reasons we proposed to add CPT code 99354 to our list of primary care services. Because the proposed definition of HCPCS code GPRO1 also includes prolonged services for certain psychotherapy services, which are not currently included on our list of primary care services, we proposed to include the allowed charges for HCPCS code GPRO1, for purposes of assigning beneficiaries to ACOs, only when the base code is also on the list of primary care services.

We proposed to include these codes in the definition of primary care services when performing beneficiary assignment under § 425.402, for performance years starting on January 1, 2019, and subsequent years. However, we noted that our proposal to include the three proposed new ''add-on codes'', GPC1X, GCG0X, and GPRO1, was contingent on CMS finalizing its proposal to create these new codes for use starting in 2019.

As discussed in section V.B.2.c.(1) of this final rule, ACOs and other commenters have expressed concerns regarding our current policy of identifying services billed under CPT codes 99304 through 99318 furnished in a SNF by using the POS modifier 31. We continue to believe it is appropriate to exclude from assignment services billed under CPT codes 99304 through 99318 when such services are furnished in a SNF. However, as we explained in the August 2018 proposed rule (83 FR 41899), we agree with commenters that it might increase the accuracy of beneficiary assignment for these vulnerable and generally high cost beneficiaries if we were to revise our method for determining whether services identified by CPT codes 99304 through 99318 were furnished in a SNF to focus on whether the beneficiary also received SNF facility services on the same day. We believe it would be feasible for us to directly and more precisely determine whether services identified by CPT codes 99304 through

99318 were furnished in a SNF by analyzing our facility claims data files rather than by using the POS modifier 31 in our professional claims data files. Operationally, we would exclude professional services claims billed under CPT codes 99304 through 99318 from use in the assignment methodology when there is a SNF facility claim in our claims files with dates of service that overlap with the date of service for the professional service. Therefore, we proposed to revise the regulation at § 425.400(c)(1)(iv)(A)(*2*), effective for performance years starting on January 1, 2019 and subsequent performance years, to remove the exclusion of claims including the POS code 31 and in its place to indicate more generally that we will exclude services billed under CPT codes 99304 through 99318 when such services are furnished in a SNF.

Under our current process, if CMS' HCPCS committee or the American Medical Association's CPT Editorial Panel modifies or replaces any of the codes that we designate as primary care service codes in § 425.400(c), we must revise the primary care service codes listed in § 425.400(c) as appropriate through further rulemaking before the revised codes can be used for purposes of assignment. As noted previously, effective for CY 2018, the HCPCS codes for behavioral health integration G0502, G0503, G0504 and G0507 have been replaced by CPT codes 99492, 99493, 99494 and 99484. Therefore, consistent with our current process, we proposed to revise the primary care service codes in § 425.400(c)(1)(iv) to replace HCPCS codes G0502, G0503, G0504 and G0507 with CPT codes 99492, 99493, 99494 and 99484 for performance years starting on January 1, 2019, and subsequent performance years.

We also noted that the regulations text at § 425.400(c)(1)(iv) includes brief descriptions for the HCPCS codes that we have designated as primary care service codes, but does not include such descriptions for the CPT codes that we have designated as primary care service codes. For consistency, we proposed a technical change to the regulations at § 425.400(c)(1)(iv)(A) to also include descriptions for the CPT codes. We also noted that one of the Chronic Care Management (CCM) codes, CPT code 99490, is inadvertently listed in the regulations text at § 425.400(c)(1)(iv)(A)(*6*) along with the codes for Transitional Care Management (TCM) services. We proposed a technical change to the regulations to move CPT code 99490 up to § 425.400(c)(1)(iv)(A)(*5*) with the other CCM codes.

We welcomed comments on the new codes we proposed to add to the definition of primary care services used for purposes of assigning beneficiaries to Shared Savings Program ACOs. In addition, we sought comment on our proposal to revise our method for excluding services identified by CPT codes 99304 through 99318 when furnished in a SNF. We also sought comment on the other proposed technical changes to § 425.400(c)(1)(iv). We also welcomed comments on any additional existing HCPCS/CPT codes that we should consider adding to the definition of primary care services in future rulemaking.

Comment: Some commenters supported the proposed changes to the definition of primary care services. One commenter suggested we include the Initial Preventive Physician Examination, or Welcome to Medicare Visit, as well as the annual wellness visit CPT codes in the definition.

Response: We appreciate the commenters' support for the proposed amendments to the definition of primary care services. We also note we currently include the Welcome to Medicare (G0402) and annual wellness visit (G0438 and G0439) CPT codes in the definition of primary care services under § 425.400(c).

Comment: Many commenters supported the proposal to modify § 425.400(c)(1)(iv)(A)(*2)* to remove the exclusion of claims including the POS code 31 and in its place indicate more generally that we will exclude services billed under CPT codes 99304 through 99318 from use in the assignment methodology when such services are furnished in a SNF, as determined based on whether there is a SNF facility claim with dates of service that overlap with the date of service for the professional service. One commenter supported this proposal because they noted it would better identify beneficiaries who have received short-term care and appropriately exclude them from assignment.

Response: We appreciate the commenters' support for the proposal to modify § 425.400(c)(1)(iv)(A)(*2)* to remove the exclusion of claims including the POS code 31 modifier and in its place to exclude services billed under CPT codes 99304 through 99318 when such services are furnished in a SNF. We are finalizing the policy as proposed.

Comment: Concerning the proposal to remove the exclusion of claims including the POS code 31, one commenter suggested we use a longer claims run-out period to account for the institutional billing practices for SNFs. This commenter also stated they would ''welcome transparency related to POS 31 and 32 claims-based attribution'' in the claim and claims line feed files we provide to participating ACOs under § 425.704.

Response: As we noted in the 2011 Shared Savings Program final rule (76 FR 67837), a 3-month claims run-out results in a completion percentage of approximately 98.5 percent for physician services and 98 percent for Part A services. Additionally, the claim and claim line feed files furnished to ACOs under § 425.704 contain Parts A and B claims data regarding beneficiaries who are either prospectively assigned to the ACO or who may be assigned to the ACO at the end of the performance year, depending on the assignment methodology under which the ACO participates. As long as the beneficiary has not declined to share their claims data, and the claim does not include protected health information related to substance use disorder treatment, ACOs receive both the claims for physician services and the facility level claims that would be used to determine whether a service billed under CPT codes 99304 through 99318 was furnished in a SNF.

Comment: A few commenters suggested we only include the newly proposed CPT/HCPCS codes under step 1 of the two-step assignment methodology. The commenters stated these codes should be used for ''assigning beneficiaries on the basis of care furnished specifically by primary care physicians and not all ACO professionals.''

Response: We disagree with these comments. We continue to believe our current assignment methodology generally provides an appropriate balance between maintaining a strong emphasis on primary care while ultimately allowing for assignment of beneficiaries on the basis of how they actually receive their primary care services (80 FR 32748). We also note that the list of specialty types included in step 1 and step 2 of the assignment methodology was informed by CMS medical officers knowledgeable about the services typically performed by physicians and non-physician practitioners (80 FR 32750) as well as comments received in response to the 2014 Shared Savings Program proposed rule.

Comment: One commenter suggested an alternative assignment methodology that the commenter believed would be similar to a methodology discussed in the CY 2019 PFS proposed rule which would distinguish between primary and secondary specialties for practitioners

billing under the same TIN as part of a multispecialty group. The commenter stated this approach would improve the accuracy of the assignment methodology by focusing on evaluation and management services furnished by primary care providers, rather than specialists. Alternatively, this commenter suggested an assignment methodology similar to methodologies used by state agencies. According to the commenter, this assignment methodology would allow for exclusions, attribution, and tie-breaking steps to support a valid beneficiary population.

Response: We encourage the commenter to review our assignment methodology under the Shared Savings Program regulations at 42 CFR part 425, subpart E. Our current assignment methodology emphasizes primary care services provided by primary care clinicians in step one, before considering primary care services furnished by certain specialists in step two. However, we will continue to monitor this issue to determine whether there have been any changes or refinements that would allow us to more precisely identify both primary and secondary practitioner specialties in Medicare claims data and whether those changes should be accounted for in the assignment methodology used in the Shared Savings Program. Any changes to our assignment methodology would be proposed through future rulemaking for the Shared Savings Program.

As discussed earlier in this final rule, the proposal to create three new HCPCS G-codes as part of a broader proposal to simplify the documentation requirements and to more accurately pay for the office or other outpatient evaluation and management services represented by CPT codes 99201 through 99215 is not being finalized. Therefore, the proposal to include HCPCS ''add-on codes'', GPC1X, GCG0X, and GPRO1 in the definition of ''primary care services'' will not be finalized at this time. We will revisit this proposal in future rulemaking and continue to monitor the annual rulemaking for the PFS to determine if we should propose any changes to the definition of primary care services for the Shared Savings Program to reflect proposed HCPCS/CPT coding changes.

We received no comments on the proposed technical changes to § 425.400(c)(1)(iv). After considering the comments received, we are finalizing our proposed revisions to the definition of primary care services, with the exception of the proposal to include the three add-on HCPCS codes GPC1X, GCG0X, and GPRO1. Specifically, we are revising the definition of primary care services in § 425.400(c) to add CPT codes 99497, 99498, 96160, 96161, 99354, and 99355, and HCPCS codes G0444, G0442, and G0443. Additionally, we are finalizing, as proposed, the revisions to our method for excluding services identified by CPT codes 99304 through 99318 when furnished in a SNF and the proposed technical changes to § 425.400(c)(1)(iv).

Consistent with the approach we have taken in the past when implementing changes to the assignment methodology, we will adjust ACOs' historical benchmarks for the performance year starting on January 1, 2019, to account for the changes to the assignment methodology that we are finalizing in this final rule.

d. Extreme and Uncontrollable Circumstances Policies for the Shared Savings Program

(1) Background

Following the 2017 California wildfires and Hurricanes Harvey, Irma, Maria, and Nate, stakeholders expressed concerns that the effects of these types of disasters on ACO participants, ACO providers/suppliers, and the assigned beneficiary population could undermine an ACO's ability to successfully meet the quality performance standards, and adversely affect financial performance, including, in the case of ACOs under performance-based risk, increasing shared losses. To address these concerns, we published an interim final rule with comment period titled Medicare Program; Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017 (hereinafter referred to as the Shared Savings Program IFC) that appeared in the December 26, 2017 **Federal Register** (82 FR 60912). In the Shared Savings Program IFC, we established policies for addressing ACO quality performance scoring and the determination of the shared losses owed by ACOs participating under performance-based risk tracks for ACOs that were affected by extreme or uncontrollable circumstances during performance year 2017. The policies adopted in the Shared Savings Program IFC were effective for performance year 2017, including the applicable quality data reporting period for the performance year. We have considered the comments received on the Shared Savings Program IFC in developing the policies for 2018 and subsequent years.

The extreme and uncontrollable circumstances policies established in the Shared Savings Program for performance year 2017 align with the policies established under the Quality Payment Program for the 2017 MIPS performance period and subsequent MIPS performance periods (see CY 2018 Quality Payment Program final rule with comment, 82 FR 53780 through 53783 and Quality Payment Program IFC, 82 FR 53895 through 53900). In particular, in the Shared Savings Program IFC (82 FR 60914), we indicated that we would determine whether an ACO had been affected by an extreme and uncontrollable circumstance by determining whether 20 percent or more of the ACO's assigned beneficiaries resided in counties designated as an emergency declared area in performance year 2017 as determined under the Quality Payment Program or the ACO's legal entity was located in such an area. In the Quality Payment Program IFC (82 FR 53897), we explained that we anticipated that the types of events that could trigger the extreme and uncontrollable circumstances policies would be events designated a Federal Emergency Management Agency (FEMA) major disaster or a public health emergency declared by the Secretary, although we indicated that we would review each situation on a case-by-case basis.

Because ACOs may face extreme and uncontrollable circumstances in 2018 and subsequent years, we proposed to extend the policies adopted in the Shared Savings Program IFC for addressing ACO quality performance scoring and the determination of the shared losses owed for ACOs affected by extreme or uncontrollable circumstances to performance year 2018 and subsequent performance years. In addition, in the Shared Savings Program IFC, we indicated that we planned to observe the impact of the 2017 hurricanes and wildfires on ACOs' expenditures for their assigned beneficiaries during performance year 2017, and might revisit the need to make adjustments to the methodology for calculating the benchmark in future rulemaking. We considered this issue further in the August 2018 proposed rule (see 83 FR 41904 through 41906).

(2) Proposed Revisions

The financial and quality performance of ACOs located in areas subject to extreme and uncontrollable circumstances could be significantly and adversely affected. Disasters may have several possible effects on ACO quality and financial performance. For instance, displacement of beneficiaries may make it difficult for ACOs to access medical record data required for quality

reporting, as well as, reduce the beneficiary response rate on survey measures. Further, for practices damaged by a disaster, the medical records needed for quality reporting may be inaccessible. We also believe that disasters may affect the infrastructure of ACO participants, ACO providers/suppliers, and potentially the ACO legal entity itself, thereby disrupting routine operations related to their participation in the Shared Savings Program and achievement of program goals. The effects of a disaster could include challenges in communication between the ACO and its participating providers and suppliers and in implementation of and participation in programmatic activities. Catastrophic events outside the ACO's control can also increase the difficulty of coordinating care for patient populations, and due to the unpredictability of changes in utilization and cost of services furnished to beneficiaries, may have a significant impact on expenditures for the applicable performance year and the ACO's benchmark in the subsequent agreement period. These factors could jeopardize ACOs' ability to succeed in the Shared Savings Program, and ACOs, especially those in performance-based risk tracks, may reconsider whether they are able to continue their participation in the program.

As we stated in the August 2018 proposed rule (83 FR 41900), because widespread disruptions could occur during 2018 or subsequent performance years, we believe it is appropriate to have policies in place to change the way in which we assess the quality and financial performance of Shared Savings Program ACOs in any affected areas. Accordingly, we proposed to extend the automatic extreme and uncontrollable circumstances policies under the Shared Savings Program that were established for performance year 2017 to performance year 2018 and subsequent performance years. Specifically, we proposed that the Shared Savings Program extreme and uncontrollable circumstances policies for performance year 2018 and subsequent performance years would apply when we determine that an event qualifies as an automatic triggering event under the Quality Payment Program. As we discussed in the Shared Savings Program IFC (82 FR 60914), we believe it is also appropriate to extend these policies to encompass the quality reporting period, unless the reporting period is extended, because if an ACO is unable to submit its quality data as a result of a disaster occurring during the quality data submission window, we would not have the quality data necessary to measure the ACO's quality performance for the performance year. For example, if an extreme and uncontrollable event were to occur in February 2019, which we anticipate would be during the quality data reporting period for performance year 2018, then the extreme and uncontrollable circumstances policies would apply for quality data reporting and quality performance scoring for performance year 2018, if the reporting period is not extended. We explained that we do not believe it is appropriate to extend this policy to encompass the quality data reporting period if the reporting period is extended because affected ACOs would have an additional opportunity to submit their quality data, enabling us to measure their quality performance in the applicable performance year. Accordingly, we also proposed that the policies regarding quality reporting would apply with respect to the determination of the ACO's quality performance in the event that an extreme and uncontrollable event occurs during the applicable quality data reporting period for a performance year and the reporting period is not extended. However, we noted that, because a disaster that occurs after the end of the performance year would have no impact on the determination of an ACO's financial performance for that performance year, it would not be appropriate to make an adjustment to shared losses in the event an extreme or uncontrollable event occurs during the quality data reporting period.

Comment: Commenters overwhelmingly supported adopting permanent policies to mitigate the impacts of extreme and uncontrollable circumstances. Several commenters supported finalizing the proposals without modification; however, the majority of commenters suggested modifications to the proposed policies or requested that CMS adopt additional means of providing relief to disaster affected ACOs. The comments and recommendations are discussed below in sections V.B.2.d.(1), (2), and (3) of this final rule.

Response: We appreciate commenters' support for adopting permanent policies to provide relief to ACOs that are affected by extreme and uncontrollable circumstances.

Comment: A few commenters recommended that CMS take into consideration whether an ACO has experienced an extreme and uncontrollable event during its agreement period when applying certain policies proposed in other sections of the August 2018 proposed rule, if finalized. These included proposed policies related to monitoring for financial performance, repayment mechanism amounts, reconciliation after termination and the determination of participant Medicare FFS revenue and prior participation for purposes of determining participation options.

Response: We thank commenters for their suggestions on ways to further limit the potential negative impacts of extreme and uncontrollable circumstances on ACOs affected by such events. We believe that these suggestions fall outside the scope of the proposals described in section II.E.4 of the August 2018 proposed rule that we are addressing in this final rule. We anticipate discussing our proposals related to other sections of the August 2018 proposed rule in a forthcoming final rule and will address comments related to those sections at that time.

(a) Modification of Quality Performance Scores for All ACOs in Affected Areas

As we explained in the Shared Savings Program IFC (82 FR 60914 through 60916), ACOs and their ACO participants and ACO providers/suppliers are frequently located across several different geographic regions or localities, serving a mix of beneficiaries who may be differentially impacted by hurricanes, wildfires, or other triggering events. Therefore, for 2017, we established a policy for determining when an ACO, which may have ACO participants and ACO providers/suppliers located in multiple geographic areas, would qualify for the automatic extreme and uncontrollable circumstance policies for the determination of quality performance. Specifically, we adopted a policy for performance year 2017 of determining whether an ACO had been affected by extreme and uncontrollable circumstances by determining whether 20 percent or more of the ACO's assigned beneficiaries resided in counties designated as an emergency declared area in the performance year, as determined under the Quality Payment Program as discussed in the Quality Payment Program IFC (82 FR 53898) or the ACO's legal entity was located in such an area. For 2017, we adopted a policy under which the location of an ACO's legal entity was determined based on the address on file for the ACO in CMS' ACO application and management system. We used 20 percent of the ACO's assigned beneficiary population as the minimum threshold to establish an ACO's eligibility for the policies regarding quality reporting and quality

performance scoring for 2017 because, as we stated in the Shared Savings Program IFC, we believe the 20 percent threshold provides a reasonable way to identify ACOs whose quality performance may have been adversely affected by an extreme or uncontrollable circumstance, while excluding ACOs whose performance would not likely be significantly affected.

The 20 percent threshold was selected to account for the effect of an extreme or uncontrollable circumstance on an ACO that has the minimum number of assigned beneficiaries to be eligible for the program (5,000 beneficiaries), and in consideration of the average total number of unique beneficiaries for whom quality information is required to be reported in the combined CAHPS survey sample (860 beneficiaries) and the CMS Web Interface sample (approximately 3,500 beneficiaries). (There may be some overlap between the CAHPS sample and the CMS Web Interface sample.) Therefore, we estimated that an ACO with an assigned population of 5,000 beneficiaries typically would be required to report quality information on a total of 4,000 beneficiaries. Thus, we indicated that we believe the 20 percent threshold ensures that an ACO with the minimum number of assigned beneficiaries would have an adequate number of beneficiaries across the CAHPS and CMS Web Interface samples in order to fully report on these measures. However, we also noted that it is possible that some ACOs that have fewer than 20 percent of their assigned beneficiaries residing in affected areas may have a legal entity that is located in an emergency declared area. Consequently, their ability to quality report may be equally impacted because the ACO legal entity may be unable to collect the necessary information from their ACO participants or may experience infrastructure issues related to capturing, organizing, and reporting the data to CMS. We stated that if less than 20 percent of the ACO's assigned beneficiaries reside in an affected area and the ACO's legal entity is not located in a county designated as an affected area, then we believe that there is unlikely to be a significant impact upon the ACO's ability to report or on the representativeness of the quality performance score that is determined for the ACO. For performance year 2017, we determined what percentage of the ACO's performance year assigned population was affected by a disaster based on the final list of beneficiaries assigned to the ACO for the performance year. Although beneficiaries are assigned to ACOs under Track 1 and Track 2 based on preliminary prospective assignment with retrospective reconciliation after the end of the performance year, these ACOs were able to use their quarterly assignment lists, which include beneficiaries' counties of residence, for early insight into whether they were likely to meet the 20 percent threshold.

In the Shared Savings Program IFC, we modified the quality performance standard specified under § 425.502 by adding a new paragraph (f) to address potential adjustments to the quality performance scores for performance year 2017 of ACOs determined to be affected by extreme and uncontrollable circumstances. We also modified § 425.502(e)(4) to specify that an ACO receiving the mean Shared Savings Program ACO quality score for performance year 2017 based on the extreme and uncontrollable circumstances policies would not be eligible for bonus points awarded based on quality improvement in that year because quality data would not be available to determine if there was improvement from year to year.

In the Shared Savings Program IFC, we established policies with respect to quality reporting and quality performance scoring for the 2017 performance year. In anticipation of any future extreme and uncontrollable events, in the August 2018 proposed rule (83 FR 41901) we proposed to extend these policies, with minor modifications, to subsequent performance years as well. In order to avoid confusion and reduce unnecessary burdens on affected ACOs, we proposed to align our policies for 2018 and subsequent years with policies established for the Quality Payment Program in the final rule with comment period, entitled CY 2018 Updates to the Quality Payment Program (82 FR 53568). Specifically, we proposed to apply determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred and the identification of the affected geographic areas and the applicable time periods. Generally, in line with the approach taken for 2017 in the Quality Payment Program IFC (82 FR 53897), we anticipated that the types of events that would be considered an automatic triggering event would be events designated as a Federal Emergency Management Agency (FEMA) major disaster or a public health emergency declared by the Secretary, but indicated that CMS would review each situation on a case-by-case basis. We also proposed that CMS would have sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred, the percentage of the ACO's assigned beneficiaries residing in the affected areas, and the location of the ACO legal entity. Additionally, we proposed to determine an ACO's legal entity location based on the address on file for the ACO in CMS' ACO application and management system.

In the Shared Savings Program IFC, we established a policy for performance year 2017 under which we determined the percentage of the ACO's assigned population that was affected by a disaster based on the final list of beneficiaries assigned to the ACO for the performance year. We begin producing the final list of assigned beneficiaries after allowing for 3 months of claims run out following the end of a performance year. However, the quality reporting period ends before the 3-month claims run out period ends. Therefore, in the August 2018 proposed rule we expressed concern that if, for future performance years, we continue to calculate the percentage of affected beneficiaries based on the ACO's final list of assigned beneficiaries, it would not be operationally feasible for us to notify an ACO as to whether it meets the 20 percent threshold prior to the end of the quality reporting period because the final list of assigned beneficiaries is not available until after the close of the quality reporting period. We explained that we now believe it would be appropriate to base this calculation on the list of assigned beneficiaries used to generate the Web Interface quality reporting sample, which would be available with the quarter three program reports, generally in November of the applicable performance year. We also indicated this report would be available to ACOs participating in the proposed 6-month performance year from January 1, 2019 through June 30, 2019. By basing the calculation on the list of assigned beneficiaries used to generate the Web Interface quality reporting sample, we would be able to notify ACOs earlier as to whether they exceed the 20 percent threshold, and ACOs could then use this information to decide whether to report quality data for the performance year. Therefore, for performance year 2018 and subsequent performance years, we proposed to determine the percentage of an ACO's assigned beneficiaries that reside in an area affected by an extreme and uncontrollable circumstance using the list of assigned beneficiaries used to generate the Web Interface quality reporting sample. We indicated that we

could use this assignment list report regardless of the date(s) the natural disaster occurred. The assignment list report provides us with a list of beneficiaries who have received the plurality of their primary care services from ACO professionals in the ACO at a specific point in time. As this is the list that is used to determine the quality reporting sample, we believe it is appropriate to use the same list to determine how many of the ACO's beneficiaries reside in an area affected by a disaster, such that the ACO's ability to report quality data could be compromised. We proposed to revise § 425.502(f) to reflect this proposal for performance year 2018 and subsequent years.

In the Shared Savings Program IFC (82 FR 60916), we described the policies under the MIPS APM scoring standard that would apply for performance year 2017 for MIPS eligible clinicians in an ACO that did not completely report quality. The existing tracks of the Shared Savings Program (Track 1, Track 2 and Track 3), and the Track 1+ Model are all MIPS APMs under the APM scoring standard.[35] If finalized, we expect the BASIC track and ENHANCED track (based on Track 3) proposed in the August 2018 proposed rule would similarly be considered MIPS APMs under the APM scoring standard. In the August 2018 proposed rule (83 FR 41902), we noted, for purposes of the APM scoring standard, MIPS eligible clinicians in an ACO that has been affected by an extreme and uncontrollable circumstance and does not report quality for a performance year, and therefore, receives the mean ACO quality score under the Shared Savings Program, would have the MIPS quality performance category reweighted to zero percent resulting in MIPS performance category weighting of 75 percent for the Promoting Interoperability performance category and 25 percent for the Improvement Activities performance category under the APM scoring standard per our policy at § 414.1370(h)(5)(i)(B). In the event an ACO that has been affected by an extreme and uncontrollable circumstance is able to completely and accurately report all quality measures for a performance year, and therefore receives the higher of the ACO's quality performance score or the mean quality performance score under the Shared Savings Program, we would not reweight the MIPS quality performance category to zero percent under the APM scoring standard. Additionally, unless otherwise excepted, the ACO participants will receive a Promoting Interoperability (PI) (formerly called Advancing Care Information (ACI)) performance category score under the APM scoring standard based on their reporting, which could further increase their final score under MIPS.

We proposed to revise § 425.502(f) to extend the policies established for performance year 2017 to performance year 2018 and subsequent performance years. Specifically, we proposed that for performance year 2018 and subsequent performance years, including the applicable quality data reporting period for the performance year if the reporting period is not extended, in the event that we determine that 20 percent or more of an ACO's assigned beneficiaries, as determined using the list of beneficiaries used to generate the Web Interface quality reporting sample, reside in an area that is affected by an extreme and uncontrollable circumstance, as determined under the Quality Payment Program, or that the ACO's legal entity is located in such an area, we would use the following approach to calculate the ACO's quality performance score as specified in proposed revisions to paragraphs (e) and (f) of § 425.502.

- The ACO's minimum quality score would be set to equal the mean quality performance score for all Shared Savings Program ACOs for the applicable performance year.
- If the ACO is able to completely and accurately report all quality measures, we would use the higher of the ACO's quality performance score or the mean quality performance score for all Shared Savings Program ACOs. If the ACO's quality performance score is used, the ACO would also be eligible for quality improvement points.
- If the ACO receives the mean Shared Savings Program quality performance score, the ACO would not be eligible for bonus points awarded based on quality improvement during the applicable performance year.
- If an ACO receives the mean Shared Savings Program ACO quality performance score for a performance year, in the next performance year for which the ACO reports quality data and receives a quality performance score based on its own performance, we would measure quality improvement based on a comparison between the ACO's performance in that year and in the most recently available prior performance year in which the ACO reported quality. Under this approach, the comparison would continue to be between consecutive years of quality reporting, but these years may not be consecutive calendar years.

Additionally, we proposed to address the possibility that ACOs that have a 6-month performance year (or performance period) during 2019 may be affected by extreme and uncontrollable circumstances. In this final rule, we are addressing the proposals specific to the 6-month performance year from January 1, 2019 through June 30, 2019. In a forthcoming final rule, we anticipate discussing comments received on the proposals related to policies for the 6-month performance year from July 1, 2019 through December 31, 2019, and the performance period from January 1, 2019 through June 30, 2019, for ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019. We anticipate this discussion will include a description of the applicability of policies for addressing extreme and uncontrollable circumstances.

As described in section II.A.7 of the August 2018 proposed rule, we proposed to use 12 months of data, based on the calendar year, to determine quality performance for the 6-month performance year from January 2019 through June 2019 (83 FR 41856 through 41858). We explained our belief that it is necessary to account for disasters occurring in any month(s) of CY 2019 for ACOs participating in a 6-month performance year during 2019 regardless of whether the ACO is actively participating in the Shared Savings Program at the time of the disaster. Therefore, for ACOs with a 6-month performance year from January 1, 2019 through June 30, 2019, affected by a disaster in any month of 2019, we would use the alternative scoring methodology specified in § 425.502(f) to determine the quality performance score for the 2019 quality reporting period, if the reporting period is not extended. For example, assume that an ACO participates in the Shared Savings Program for a 6-month performance year from January 1, 2019 through June 30, 2019, and does not continue its participation in the program for a new agreement period beginning July 1, 2019 (as proposed). Further assume that we determine that 20 percent or more of the ACO's assigned beneficiaries, as determined using the list of beneficiaries used to generate the Web Interface quality reporting sample, reside in an area that is affected by an extreme and uncontrollable circumstance, as determined under the

[35] See, for example Alternative Payment Models in the Quality Payment Program as of February 2018, available at *https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Comprehensive-List-of-APMs.pdf.*

Quality Payment Program, in September 2019. The ACO's quality performance score for the 2019 reporting period would be adjusted according to the policies in § 425.502(f).

We proposed to specify the applicability of the alternative scoring methodology in § 425.502(f) for the 6-month performance year from January 1, 2019 through June 30, 2019, in the proposed new section of the regulations at § 425.609(d).

We solicited comments on the proposed policies for assessing the quality performance of ACOs affected by an extreme or uncontrollable circumstance during performance year 2018 and subsequent years, including the applicable quality data reporting period for the performance year, unless the reporting period is extended.

Comment: One commenter incorrectly stated that CMS proposed to continue to use a threshold of 25 percent to determine the applicability of the proposed alternative quality scoring policies (rather than the actual 20 percent proposed) and noted that they agreed that this threshold was reasonable. This commenter also suggested that CMS consider other percentage thresholds, such as 5 percent or 10 percent, as test cases. The same commenter also encouraged CMS to look at the percentage of an ACO's physicians and other health clinicians located in an impacted area as another means of determining which ACOs should be automatically eligible for the alternative quality scoring policy. This commenter suggested, for example, using a threshold of 50 percent of NPIs located in an impacted area, based on the practice locations listed in the Provider Enrollment, Chain, and Ownership System (PECOS).

Response: We are finalizing our proposal to continue to use 20 percent of assigned beneficiaries residing in a disaster-affected as one of the criteria for determining whether an ACO is eligible for the alternative quality scoring methodology. We will continue to monitor this criterion as we gain more experience with these policies. However, at present we believe that the 20 percent threshold, which was influenced by considerations related to ensuring a sufficient population size to allow affected ACOs to fully report on quality, remains a reasonable level. While we considered the commenter's suggestion to expand the criteria for identifying affected ACOs to include ACOs for which 50 percent or more of the NPIs billing under the ACO participant TINs are located in an impacted area, we believe that including this additional criterion would create additional operational complexity and less transparency as we do not currently include information on the location of ACO providers/suppliers in program reports.

Comment: Several commenters stated that the proposed policy of using the higher of an ACO's own quality score in the affected year or the national mean score unfairly penalizes ACOs that have had historically high quality performance. One commenter also noted that this approach could unfairly reward ACOs with historically low quality performance to the detriment of the Medicare Trust Funds. These commenters recommended that CMS should adopt an approach that considers an ACO's own quality score from one or more prior years, if available. Some of the commenters explained this approach would be similar to a policy used in Medicare Advantage.

Commenters offered various suggestions on how to implement a policy that considers an ACO's historic quality performance. A few commenters recommended that CMS use the highest of the ACO's quality score for the affected performance year, the ACO's quality score for the prior performance year (if available), or the national mean quality score. One commenter recommended following this approach for each individual quality measure. Suggestions from other commenters included: Using the higher of the ACO's average quality score for the prior two years and the national mean for ACOs in their third or subsequent year in the program and using the national average score for ACOs in their first or second year in the program; Using the higher of the affected year quality score and the prior year quality score, if one is available, and otherwise using the higher of the affected year score and the national mean score; Using the ACO's historical quality performance instead of the mean when an ACO is in its third or subsequent performance year in the program.

Several commenters also recommended that the proposed policies in this section be extended to include all ACOs affected by a natural disaster, not just those that cannot report quality data. A few commenters provided suggestive evidence that quality outcome measures such as readmission measures may be subject to immediate and significant impacts in the event of a natural disaster, which could have an adverse impact on an ACO's quality score, particularly given the non-linear nature of the program's quality scoring methodology under which an ACO receives zero points on a measure if it falls below the 30th percentile. Several commenters requested that that those ACOs whose scores on readmissions measures (ACO–8, all-cause readmissions and ACO–35, SNF readmissions) fall below the 30th percentile should be eligible to have their quality score adjusted to account for the natural disaster.

Response: We acknowledge that for some ACOs, the mean quality score could be lower, or higher, than the score those ACOs would have received in the absence of a disaster. However, we have concerns with the recommended alternatives which would potentially apply an ACO's score from the prior year or apply a score that is an average of prior year scores, particularly for ACOs in their early years of participation in the Shared Savings Program and for which the prior years may have included a higher number of pay-for-reporting measures, thus making the quality scores incomparable. Likewise, in section III.F.1.b. of this final rule we are finalizing several quality measures for use beginning in performance year 2019. These measures will be pay-for-reporting for the first 2 years of use (2019 and 2020). All else being equal, the addition of these new pay-for-reporting measures will increase ACOs' quality scores. Also, we note that ACO quality performance can vary from year to year and the fact that an ACO had a high quality score in prior years does not necessarily guarantee that the ACO would have had an above average score in the affected year in the absence of the natural disaster. Lastly, we would remind commenters that the national mean quality score includes the quality scores of 100 percent earned by ACOs in their first performance year, thus increasing the mean.

For these reasons, we are declining at this time to adopt commenters' recommendations that we consider prior year quality scores as part of determining the quality performance scores of ACOs affected by extreme and uncontrollable circumstances and are finalizing the proposed policy. We are also declining to adopt the commenter's recommendation to give special consideration to ACOs based on their performance on the ACO–8 and ACO–35 readmissions measures. We would also like to clarify that both the policy that we finalized for performance year 2017 in the Shared Savings Program IFC and the policy we are finalizing in this rule for performance year 2018 and subsequent performance years would apply to all ACOs deemed to be affected by an extreme and uncontrollable circumstance (20 percent or more of assigned beneficiaries residing in an

affected area or legal entity located in such an area), including those ACOs that were able to report quality and those for which scores on ACO–8 and ACO–35 fell below the 30th percentile. We will continue to monitor quality performance among ACOs affected by extreme and uncontrollable circumstances, and as we gain more experience will consider whether any changes to the finalized policy are warranted.

Comment: One commenter agreed with setting a disaster-affected ACO's quality score to the national mean but opposed using the mean score to calculate ''future benchmarks or subsequent year thresholds until complete and accurate reporting can be achieved.'' They noted that ''setting quality benchmarks to an artificial mean is not a valid approach to determine legitimate savings and losses.''

Response: We clarify that ACOs' quality performance scores are not used to calculate quality measure benchmarks. Rather, the quality measure benchmarks are calculating using actual ACO performance and all other available and applicable Medicare FFS data.

Comment: One commenter recommended that all affected ACOs should receive the higher of the 2018 or 2019 Star Rating for each CAHPS measure.

Response: We note that the Shared Savings Program does not provide a Star Rating to ACOs based on their CAHPS performance. Star Ratings are used for Medicare Advantage and Medicare Prescription Drug plans to provide quality and performance information to Medicare beneficiaries to assist them in choosing their health and drug services and, solely for Medicare Advantage plans, to implement the quality bonus payment adopted by Congress in the Patient Protection and Affordable Care Act. We believe that incorporating Star Ratings into the Shared Savings Program would need to be part of a larger effort that was not contemplated in the August 2018 proposed rule. In contrast, we believe our proposal of using the higher of an ACO's own calculated quality score or the mean quality score serves as a way to mitigate negative impacts for disaster-affected ACOs in manner that can be readily incorporated into the existing structure of the Shared Savings Program quality scoring methodology.

Comment: A few commenters recommended that CMS remove claims associated with disaster-impacted beneficiaries and time periods or claims with disaster payment modifier codes when calculating the numerator and denominator of the readmissions measures and other claims-based quality measures.

Response: As we describe in section V.B.2.b. of this final rule, we have examined the use of existing disaster payment modifiers during 2017 and have found their utilization to be low overall and to vary across ACOs, including those with comparably high shares of beneficiaries residing in disaster affected areas. Therefore, we have concerns that these codes would not serve as a useful means for comprehensively identifying relevant claims. We also have concerns about removing claims for beneficiaries residing in affected areas during affected time periods. In addition to adding considerable complexity, this approach could lead to the elimination of a large number of claims for some ACOs. This could lead to bias if the claims removed are systematically different from other claims for reasons apart from the natural disaster, such as because they are concentrated in a specific geographic area or time period and may also make it more difficult for CMS to provide an oversample of beneficiaries to ACOs for the CMS Web Interface sample.

Comment: One commenter requested that CMS provide additional clarity before finalizing any of the policies for extreme and uncontrollable circumstances proposed in the August 2018 proposed rule. In particular, the commenter requested that CMS provide additional clarification on how the agency would determine and announce whether the extreme and uncontrollable circumstances policies would apply or if the reporting period would be extended.

Response: We intend to make an initial determination about whether an ACO meets the criteria for being considered a disaster-affected ACO after quarter 3 assignment has been determined and before the start of the quality reporting period. We will make the final determination with respect to affected ACOs after the end of the calendar year in order to capture any additional extreme and uncontrollable circumstances that may occur in the remainder of the year or during the quality reporting period, if not extended. We will continue to use the quarter 3 assignment list as the basis for this final determination. In the event that CMS decides to extend the quality reporting period, we would provide notification to ACOs through existing communication channels such as the Shared Savings Program newsletter or an email blast. We also note that if an ACO is determined to be an affected ACO as a result of an extreme or uncontrollable circumstance during the performance year, the alternative quality scoring methodology would apply, regardless of whether the quality reporting period is extended.

Comment: One commenter recommended that CMS adopt the same period as any Declaration of Emergency by the Secretary when determining the applicable time period for an extreme and uncontrollable circumstance instead of an alternative period selected by CMS that may not be as well-aligned with the reality of health services instability for areas under a declaration of emergency. Another commenter encouraged CMS to be transparent regarding the criteria used to determine the applicable time period and to work closely with Medicare Administrative Contractors and the Federal Emergency Management Agency to communicate these policies to ACOs.

Response: We are finalizing our proposals for extreme and uncontrollable circumstances, including our proposal that CMS will have the sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred. Although we are not adopting fixed criteria for determining the applicable time periods, we note that for performance year 2017 we used the time periods associated with public health emergencies declared by the Secretary and listed on the CMS Emergency Response and Recovery website (now renamed the Emergency Preparedness & Response Operations website at *https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/EPRO-Home.html*). We anticipate continuing this practice, which we believe to be transparent, going forward. Furthermore, for events for which the public health emergency declaration spans calendar years, we intend to treat the portion of the period falling within each year as if it were a separate event for purposes of identifying ACOs eligible for the alternative quality scoring methodology and for computing any adjustment to shared losses.

Comment: One commenter expressed concerns about what they described as CMS' ''one-size-fits-all'' approach for determining the time period during which an ACO would be subject to the extreme and uncontrollable circumstances policies. They encouraged CMS to allow ACOs an opportunity to request relief from shared losses and negative quality adjustments over a longer period of time, up to a full performance year, to be evaluated by CMS on a case-by-case basis. The commenter noted that the impact of a disaster occurring early in the year may have a different impact

than one occurring later in the year and there may be long-lasting effects, which should not have counted against affected ACOs. They stated that the hardship exemption, which would be approved by CMS on a case-by-case basis, would have limited effect on the Trust Funds, but would be important for the integrity of the program by establishing a formal process for ACOs to request an exemption based on extenuating circumstances.

Response: We have elected to adopt automatic policies to address extreme and uncontrollable circumstances in lieu of hardship requests that must be considered on a case-by-case basis in order to increase certainty and reduce administrative burden for both ACOs and CMS. We will continue to monitor the impact of the policies that we are finalizing in this rule, and as we gain more experience, if warranted, we will propose additional modifications through future notice and comment rulemaking.

After considering the comments received, we are finalizing our proposals to extend the policies for determining the quality scores for ACOs affected by extreme and uncontrollable circumstances established for performance year 2017 to performance year 2018 and subsequent performance years. Specifically, we are revising §§ 425.502(e) and 425.502(f) to state that for performance year 2018 and subsequent performance years, including the applicable quality data reporting period for the performance year, if the reporting period is not extended, in the event that we determine that 20 percent or more of an ACO's assigned beneficiaries, as determined using the list of assigned beneficiaries used to generate the Web Interface quality reporting sample, reside in an area that is affected by an extreme and uncontrollable circumstance, as determined under the Quality Payment Program, or that the ACO's legal entity is located in such an area, we will use the following approach to calculate the ACO's quality performance score:

- The ACO's minimum quality score will be set to equal the mean quality performance score for all Shared Savings Program ACOs for the applicable performance year.
- If the ACO is able to completely and accurately report all quality measures, we will use the higher of the ACO's quality performance score or the mean quality performance score for all Shared Savings Program ACOs. If the ACO's quality performance score is used, the ACO will also be eligible for quality improvement points.
- If the ACO receives the mean Shared Savings Program quality performance score, the ACO will not be eligible for bonus points awarded based on quality improvement during the applicable performance year.
- If an ACO receives the mean Shared Savings Program ACO quality performance score for a performance year, in the next performance year for which the ACO reports quality data and receives a quality performance score based on its own performance, we will measure quality improvement based on a comparison between the ACO's performance in that year and in the most recently available prior performance year in which the ACO reported quality.

We clarify that if an ACO reports quality data in a year in which it is affected by an extreme and uncontrollable circumstance, but receives the national mean quality score, we will use the ACO's own quality performance score to determine quality improvement bonus points in the following year. For example, if an ACO reported quality data in years 1, 2, and 3 of an agreement period, but received the national mean quality score in year 2 as the result of an extreme or uncontrollable circumstance, we would determine quality improvement bonus points for year 3 by comparing the ACO's year 3 quality score with its year 2 score. If the ACO received the mean score in year 2 because it did not report quality, we would compare year 3 with year 1 to determine the bonus points for year 3.

We also want to clarify one point regarding the interaction between this alternative quality scoring methodology and MIPS. As we noted above, the MIPS quality performance category is reweighted to zero if a disaster-affected ACO receives the mean quality score under the Shared Savings Program's extreme and uncontrollable circumstance policy, because it did not or could not report quality data at the ACO (APM Entity) level, regardless of whether or not any of the ACOs participant TINs reported quality outside the ACO. This reweighting under MIPS results in MIPS performance category weighting of 75 percent for the PI performance category and 25 percent for IA performance category. If, for any reason, the PI performance category also is reweighted to zero, which could be more likely when there is a disaster, there would be only one performance category triggering the policy under which the ACO in question would receive a neutral (threshold) MIPS score, as per § 414.1380(c) (see discussion at 83 FR 53778). If any of the ACO's participant TINs do report PI, then the TIN or TINs' PI performance category scores will be used to score the ACO under the MIPS scoring standard, the PI performance category will not be reweighted, and the policy to assign a neutral (threshold) MIPS score will not be triggered.

(b) Mitigating Shared Losses for ACOs Participating in a Performance-Based Risk Track

In the Shared Savings Program IFC (82 FR 60916) we modified the payment methodology for performance year 2017 for performance-based risk tracks established under the authority of section 1899(i) of the Act, to mitigate shared losses owed by ACOs affected by extreme and uncontrollable circumstances during 2017. Under this approach, we reduced the ACO's shared losses, if any, determined to be owed for performance year 2017 under the existing methodology for calculating shared losses in the Shared Savings Program regulations at 42 CFR part 425 subpart G by an amount determined by multiplying the shared losses by two factors: (1) The percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance; and (2) the percentage of the ACO's assigned beneficiaries who resided in an area affected by an extreme and uncontrollable circumstance. For performance year 2017, we determined the percentage of the ACO's performance year assigned beneficiary population that was affected by the disaster based on the final list of beneficiaries assigned to the ACO for the performance year. For example, assume that an ACO was determined to owe shared losses of $100,000 for performance year 2017, a disaster was declared for October through December during the performance year, and 25 percent of the ACO's assigned beneficiaries resided in the disaster area. In this scenario, we would have adjusted the ACO's shared losses in the following manner: $\$100{,}000 - (\$100{,}000 \times 0.25 \times 0.25) = \$100{,}000 - \$6{,}250 = \$93{,}750$. The policies for performance year 2017 are specified in paragraph (i) in § 425.606 for ACOs under Track 2 and § 425.610 for ACOs under Track 3.

In the August 2018 proposed rule (83 FR 41903), we stated our belief that it would be appropriate to continue to apply these policies in performance year 2018 and subsequent years to address stakeholders' concerns that ACOs participating under a performance-based risk track could be held responsible for sharing losses with the Medicare program resulting from catastrophic events outside the ACO's control given

the increase in utilization, difficulty of coordinating care for patient populations leaving the impacted areas, and the use of natural disaster payment modifiers making it difficult to identify whether a claim would otherwise have been denied under normal Medicare FFS rules. Absent this relief, we believe that ACOs participating in performance-based risk tracks might reconsider whether they are able to continue their participation in the Shared Savings Program under a performance-based risk track. The approach we adopted for performance year 2017 in the Shared Savings Program IFC, and which we proposed to continue for performance year 2018 and subsequent years, balances the need to offer relief to affected ACOs with the need to continue to hold those ACOs accountable for losses incurred during the months in which there was no applicable disaster declaration and for the portion of their final assigned beneficiary population that was outside the area affected by the disaster. In the August 2018 proposed rule, we explained our belief that, consistent with the policy adopted for performance year 2017 in the Shared Savings Program IFC, it would be appropriate to continue to use the final assignment list report for the performance year for purposes of this calculation. This final assignment list report would be available at the time we conduct final reconciliation and provides the most complete information regarding the extent to which an ACO's assigned beneficiary population was affected by a disaster.

Additionally, we proposed to also address the possibility that ACOs that have a 6-month performance year during 2019 may be affected by extreme and uncontrollable circumstances. In this final rule, we are addressing the proposals specific to the 6-month performance year from January 1, 2019 through June 30, 2019. In a forthcoming final rule, we anticipate discussing comments received on the proposals related to policies for the 6-month performance year from July 1, 2019 through December 31, 2019, and the performance period from January 1, 2019 through June 30, 2019 for ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019. We anticipate this discussion will include a description of the applicability of policies for determining shared losses for ACOs affected by extreme and uncontrollable circumstances.

As described in section II.A.7. of the August 2018 proposed rule (83 FR 41849 through 41853) and the proposed provision at § 425.609, we proposed to use 12 months of expenditure data, based on the calendar year, to perform financial reconciliation for the 6-month performance year from January 1, 2019 through June 30, 2019. Accordingly, for ACOs participating in a 6-month performance year during the first half of 2019, we believed it would be necessary to account for disasters occurring in any month(s) of CY 2019, regardless of whether the ACO is actively participating in the Shared Savings Program at the time of the disaster.

For ACOs with a 6-month performance year that are affected by an extreme or uncontrollable circumstance during CY 2019, we proposed to first determine shared losses for the ACO over the full calendar year, adjust the shared losses for extreme and uncontrollable circumstances, and then determine the portion of shared losses for the 6-month performance year according to the methodology proposed under § 425.609. For example, assume that: A disaster was declared for October 2019 through December 2019; an ACO is being reconciled for its participation during the performance year from January 1, 2019 through June 30, 2019; the ACO is determined to have shared losses of $100,000 for CY 2019; and 25 percent of the ACO's assigned beneficiaries reside in the disaster area. In this scenario, we would adjust the ACO's losses in the following manner: $\$100{,}000 - (\$100{,}000 \times 0.25 \times 0.25) = \$100{,}000 - \$6{,}250 = \$93{,}750$, then we would multiply these losses by the portion of the year the ACO participated $= \$93{,}750 \times 0.5 = \$46{,}875$.

Therefore, we proposed to amend §§ 425.606(i) and 425.610(i) to extend the policies regarding extreme and uncontrollable circumstances that were established for performance year 2017 to performance year 2018 and subsequent years. In addition, we proposed to include a provision at § 425.609(d) to provide that the policies on extreme and uncontrollable circumstances would apply to the determination of shared losses for ACOs participating in a 6-month performance year during 2019.

In the August 2018 proposed rule (83 FR 41904), we noted that to the extent that our proposal to extend the policies adopted in the Shared Savings Program IFC to 2018 and subsequent performance years constitutes a proposal to change the payment methodology for 2018 after the start of the performance year, we believe that consistent with section 1871(e)(1)(A)(ii) of the Act, and for the reasons discussed in section II.E.4 of the August 2018 proposed rule (83 FR 41899 through 41906), it would be contrary to the public interest not to propose to establish a policy under which we would have the authority to adjust the shared losses calculated for ACOs in Track 2 and Track 3 for performance year 2018 to reflect the impact of any extreme or uncontrollable circumstances that may occur during the year.

We also explained that these proposed policies would not change the status of those payment models that meet the criteria to be Advanced APMs under the Quality Payment Program (see § 414.1415). Our proposed policies would reduce the amount of shared losses owed by ACOs affected by a disaster, but the overall financial risk under the payment model would not change and participating ACOs would still remain at risk for an amount of shared losses in excess of the Advanced APM generally applicable nominal amount standard. Additionally, these policies would not prevent an eligible clinician from satisfying the requirements to become a QP for purposes of the APM Incentive Payment (available for payment years through 2024) or higher physician fee schedule updates (for payment years beginning in 2026) under the Quality Payment Program.

We also emphasized that all ACOs would continue to be entitled to share in any savings they may achieve for a performance year. ACOs in all tracks of the program will continue to receive shared savings payments, if any, as determined under subpart G of the regulations. The calculation of savings and the determination of shared savings payment amounts for a performance year would not be affected by the proposed policies to address extreme and uncontrollable circumstances, except that the quality performance score for an affected ACO may be adjusted as described in section II.E.4 of the proposed rule.

We solicited comments on the proposed policies for assessing the financial performance of ACOs affected by an extreme or uncontrollable circumstance during performance year 2018 and subsequent years.

Comment: Several commenters noted that ACOs are likely to experience increased expenditures as the result of a natural disaster. One commenter noted that studies have shown that natural disasters materially increase Medicare costs per beneficiary. A few other commenters noted that costs can increase because of the impact of the disaster on beneficiaries' health, safety and anxiety causing increased utilization of services but also because waivers effected during declared Public

Health Emergencies relax Medicare payment rules allowing more services to be covered than usual. Another commenter stated that an ACO may experience expenditure increases because its assigned beneficiaries migrate to areas with higher FFS payment rates in search of health care services in the wake of a natural disaster. This commenter noted that ACOs based in Puerto Rico could be significantly affected given that after a natural disaster many beneficiaries migrate to the U.S. mainland where the FFS payment rates are substantially higher than on the island.

Several commenters shared the opinion that the proposed policy of adjusting shared losses adequately addresses the situation of ACOs that would have had shared losses in the absence of a natural disaster, but had higher shared losses as the result of the disaster. However, they expressed concern that the policy does not provide relief to ACOs that receive a smaller shared savings payment as a result of the disaster or ACOs for which an expenditure increase resulting from a disaster causes the ACO to fall short of its MSR (and thus miss out on shared savings entirely) or to exceed its MLR (and thus owe shared losses when it otherwise would not have had shared losses).

A few commenters recommended addressing this issue by modifying the update that is applied to an ACO's benchmark for a performance year that is affected by an extreme and uncontrollable circumstance. For example, these commenters recommended that CMS apply a growth rate that is the higher of the national growth rate for assignable beneficiaries or the regional growth rate for assignable beneficiaries (excluding an ACO's own assigned beneficiaries). They suggested that their recommendation should be used instead of the ''current policy'' for accounting for the impact of disasters on performance year expenditures, which they believed relies on the use of natural disaster payment modifiers. A few other commenters recommended that CMS use a blend of national and regional expenditure growth rates to update the benchmark as proposed in the August 2018 rule in ''normal times'' but use a purely regional growth rate in the event of an extreme and uncontrollable circumstance. The same commenters also suggested that CMS remove claims associated with disaster-affected beneficiaries during the relevant time periods or claims with a natural disaster payment modifier code, pending changes to improve these codes, when calculating performance or benchmark year expenditures. It was unclear, however, whether they meant for these claims adjustments to be made instead of or in addition to their recommended changes to the update factors applied to the historical benchmark.

Several commenters raised concerns about the existing natural disaster modifier codes and whether, in their current form, they could be used to try to capture the negative impact on an ACO's performance. They noted that some health care providers may not be aware of the existence of such codes and that the codes may not be used properly due to lack of training and competing priorities during an emergency event. They also noted that the existing codes do not capture instances of ''unsafe place of discharge'', which they believe is a common reason for lengths of stay to be increased during a disaster and recommended that CMS expand existing modifier codes or add a new code to cover this circumstance. A few commenters recommended providing proper education on the use of such codes, which would allow these codes to serve as a more accurate means for identifying the impacts of natural disasters. Another commenter recommended that CMS allow an additional 6 to 12 months for providers to submit such codes to be considered in expenditure calculations.

Response: We are finalizing our proposed approach to mitigate shared losses for ACOs affected by extreme and uncontrollable circumstances without modification in this final rule. We acknowledge commenters' concerns regarding the potential impact of extreme and uncontrollable circumstances on the financial performance of ACOs that do not owe shared losses and we appreciate the commenters' recommendations for how to mitigate these impacts. However, because we did not propose to make any adjustments under these circumstances, these recommendations are outside the scope of this rulemaking. We will continue to monitor the financial performance of ACOs affected by extreme and uncontrollable circumstances, and as we gain more experience will consider whether any changes to our policies for mitigating the effects of extreme and uncontrollable circumstances are warranted.

Furthermore, we note that although we considered the use of natural disaster payment modifiers in developing the original extreme and uncontrollable circumstances policy for performance year 2017, we did not adopt a policy that used such codes in the Shared Savings Program IFC, nor did we propose in the August 2018 proposed rule to use such codes to adjust benchmark or performance year expenditure calculations for performance year 2018 or subsequent years. We have examined the existing natural disaster payment modifiers (specifically the ''DR'' condition code used on institutional claims and the ''CR'' modifier code used on Part B institutional and non-institutional claims) in 2017 claims for ACO assigned beneficiaries. We found that these codes were not widely or consistently used and that there appears to be variation in their use among ACOs. For example, among 69 ACOs with 90 percent or more of assigned beneficiaries residing in a disaster affected area, we found that only 0.01 percent of institutional claims and only 0.0006 percent of non-institutional claims included such a code. Among this same group of ACOs, the total number of claims (institutional or non-institutional) containing one of these codes ranged from 0 to 155 with a mean of 14 and a median of 8. In a separate analysis, we found that claims completion rates were comparable in disaster-affected and non-affected years which suggests that the low levels of modifier usage are not necessarily due to delayed claim submission. Based on these analyses, as well as the comments offered in response to the August 2018 proposed rule, we also have concerns that these codes would not serve as a useful means for comprehensively identifying relevant claims.

As we described in the August 2018 proposed rule, and have recounted in this final rule, we have some concerns about removing claims for affected beneficiaries and time periods from benchmark year expenditure calculations. As we develop additional experience, we may revisit this policy and, if warranted, propose modifications to performance or benchmark year expenditure calculations for ACOs affected by extreme and uncontrollable circumstances through further notice and comment rulemaking.

We also note that, although the policies regarding extreme and uncontrollable circumstances we are finalizing in this final rule do not include an explicit adjustment to the shared savings payment of a disaster-affected ACO, our alternative methodology for quality scoring can indirectly increase an ACO's shared savings payment. In performance year 2017, 62 of 117 disaster-affected ACOs received the national mean quality score, as it was higher than the score the

ACO would have received in the absence of the policy.

After considering the comments received, we are finalizing our proposal to extend the policy for mitigating shared losses owed by ACOs affected by extreme and uncontrollable circumstances established for performance year 2017 to performance year 2018 and subsequent performance years. We are revising §§ 425.606(i) and 425.610(i) to indicate that we will reduce the amount of shared losses calculated for the performance year by an amount determined by multiplying (1) the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance; and (2) the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance. We are also finalizing our proposal, through a new provision at § 425.609(d), to adjust shared losses for ACOs with a 6-month performance year from January 1, 2019 through June 30, 2019. For ACOs in a 6-month performance year we will first determine shared losses for the ACO over the full calendar year, reduce the ACO's shared losses for the calendar year for extreme and uncontrollable circumstances, and then determine the portion of shared losses for the 6-month performance year.

(c) Determination of Historical Benchmarks for ACOs in Affected Areas

In the Shared Savings Program IFC, we sought comment on how to address the impact of extreme and uncontrollable circumstances on the expenditures for an ACO's assigned beneficiary population for purposes of determining the benchmark (82 FR 60917). As we explained in the Shared Savings Program IFC (82 FR 60913), the impact of disasters on an ACO's financial performance could be unpredictable as a result of changes in utilization and cost of services furnished to the Medicare beneficiaries it serves. In some cases, ACO participants might be unable to coordinate care because of migration of patient populations leaving the impacted areas. On the other hand, patient populations remaining in impacted areas might receive fewer services and have lower overall costs to the extent that healthcare providers are unable to reopen their offices because they lack power and water or have limited access to fuel for operating alternate power generators. Significant changes in costs incurred, whether increased or decreased, as a result of an extreme or uncontrollable circumstance may impact the benchmark determined for the ACO's subsequent agreement period in the Shared Savings Program, as performance years of the current agreement period become the historical benchmark years for the subsequent agreement period. An increase in expenditures for a particular calendar year would result in a higher benchmark value when the same calendar year is used to determine the ACO's historical benchmark, and in calculating adjustments to the rebased benchmark based on regional FFS expenditures. Likewise, a decrease in expenditures for a particular calendar year would result in a lower benchmark value when the same calendar year is used to determine the ACO's historical benchmark.

While considering options for adjusting ACOs' historical benchmarks to account for disasters occurring during a benchmark year, we considered the effect that the proposed regional factors, that are discussed in section II.D.3. of the August 2018 proposed rule (83 FR 41886 through 41891), might have on the historical benchmarks for ACOs located in a disaster area. After review, we explained that we believe that when regional factors are applied to an ACO's historical benchmark, the regional factors would inherently adjust for variations in expenditures from year to year, and thus would also adjust for regional variations in expenditures related to extreme and uncontrollable circumstances. For example, assume that an ACO experienced a reduction in beneficiary expenditures in performance year 2017 because a portion of its assigned beneficiaries resided in counties that were impacted by a disaster. Then, also assume expenditures returned to their previously higher level in 2018 and this ACO subsequently renewed its ACO participation agreement in 2020. In 2020, when the ACO's historical benchmark would be reset (rebased), the expenditures for 2017 (now a historical benchmark year) would be subject to a higher regional trend factor because expenditures increased back to the expected level in 2018, which would increase the 2017 benchmark year expenditures. Additionally, this ACO could also have its historical benchmark increased even further as a result of its performance compared to others in its region, as reflected in the regional adjustment to the ACO's historical benchmark. In contrast, consider an ACO that experienced an increase in beneficiary expenditures in performance year 2017 because a portion of its assigned beneficiaries resided in counties that were impacted by a disaster. Then, assume expenditures returned to their previously lower level in 2018 and this ACO renewed its ACO participation agreement in 2020. In 2020, when the ACO's historical benchmark would be reset, the expenditures for 2017 would be subject to a lower regional trend factor because expenditures decreased back to the expected level in 2018, which would decrease the 2017 benchmark year expenditures. Additionally, this ACO could also have its historical benchmark decreased further as a result of its performance compared to others in its region, as reflected in the regional adjustment to the ACO's historical benchmark.

Our expectation that the proposed regional factors that would be used to establish an ACO's historical benchmark would also adjust for variations in expenditures related to extreme and uncontrollable circumstances was supported by a preliminary analysis of data for areas that were affected by the disasters that occurred in performance year 2017. Our analysis of the data showed that, as a result of the disasters in these areas, expenditure trends for the performance year appeared below projections. For these areas, the expenditures began to increase after the disaster incident period ended, but expenditures were still below expectations for the year. Based on the expenditure trends beginning to return to expected levels after the disaster period, it would be reasonable to expect that expenditures would continue to increase to expected levels in 2018. This difference between the lower than expected levels of expenditures in 2017 and a return to expected expenditures in 2018, would result in a higher regional trend factor being applied to 2017 expenditures when they are used to determine an ACO's historical benchmark. Although our analysis for the proposed rule was performed using the proposed regional factors, we expect that our existing benchmarking methodology at § 425.603, which also incorporates regional factors in the determination of an ACO's historical benchmark for its second or subsequent agreement period beginning in 2017 or later years, would have a similar result.

In the August 2018 proposed rule (83 FR 41905), in considering whether it might be necessary to make an additional adjustment to ACOs' historical benchmarks to account for expenditure variations related to extreme and uncontrollable circumstances, we considered an approach where we would adjust the historical benchmark by reducing the weight of expenditures for beneficiaries who resided in a disaster area during a

disaster period and placing a correspondingly larger weight on expenditures for beneficiaries residing outside the disaster area during the disaster period. Such an approach would be expected to proportionally increase the historical benchmark for ACOs that experienced a decrease in expenditures, and conversely proportionally decrease the historical benchmark for ACOs that experienced an increase in expenditures for their assigned beneficiaries who were impacted by a disaster. Under this approach, for each of the historical benchmark years, we would identify each ACO's assigned beneficiaries who had resided in a disaster area during a disaster period. The portion of expenditures for these assigned beneficiaries that was impacted by the disaster would be removed from the applicable historical benchmark year(s). The removal of these expenditures from the historical benchmark year(s) would allow the historical benchmark calculations to include only expenditures that were not impacted by the disaster. We believe this methodology for calculating benchmark expenditures would adjust for expenditure increases or decreases that may occur as a result of impacts related to a disaster.

We noted that if we were to implement such an adjustment to the historical benchmark, we believed it would be appropriate to avoid making minor historical benchmark adjustments for an ACO that was not significantly affected by a disaster by establishing a minimum threshold for the percentage of an ACO's beneficiaries located in a disaster area. Based on data from 2017, quarter 3, over 80 percent of ACOs had less than 50 percent of their assigned beneficiaries residing in disaster counties, with over 75 percent having less than 10 percent of their assigned beneficiaries residing in disaster counties. Based on this data, we noted our belief that a minimum threshold of 50 percent of assigned beneficiaries residing in disaster counties could be an appropriate threshold for the adjustment to historical benchmarks because historical benchmarks are calculated based on the ACO's entire assigned beneficiary population in each benchmark year, rather than a sample as is used for quality reporting.

However, we were concerned that this methodology for calculating an adjustment might not be as accurate as the inherent adjustment that would result from applying regional factors when resetting the benchmark and may impact other expected expenditure variations occurring in the impacted areas. For example, if an additional disaster adjustment were to be applied, it might have unintended impacts when expenditure truncation is applied, it might inappropriately weight and not account for expected variations in expenditures between areas that were and were not impacted by the disaster, and it might compound effects that have already been offset by the regional adjustment. In addition, the expenditures, as adjusted, may not be representative of the ACO's actual performance and aggregate assigned beneficiary population during the benchmark period.

In summary, we noted our belief that the regional factors that we had proposed to apply as part of the methodology for determining an ACO's historical benchmark would reduce the expenditures in a historical benchmark year when they are greater than expected (relative to other historical benchmark years) as a result of a disaster and conversely increase expenditures in a historical benchmark year when they are below the expected amount. For these reasons, we believed that the proposal in section II.D.3. of the August 2018 proposed rule (83 FR 41887 through 41888) to apply regional factors when determining ACOs' historical benchmarks, starting with an ACO's first agreement period for agreement periods starting on July 1, 2019, and in subsequent years, would be sufficient to address any changes in expenditures during an ACO's historical benchmark years as a result of extreme and uncontrollable circumstances, and an additional adjustment, such as the method discussed previously in this section would not appear to be necessary. However, we noted that we would continue to evaluate the impact of the 2017 disasters on ACOs' assigned beneficiary expenditures, and that we intended to continue to consider whether it might be appropriate to make an additional adjustment to the historical benchmark to account for expenditures that may have increased or decreased in a historical benchmark year as a result of an extreme or uncontrollable circumstance.

We solicited comments on these issues, including whether it is necessary to adjust ACOs' historical benchmarks to account for extreme and uncontrollable circumstances that might occur during a benchmark year, and appropriate methods for making such benchmark adjustments. We also noted that the proposal in section II.D.3. of the August 2018 proposed rule to apply regional factors to determine ACOs' historical benchmarks would apply starting with an ACO's first agreement period for agreement periods starting on July 1, 2019, and in subsequent years and would therefore have no effect on benchmarks for ACOs in a first agreement period starting before July 1, 2019 (see 83 FR 41887). Accordingly, we solicited comments on whether and how an adjustment should be made for ACOs whose benchmarks do not reflect regional factors. We also invited comments on any additional areas where relief may be helpful or other ways to mitigate unexpected issues that may arise in the event of an extreme and uncontrollable circumstance.

Comment: A few commenters noted that expenditure increases in a performance year due to a natural disaster could lead to unjustly high benchmark year expenditures in an ACO's subsequent agreement period which could create vulnerabilities for the Trust Funds. As described in the prior section V.B.2.d.(2) of this final rule, we received a few comments recommending modifications to the update that is applied to an ACO's benchmark for a performance year that is affected by an extreme and uncontrollable circumstance. Another commenter suggested removing claims from benchmark and performance year expenditures that have a disaster modifier code or are associated with a beneficiary residing a disaster-affected area during an affected time period.

Response: As discussed in the prior section V.B.2.d.(2) of this final rule, we intend to further consider commenters' recommendations that we address the financial impacts of extreme and uncontrollable circumstances through the update that is applied to the historical benchmark and how this approach could mitigate potential negative impacts to ACOs or to the Medicare Trust Funds for the performance year in which a disaster occurs, performance years for which there was a disaster in one or more of the benchmark years, or cases where an ACO was affected by disasters in both the benchmark period and the performance year.

As described in the prior section V.B.2.d.(2) of this final rule, we have concerns about commenters' recommendation to exclude claims with a natural disaster modifier code, or claims associated with disaster affected beneficiaries and time periods from benchmark or performance year expenditures. As we develop additional experience, we may revisit this policy and, if warranted, propose modifications to our methodology for calculating performance year or benchmark year expenditures through further notice and comment rulemaking.

Comment: One commenter opposed using regional factors as currently calculated by CMS to address concerns about the effect of extreme and uncontrollable circumstances on ACOs' historical benchmarks. This commenter disagreed with CMS' current approach, which includes ACO assigned beneficiaries when calculating regional expenditures. They stated that ''[A]bsent a reform that addresses the underlying issue with the regional adjustment factor, applying it to ACOs in a region recovering from an extreme or uncontrollable circumstance will perpetuate the flaws.''

Response: We continue to believe that the use of regional factors in establishing and updating the benchmark will provide an inherent adjustment for regional variations in expenditures related to extreme and uncontrollable circumstances. As the commenter notes, and under the June 2016 final rule, regional expenditure calculations in the Shared Savings Program are based on all assignable beneficiaries in an ACO's regional service area including ACO assigned beneficiaries. We have detailed in that earlier rule our reasons for not excluding assigned beneficiaries from these calculations (see 81 FR 37960). Furthermore, we do not believe that inclusion of an ACO's assigned beneficiaries would reduce the effectiveness of regional factors to inherently adjust for regional variations in expenditures related to extreme and uncontrollable circumstances as we have no reason to believe that such an event would have a differential impact on expenditures for assigned beneficiaries relative to expenditures for assignable beneficiaries that are not assigned to an ACO.

After considering comments we received on the determination of historical benchmarks for ACOs in areas affected by extreme and uncontrollable circumstances, we are not making any changes to the benchmarking methodology to address such events at this time. We will continue to monitor the impact of extreme and uncontrollable circumstances on benchmark expenditures and, if applicable, the extent to which any impact is mitigated by the use of regional factors in establishing and updating the benchmark. If warranted, we will propose additional modifications to our benchmarking methodology to address the effects of extreme and uncontrollable circumstances through future notice and comment rulemaking.

e. Program Data and Quality Measures

In section II.E.5. of the August 2018 proposed rule (41906 through 41908), we solicited comments on possible changes to the quality measure set and modifications to program data shared with ACOs to support CMS' Meaningful Measures initiative and respond to the nation's opioid misuse epidemic. As part of the Meaningful Measures initiative, the agency's efforts are focused on updating quality measures, reducing regulatory burden, and promoting innovation (see CMS Press Release, CMS Administrator Verma Announces New Meaningful Measures Initiative and Addresses Regulatory Reform; Promotes Innovation at LAN Summit, October 30, 2017, available at *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-10-30.html*). Under the Meaningful Measures initiative, we are working towards assessing performance on only those core issues that are most vital to providing high-quality care and improving patient outcomes, with an emphasis on outcome-based measures, reducing unnecessary burden on providers, and putting patients first. When we developed the quality reporting requirements under the Shared Savings Program, we considered the quality reporting requirements under other initiatives, such as the Physician Quality Reporting System (PQRS) and Million Hearts Initiative, and consulted with the measures community to ensure that the specifications for the measures used under the Shared Savings Program are up-to-date and reduce reporting burden.

Since the Shared Savings Program was first established in 2012, we have not only updated the quality measure set to reduce reporting burden, but also to focus on more meaningful outcome-based measures. The most recent updates to the Shared Savings Program quality measure set were made in the CY 2017 PFS Final Rule (81 FR 80484 through 80489) to adopt the ACO measure recommendations made by the Core Quality Measures Collaborative, a multi-stakeholder group with the goal of aligning quality measures for reporting across public and private stakeholders in order to reduce provider reporting burden. Currently, more than half of the 31 Shared Savings Program quality measures are outcome-based, including—

- Patient-reported outcome measures collected through the CAHPS for ACOs Survey that strengthen patient and caregiver experience;
- Outcome measures supporting care coordination and effective communication, such as unplanned admission and readmission measures; and
- Intermediate outcome measures that address the effective treatment of chronic disease, such as hemoglobin A1c control for patients with diabetes and control of high blood pressure.

As we explained in the August 2018 proposed rule (83 FR 41906), it is important that the quality reporting requirements under the Shared Savings Program align with the reporting requirements under other Medicare initiatives and those used by other payers in order to minimize the need for Shared Savings Program participants to devote excessive resources to understanding differences in measure specifications or engaging in duplicative reporting. We sought comment, including recommendations and input on meaningful measures, on how we may be able to further advance the quality measure set for ACO reporting, consistent with the requirement under section 1899(b)(3)(C) of the Act that the Secretary seek to improve the quality of care furnished by ACOs by specifying higher standards, new measures, or both.

One particular area of focus by the Department of Health and Human Services is the opioid misuse epidemic. The Centers for Disease Control and Prevention (CDC) reports that the number of people experiencing chronic pain lasting more than 3 months is estimated to include 11 percent of the adult population. According to a 2016 CDC publication, 2 million Americans had opioid use disorder (OUD) associated with prescription opioids in 2014 (*https://www.cdc.gov/drugoverdose/prescribing/guideline.html*). Since the implementation of Medicare Part D in 2006 to cover prescription medications, the Medicare program has become the largest payer for prescription opioids in the United States (Zhou et al., 2016; *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4955937/*). Safe and effective opioid prescribing for older adults is of particular importance because misuse and abuse of opioids can lead to increased adverse events in this population (for example, increased falls, fractures, hospitalization, ER visits, mortality), especially given the high prevalence of polypharmacy in the elderly. Polypharmacy is the simultaneous use of multiple drugs by a single patient, for one or more conditions, which increases the risk of adverse events. For example, a study by MedPAC found that some beneficiaries

who use opioids fill more than 50 prescriptions among 10 drug classes annually (*http://www.medpac.gov/docs/default-source/reports/chapter-5-polypharmacy-and-opioid-use-among-medicare-part-d-enrollees-june-2015-report-.pdf?sfvrsn=0,* MedPAC, 2015).

As part of a multifaceted response to address the growing problem of overuse and abuse of opioids in the Part D program, CMS adopted a policy in 2013 requiring Medicare Part D plan sponsors to implement enhanced drug utilization review. Between 2011 through 2014, there was a 26 percent decrease or 7,500 fewer Medicare Part D beneficiaries identified as potential opioid over-utilizers which may be due, at least in part, to these new policies. On January 5, 2017, CMS released its Opioid Misuse Strategy. This document outlines CMS' strategy and the array of actions underway to address the national opioid misuse epidemic and is available at *https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy-2016.pdf.*

We aim to align our policies under the Shared Savings Program with the priorities identified in the Opioid Misuse Strategy and the Department of Health and Human Services Strategy to Combat Opioid Abuse, Misuse, and Overdose [36] and to help ACOs and their participating providers and suppliers in responding to and managing opioid use, and are therefore considering several actions to improve alignment. Specifically, as we described in the August 2018 proposed rule, we are considering what information regarding opioid use, including information developed using aggregate Medicare Part D data, could be shared with ACOs. We are also considering the addition of one or more measures specific to opioid use to the ACO quality measures set. The potential benefits of such policies would be to focus ACOs on the appropriate use of opioids for their assigned beneficiaries and support their opioid misuse prevention efforts.

First, we are considering what information, including what aggregated Medicare Part D data, could be useful to ACOs to combat opioid misuse in their assigned beneficiary population. We recognize the importance of available and emerging resources regarding the opioid epidemic at the federal, state, and local level, and intend to work with our federal partners to make relevant resources available in a timely manner to support ACOs' goals and activities. We will also continue to share information with ACOs highlighting Federal opioid initiatives, such as the CDC Guideline for Prescribing Opioids for Chronic Pain (*https://www.cdc.gov/drugoverdose/prescribing/guideline.html*), which reviews the CDC's recommended approach to opioid prescribing, and the Surgeon General's report on Substance Use and Addiction, Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health, (*https://addiction.surgeongeneral.gov/*) which focuses on educating and mobilizing prescribers to take action to end the opioid epidemic by improving prescribing practices, informing patients about the risks of and resources for opioid addiction, and encouraging health care professionals to take a pledge to end the opioid crisis. We also intend to continue to highlight information about the opioid crisis and innovations for opioid treatment and prevention strategies in ACO communications and webinars by including topics such as innovative uses of health IT for opioid use disorder treatment and specifically for electronic clinical decision support consistent with the CDC guidelines, as available.

Although we recognize that not all beneficiaries assigned to Shared Savings Program ACOs have Part D coverage, we believe a sufficient number do have Part D coverage to make aggregate Part D data regarding opioid use helpful for the ACOs. As an example, we have found the following information for performance year 2016:

- Approximately 70 percent of beneficiaries assigned to ACOs participating in the Shared Savings Program had continuous Part D coverage.
- For assigned beneficiaries with continuous Part D enrollment, almost 37 percent had at least one opioid prescription. This percentage ranged from 10.6 percent to 58.3 percent across ACOs.
- The mean number of opioid medications filled per assigned beneficiary (with continuous Part D coverage) varied across ACOs, ranging from 0.3 to 4.5 prescriptions filled, with an average of 2.1 prescriptions filled.
- The number of opioid prescriptions filled for each assigned beneficiary with at least one opioid prescription filled varied across ACOs and ranged from 2.6 to 8.4 prescriptions, with an average of 5.5 opioid prescriptions filled.

ACOs currently receive, as part of the monthly claims and claims line feed data, Part D prescription drug event (PDE) data on prescribed opioids for their assigned beneficiaries who have not opted out of data sharing. We encourage ACOs to use this beneficiary-level data in their care delivery practices.

In the August 2018 proposed rule (83 FR 41907), we sought suggestions for other types of aggregate data related to opioid use that could be added for informational purposes to the aggregate quarterly and annual reports CMS provides to ACOs. The aim would be for ACOs to utilize this additional information to improve population health management for assigned beneficiaries, including prevention, identifying anomalies, and coordinating care. The type of aggregate data should be highly relevant for a population-based program at the national level and have demonstrated value in quality improvement initiatives. We noted that we are particularly interested in high impact aggregate data that would reflect gaps in quality of care, patient safety, multiple aspects of care, and drivers of cost. We aim to provide aggregate data that have validity for longitudinal analysis to enable both ACOs and the Shared Savings Program to trend performance across time and monitor for changes. Aggregate data on both processes and outcomes are appropriate, provided that the data are readily available. Types of aggregate data that we have begun to consider, based on the information available from prescription drug event records for assigned beneficiaries enrolled in Medicare Part D, include filled prescriptions for opioids (percentage of the ACO's assigned beneficiaries with any opioid prescription, number of opioid prescriptions per opioid user), number of beneficiaries with a concurrent prescription of opioids and benzodiazepines; and number of beneficiaries with opioid prescriptions above a certain daily Morphine Equivalent Dosage threshold. We also sought comments on measures that could be added to the quality measure set for the purpose of addressing the opioid epidemic and addiction, more generally. We sought comment on measures related to various aspects of opioid use, such as prevention, pain management, or opioid use disorder treatment, and on measures related to addiction. In particular, we noted that we were considering the following relevant NQF-endorsed measures, with emphasis on Medicare beneficiaries with Part D coverage who are 18 years or older without cancer or enrolled in hospice:

- NQF #2940 Use of Opioids at High Dosage in Persons Without Cancer: Analyzes the proportion (XX out of 1,000) of Medicare Part D beneficiaries

[36] *https://www.hhs.gov/opioids/sites/default/files/2018-09/opioid-fivepoint-strategy-20180917-508compliant.pdf.*

18 years or older without cancer or enrolled in hospice receiving prescriptions for opioids with a daily dosage of morphine milligram equivalent (MME) greater than 120 mg for 90 consecutive days or longer.

- NQF #2950 Use of Opioids from Multiple Providers in Persons Without Cancer: Analyzes the proportion (XX out of 1,000) of Medicare Part D beneficiaries 18 years or older without cancer or enrolled in hospice receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies.
- NQF #2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer: Analyzes the proportion (XX out of 1,000) of Medicare Part D beneficiaries 18 years or older without cancer or enrolled in hospice with a daily dosage of morphine milligram equivalent (MME) greater than 120 mg for 90 consecutive days or longer, AND who received opioid prescriptions from four (4) or more prescribers AND four (4) or more pharmacies.

In addition, we sought input on potential measures for which data are readily available, such as measures that might be appropriately calculated using Part D data, and that capture performance on outcomes of appropriate opioid management. We requested that comments on measures that are not already NQF endorsed include descriptions of reliability, validity, benchmarking, the population in which the measure was tested, along with the data source that was used, and information on whether the measure is endorsed and by what organization. We recognized that measures of the various aspects of opioid use may involve concepts related to integrated, coordinated, and collaborative care, including as applicable for co-occurring and/or chronic conditions, as well as measures that reflect the impact of interventions on patient outcomes, including direct and indirect patient outcome measures. We also sought comment on opioid-related measures that would support effective measurement alignment of substance use disorders across programs, settings, and varying interventions.

Comment: A majority of commenters supported CMS' focus on burden reduction stating that they are encouraged by the administration's efforts to reduce reporting burden for healthcare providers. However, one commenter cautioned that although decreasing burden is a laudable goal, removing process measures could unfairly impact the quality scores of healthcare providers who care for vulnerable patients exposed to the harshest social determinants of health. Several commenters suggested that CMS strive toward a core measure set that identifies and harmonizes measures across multiple CMS programs, so that incentives and goals are aligned across healthcare providers and care settings.

Several commenters supported the agency's Meaningful Measures Initiative stating that CMS should not only consider whether a measure is a process measure, but also whether the measure is considered a low-value process measure, before removing it from the Shared Savings Program quality measure set. In addition, these commenters supported CMS' move toward the use of outcome measures, as the emphasis on improved health outcomes is an appropriate focus and goal.

Several commenters suggested future potential refinements to the Shared Savings Program measure set. One commenter urged CMS to better align the Shared Savings Program with Medicare Advantage, suggesting that there should be fewer measures that are included in a roadmap for implementation in both programs, because the different measures and the differing standards for compliance that are currently used cause confusion and require the use of limited provider and staff resources. In addition, this commenter stated that with a roadmap of measures, organizations would be able to focus their energies on achieving these metrics in a systematic and deliberate fashion.

Another commenter expressed concern with the timing and burden of quality measurement and payment, suggesting that we streamline quality efforts to include ten specific outcome measures that have a social and public health impact and offering a financial incentive in connection with each measure to encourage physicians to drive, fund, and sustain continued quality efforts.

A few commenters suggested that CMS should focus on the prevention, treatment, and management of behavioral health. They stated that in the absence of effective behavioral health assessment tools, the vast majority of people with mental health conditions go unidentified in primary care settings, which in most cases leads to non-adherent patients and higher total medical costs. In addition, they stated that behavioral health is central to the prevention, treatment, and management of the preventable manifestations of diseases and health conditions. They suggested that CMS consider including broader measures that would encourage behavioral health and medical providers to work collaboratively to provide coordinated care.

Several commenters suggested that CMS consider developing a quality measure set that would evaluate the breadth of chronic conditions common in the patient population assigned to Shared Savings Program ACOs and use appropriate outcome measures to ensure assigned beneficiaries are receiving the necessary care. They noted that the proposed Shared Savings Program quality measure set discussed in section III.F.1.c. of the CY 2019 PFS proposed rule (83 FR 35876 through 35878) does not include measures related to respiratory conditions, like chronic obstructive pulmonary disease or asthma, diabetes, or additional conditions like heart failure. They encouraged CMS to include measures that evaluate the quality of care for these conditions, such as, measures focused on the delivery of comprehensive lower extremity exams for diabetic patients, and rates of complications such as amputation. They stated that greater emphasis on management of chronic conditions is necessary to promote quality and improve patient outcomes. Another commenter suggested CMS should increase the number of claims-based measures in the Shared Savings Program measure set and provide ACOs with user-friendly, actionable reports that detail the ACO-specific data used to calculate specific measure performance. One commenter suggested that CMS consider quality measures that reinforce shared decision making, as part of treatment plans that align with the individual's goals as this is a foundational component of high-quality patient-centered care.

Response: We thank the commenters for their thoughtful input on the quality measures used to assess the performance of ACOs under the Shared Savings Program. As we plan for future updates and changes to the Shared Savings Program quality measure set, we will consider this feedback in the development of our proposals.

Comment: The majority of commenters that addressed the potential inclusion of measures related to opioid use in the Shared Savings Program quality measure set were supportive of this effort. A few commenters noted that continued support and recognition for integration of EHRs and electronic sharing of health information, would promote improved communication between healthcare providers, which may help curb opioid abuse and addiction.

Several commenters supported CMS' efforts to consider the possible addition of opioid use measures to the Shared Savings Program quality measure set in future program years, but some commenters recommended that CMS work with the measure developer and NQF to reduce the dosage threshold of two of the measures discussed in the August 2018 proposed rule to 90 MME per day to align with the CDC guidelines for Prescribing Opioids for Chronic Pain. Another commenter agreed that promoting the measurement of opioid use and overuse, monitoring, and education through quality reporting is an important step in understanding and addressing the opioid crisis. A few commenters recommended that CMS utilize the Prescription Drug Monitoring Program (PDMP) Query measure, as most states have implemented PDMPs, and the PDMP Query measure is a reasonable step to improve and measure quality in opioid prescribing.

Another commenter stated that in general they support CMS' considering the addition of opioid use measures to the Shared Savings Program measure set; however, they expressed their belief that opioid dosage measures are of low-value to the program because, ''. . . since the issuance of Centers for Disease Control (CDC) and Prevention guidelines, there have been many reports of patients who have been successfully managed on opioid analgesics for long periods of time.'' This commenter noted that implementing a quality measure that could force a health provider to abruptly reduce or discontinue this medication regimen could have extreme adverse outcomes such as depression, loss of function, or even suicide. The commenter suggested CMS consider quality measures other than dosage measures when determining the most appropriate metrics to help address and respond to the opioid crisis.

One commenter expressed concern with the specific opioid related measures on which CMS sought comment for potential inclusion in the Shared Savings Program quality measure set. The commenter stated that quality measurement needs to focus on utilization of preventive strategies, such as screening and treatment for substance abuse, as well as pain management. This commenter disagreed with the potential inclusion of *NQF #2940: Use of Opioids at Higher Dosage in Persons Without Cancer* because a measure that focuses only on daily dose and duration of therapy involving prescription opioid analgesics, on its own is not a good indication of quality patient care. In addition, they expressed concerns with the potential inclusion of *NQF #2950: Use of Opioids from Multiple Providers in Persons Without Cancer* and *NQF #2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer* in the Shared Savings Program measure set, as these measures were developed with the intention of determining the quality of care provided by prescription drug health plans and because of the lack of information on the feasibility of ACOs' collecting and reporting pharmacy claims data.

Another commenter noted that the three opioid measures CMS suggested for inclusion in the Shared Savings Program measure set are appropriately focused on the right patient population and address the major risks associated with opioid misuse—high dosages and multiple prescriptions. However, the commenter urged CMS to conduct testing to ensure the measures provide accurate, reliable data at the ACO level, as they are currently endorsed at the health plan level not the ACO level. The commenter suggested that the measures should be reported on a voluntary or pay-for-reporting basis rather than as pay-for-performance measures for the first few years after they are added to the measure set.

Another commenter expressed concern that including measures that are so specific will distract ACOs from focusing on what works for them and their assigned beneficiary population. As an alternative, the commenter suggested CMS provide webinars, education, tools, and data for ACOs to incorporate into their current structure for care management and patient engagement. Several commenters recommended that CMS provide aggregated data to ACOs on opioid use, but they also urged CMS to go further and provide aggregated beneficiary data on the use of all prescribed medications and their related diagnoses. Similarly, another commenter encouraged CMS to continue to add more real-time data to the quarterly quality reports so providers can leverage this data to improve patient care, address social inequities in health, correct inefficiencies to drive down costs, and help to address the nation's opioid epidemic and other pressing health crises.

Response: We thank the commenters for their thoughtful input on the possible addition of measures related to opioid use to the quality measure set for the Shared Savings Program. As we plan for future updates and changes to the Shared Savings Program quality measure set, we will consider this feedback from commenters before making any proposals with respect to the addition of opioid use measures.

f. Promoting Interoperability

Consistent with the call in the 21st Century Cures Act for interoperable access, exchange, and use of health information, the final rule entitled, 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications (2015 Edition final rule) (80 FR 62601) under 45 CFR part 170 [37] focused on health IT certification criteria that support patient care, patient participation in care delivery, and electronic exchange of interoperable health information. The 2015 Edition final rule, which was issued on October 16, 2015, aimed to improve interoperability by adopting new and updated vocabulary and content standards for the structured recording and exchange of health information and to facilitate the accessibility and exchange of data by including enhanced data export, transitions of care, and application programming interface capabilities. These policies are relevant to assessing the use of CEHRT under the Quality Payment Program, Shared Savings Program, and other value based payment initiatives.

Under the Shared Savings Program, section 1899(b)(2)(G) of the Act requires participating ACOs to define processes to report on quality measures and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies. Consistent with the statute, ACOs participating in the Shared Savings Program are required to coordinate care across and among primary care physicians, specialists, and acute and post-acute providers and suppliers and to have a written plan to encourage and promote the use of enabling technologies for improving care coordination, including the use of electronic health records and electronic exchange of health information (§ 425.112(b)(4)). Additionally, since the inception of the program in 2012, CMS has assessed the level of CEHRT use by certain clinicians in the ACO using a double-weighted quality measure (Use of Certified EHR Technology, ACO–11) as part of the quality reporting requirements for each performance year. Based on previously-finalized policies, for the 2018 performance year, we will use data derived from the Quality

[37] For more information, see *https://www.healthit.gov/sites/default/files/understanding-certified-health-it-2.pdf.*

Payment Program's Promoting Interoperability performance category to calculate the percentage of eligible clinicians participating in an ACO who successfully meet the Advancing Care Information Performance Category Base Score for purposes of ACO–11. Because the measure is used in determining an ACO's quality score and for determining shared savings or shared losses under the Shared Savings Program, all eligible clinicians participating in Shared Savings Program ACOs must submit data for the Quality Payment Program's Advancing Care Information performance category for performance year 2018, including those eligible clinicians who are participating in Shared Savings Program tracks that have been designated as Advanced APMs and who have met the QP threshold or are otherwise not subject to the MIPS reporting requirements.

In the August 2018 proposed rule (83 FR 41908), we noted that some alternative payment models tested by the Innovation Center, require all participants to use CEHRT even though certain tracks within those Models do not meet the financial risk standard for designation as Advanced APMs. The primary rationale for this requirement is to promote CEHRT use by eligible clinicians and organizations participating in APMs by requiring them to demonstrate a strong commitment to the exchange of health information, regardless of whether they are participating in an APM that meets the criteria to be designated as an Advanced APM. Under the Quality Payment Program, an incentive payment will be made to certain Qualifying APM Participants (QPs) participating in Advanced APMs. Beginning in 2017, an eligible clinician can become a QP for the year by participating sufficiently in an Advanced APM during the QP performance period. Eligible clinicians who are QPs for a year receive a lump sum APM incentive payment for payment years from 2019 through 2024, and are excluded from the MIPS reporting requirements for the performance year and the MIPS payment adjustment for the payment year. In the CY 2017 Quality Payment Program final rule (81 FR 77408), we finalized the criteria that define an Advanced APM based on the requirements set forth in sections 1833(z)(3)(C) and (D) of the Act. An Advanced APM is an APM that, among other criteria, requires its participants to use CEHRT. In the CY 2017 Quality Payment Program final rule, we established that Advanced APMs meet this requirement if the APM either—(1) requires at least 50 percent of eligible clinicians in each participating APM Entity, or for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or other health care providers; or (2) for the Shared Savings Program, applies a penalty or reward to an APM Entity based on the degree of the use of CEHRT of the eligible clinicians in the APM Entity (§ 414.1415(a)(1)(i) and (ii)). In the CY 2017 PFS final rule, we updated the title and specifications of the EHR quality measure (ACO–11) to align with the Quality Payment Program criterion on CEHRT use in order to ensure that certain tracks under the Shared Savings Program could meet the criteria to be Advanced APMs. Specifically, we revised the ACO–11 measure to assess ACOs on the degree of CEHRT use by all eligible clinicians participating in the ACO. Performance on the measure is determined by calculating the percentage of eligible clinicians participating in the ACO who successfully meet the Promoting Interoperability Performance Category Base Score.

In light of our additional experience with the Shared Savings Program, our desire to continue to promote and encourage CEHRT use by ACOs and their ACO participants and ACO providers/suppliers, and our desire to better align with the goals of the Quality Payment Program and the criteria for participation in certain alternative payment models tested by the Innovation Center, in the August 2018 proposed rule, we indicated that we believe it would be appropriate to amend our regulations related to CEHRT use and the eligibility requirements for ACOs to participate in the Shared Savings Program. Specifically, we proposed to add a requirement that all ACOs demonstrate a specified level of CEHRT use in order to be eligible to participate in the Shared Savings Program. Additionally, we proposed that, as a condition of participation in a track, or a payment model within a track, that meets the financial risk standard to be an Advanced APM, ACOs must certify that the percentage of eligible clinicians participating in the ACO who use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold required for Advanced APMs as defined under the Quality Payment Program (§ 414.1415(a)(1)(i)). In conjunction with this proposed new eligibility requirement, we proposed to retire the EHR quality measure (ACO–11) related to CEHRT use, thereby reducing reporting burden, effective for quality reporting for performance years starting on January 1, 2019, and subsequent performance years. In addition, consistent with our proposal to align with the Advanced APM criterion on use of CEHRT, we proposed to apply the definition of CEHRT under the Quality Payment Program (§ 414.1305), including any subsequent updates to this definition, for purposes of the Shared Savings Program by adding a definition of ''CEHRT'' to § 425.20.

First, we proposed that for performance years starting on January 1, 2019, and subsequent performance years, ACOs in a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM would have to attest and certify upon application to participate in the Shared Savings Program, and subsequently, as part of the annual certification process, that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT to document and communicate clinical care to their patients or other health care providers. ACOs would be required to submit this certification in the form and manner specified by CMS.

We stated that our proposed requirement aligned with the requirements regarding CEHRT use in many alternative payment models being tested by the Innovation Center. Additionally, we noted that at the time of application, ACOs must have a written plan to use enabling technologies, such as electronic health records and other health IT tools, to coordinate care (§ 425.112(b)(4)(i)(C)). Over the years, successful ACOs have impressed upon us the importance of ''hitting the ground running'' on the first day of their participation in the Shared Savings Program, rather than spending the first year or two developing their care processes. We stated our belief that requiring ACOs that are entering a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM to certify that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT would align with existing requirements under the Shared Saving Program and many Innovation Center alternative payment models and encourage participation by organizations that are more likely to meet the program goals. In addition, we stated that such a requirement would also promote greater emphasis on the importance of CEHRT use for care coordination. Finally, we noted that in the CY 2019 PFS proposed rule, we had proposed to increase the threshold of

CEHRT use required for APMs to meet criteria for designation as Advanced APMs under the Quality Payment Program to 75 percent (see 83 FR 35990). Given our proposed updates and modifications to the Shared Savings Program tracks in the August 2018 proposed rule, as well as the proposed changes to the requirements regarding CEHRT use under the Quality Payment Program, we explained that we believe it is important that only those ACOs that are likely to be able to meet or exceed the threshold designated for Advanced APMs should be eligible to enter and continue their participation in the Shared Savings Program. Because of this, and also our desire to align requirements across the different payment models and tracks in Shared Savings Program, as explained in more detail later in this section, we also considered whether to propose to require all Shared Savings Program ACOs, including ACOs in tracks or payment models within tracks that would not meet the financial criteria to be designated as Advanced APMs, to meet the 75 percent threshold proposed under the Quality Payment Program.

We proposed changes to the regulations at § 425.204(c) (to establish the new application requirement) and § 425.302(a)(3)(iii) (to establish the new annual certification requirement). We also proposed to add a new provision at § 425.506(f)(1) to indicate that for performance years starting on January 1, 2019, and subsequent performance years, all ACOs in a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM must certify that at least 50 percent of their eligible clinicians use CEHRT to document and communicate clinical care to their patients or other health care providers. We noted that this proposal, if finalized, would not affect the previously-finalized requirements for MIPS eligible clinicians reporting on the Promoting Interoperability (PI) performance category under MIPS. In other words, MIPS eligible clinicians who are participating in ACOs would continue to report as usual on the Promoting Interoperability performance category. We welcomed comment on these proposed changes. We also sought comment on whether the percentage of CEHRT use should be set at a level higher than 50 percent for ACOs in a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM given that average ACO performance on the Use of Certified EHR Technology measure (ACO–11) has substantially exceeded 50 percent, with ACOs reporting that on average roughly 80 percent of primary care physicians in their ACOs meet meaningful use requirements,[38] suggesting that a higher threshold may be warranted now or in the future. We noted that a higher threshold percentage (such as 75 percent) would align with the proposed changes to the CEHRT use requirement under the Quality Payment Program that were included in the CY 2019 PFS proposed rule.

Further, for ACOs in tracks or models that meet the financial risk standard to be Advanced APMs under the Quality Payment Program, we proposed to align the proposed CEHRT use threshold with the criterion on use of CEHRT established for Advanced APMs under the Quality Payment Program. We noted that, although it would be ideal for all ACOs to meet the same CEHRT thresholds to be eligible for participation in the Shared Savings Program, there may be reasons why it may be desirable for ACOs in tracks or payment models within a track that do not meet the financial risk standard for Advanced APMs to have a different threshold requirement for CEHRT use than more sophisticated ACOs that are participating in tracks or payment models that qualify as Advanced APMs under the Quality Payment Program. For example, we noted that in order for an APM to meet the criteria to be an Advanced APM under the Quality Payment Program, it must currently require at least 50 percent of eligible clinicians in each participating APM entity to use CEHRT to document and communicate clinical care to their patients or other health care providers (in addition to certain other criteria). However, as previously noted, in the CY 2019 PFS proposed rule, we proposed to increase this threshold level under the Quality Payment Program to 75 percent of eligible clinicians in each participating Advanced APM entity. Therefore, for performance years starting on January 1, 2019, and subsequent performance years for Shared Savings Program tracks (or payment models within tracks) that meet the financial risk standard to be an Advanced APM, we proposed to align the CEHRT requirement with the Quality Payment Program Advanced APM CEHRT use criterion at § 414.1415(a)(1)(i). Specifically, we proposed that such ACOs would be required to certify that they meet the higher of the 50 percent threshold proposed for ACOs in a track (or a payment model within a track) that does not meet the financial risk standard to be an Advanced APM or the CEHRT use criterion for Advanced APMs under the Quality Payment Program at § 414.1415(a)(1)(i). We stated that requiring these ACOs to meet the higher of the 50 percent threshold proposed for ACOs in a track (or a payment model within a track) that does not meet the financial risk standard to be an Advanced APM or the CEHRT use criterion for Advanced APMs would ensure alignment of eligibility requirements across all Shared Savings Program ACOs, while also ensuring that if the CEHRT use criterion for Advanced APMs were higher than 50 percent, those Shared Savings Program tracks (or payment models within a track) that meet the financial risk standard to be an Advanced APM would also meet the CEHRT threshold established under the Quality Payment Program. We anticipated that for performance years starting on January 1, 2019, the tracks (or payment models within tracks) that would be required to meet the CEHRT threshold designated at § 414.1415(a)(1)(i) would include Track 2, Track 3, and the Track 1+ Model, and for performance years starting on July 1, 2019, would include the proposed BASIC track, Level E, and the proposed ENHANCED track. ACOs in these tracks (or a payment model within such a track) would be required to attest and certify that the percentage of the eligible clinicians in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the level of CEHRT use specified under the Quality Payment Program regulation at § 414.1415(a)(1)(i). We noted that although this proposal might cause Shared Savings Program ACOs in different tracks (or different payment models within the same track) to be held to different requirements regarding CEHRT use, we believed it would be appropriate to ensure not only that ACOs that are still new to participation in the Shared Savings Program would not be excluded from the program due to a requirement that a high percentage of eligible clinicians participating in the ACO use CEHRT, but also that eligible clinicians in ACOs further along the risk continuum would have the opportunity to participate in an Advanced APM for purposes of the Quality Payment Program.

We proposed to add a new provision to the regulations at § 425.506(f)(2) to

[38] This estimate is based on calculations of primary care physician CEHRT use prior to the changes made to ACO–11 to align with the Quality Payment Program, which became effective for quality reporting for performance year 2017.

establish the CEHRT requirement for performance years starting on January 1, 2019, and subsequent performance years for ACOs in a track or a payment model within a track that meets the financial risk standard to be an Advanced APM under the Quality Payment Program. These ACOs would be required to certify that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the higher of 50 percent or the threshold for CEHRT use by Advanced APMs at § 414.1415(a)(1)(i). We sought comment on this proposal. We also sought comment on whether we should apply the same standard regarding CEHRT use across all Shared Savings Program ACOs, including ACOs participating in tracks or payment models within tracks that do not meet the financial risk standard to be designated as Advanced APMs, specifically Track 1 and the proposed BASIC track, Levels A through D, or maintain the proposed 50 percent requirement for these ACOs as they gain experience on the glide path to performance-based risk.

We stated that, as a part of these proposals to require ACOs to certify that a specified percentage of their eligible clinicians use CEHRT, CMS would reserve the right to monitor, assess, and/or audit an ACO's compliance with respect to its certification of CEHRT use among its participating eligible clinicians, consistent with §§ 425.314 and 425.316, and to take compliance actions (including warning letters, corrective action plans, and termination) as set forth at §§ 425.216 and 425.218 when ACOs fail to meet or exceed the required CEHRT use thresholds. Additionally, we proposed to adopt for purposes of the Shared Savings Program the same definition of ''CEHRT'' as is used under the Quality Payment Program. We proposed to amend § 425.20 to incorporate a definition of CEHRT consistent with the definition at § 414.1305, including any subsequent updates or revisions to that definition. Consistent with this proposal and to ensure alignment with the requirements regarding CEHRT use under the Quality Payment Program, we also proposed to amend § 425.20 to incorporate the definition of ''eligible clinician'' at § 414.1305 that applies under the Quality Payment Program.

Additionally, we stated that if the proposal to introduce a specified threshold of CEHRT use as an eligibility requirement for participation in the Shared Savings Program is finalized, we believed this new requirement should replace the current ACO quality measure that assesses the Use of Certified EHR Technology (ACO–11). We explained that the proposed new eligibility requirement, which would be assessed through the application process and annual certification, would help to meet the goals of the program and align with the approach used in other MIPS APMs. Moreover, the proposed new requirement would render reporting on the Use of Certified EHR Technology quality measure unnecessary in order for otherwise eligible tracks (and payment models within tracks) to meet the Advanced APM criterion regarding required use of CEHRT under § 414.1415(a)(1)(i). As a result, continuing to require ACOs to report on this measure would impose undue reporting burden on eligible clinicians that meet the QP threshold and would otherwise not be required to report the Promoting Interoperability performance category for purposes of the Quality Payment Program. Therefore, we proposed to remove the Use of Certified EHR Technology measure (ACO–11) from the Shared Savings Program quality measure set, effective with quality reporting for performance years starting on January 1, 2019, and subsequent performance years. We proposed corresponding changes to the regulation at § 425.506. We also reiterated that the removal of the Use of Certified EHR Technology measure (ACO–11) from the quality measure set used under the Shared Savings Program, if finalized, would not affect policies under MIPS for reporting on the Promoting Interoperability performance category and scoring under the APM Scoring Standard for MIPS eligible clinicians in MIPS APMs. In other words, eligible clinicians subject to MIPS (such as eligible clinicians in the proposed BASIC track, Levels A through D, Track 1, and other MIPS eligible clinicians who are required to report on the Promoting Interoperability performance category for purposes of the Quality Payment Program) would continue to report as usual on the Promoting Interoperability performance category. However, data reported for purposes of the Promoting Interoperability performance category under MIPS would not be used to assess the ACO's quality performance under the Shared Savings Program. We welcomed public comment on the proposal to remove the quality measure on Use of Certified EHR Technology (ACO–11) from the Medicare Shared Savings Program measure set, effective for quality reporting for performance years starting on January 1, 2019, and subsequent performance years.

Finally, as discussed previously in this section, in the CY 2017 Quality Payment Program final rule, CMS finalized a separate Advanced APM CEHRT use criterion that applies for the Shared Savings Program at § 414.1415(a)(1)(ii). To meet the Advanced APM CEHRT use criterion under the Shared Savings Program, a penalty or reward must be applied to an APM Entity based upon the degree of CEHRT use among its eligible clinicians. We believed that this alternative criterion was appropriate to assess the Advanced APM CEHRT use requirement under the Shared Savings Program because, at the time, a specific level of CEHRT use was not required for participation in the program (81 FR 77412).

As we explained in the August 2018 proposed rule (83 FR 41911), our proposal to impose specific CEHRT use requirements on ACOs participating in the Shared Savings Program would eliminate the need for the separate CEHRT use criterion applicable to the Shared Savings Program APMs found at § 414.1415(a)(1)(ii). We noted that if the proposal to incorporate specific requirements regarding the use of CEHRT by Shared Savings Program ACOs were finalized, ACOs seeking to participate in a Shared Savings Program track (or payment model within a track) that meets the financial risk standard to be an Advanced APM would be required to demonstrate that the percentage of eligible clinicians in the ACO using CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the higher of 50 percent or the percentage specified in the CEHRT use criterion for Advanced APMs at § 414.1415(a)(1)(i). As a result, a separate CEHRT use criterion for APMs under the Shared Savings Program would no longer be necessary.

Therefore, we proposed to revise the separate Shared Savings Program CEHRT use criterion at § 414.1415(a)(1)(ii) so that it would apply only for QP Performance Periods under the Quality Payment Program prior to 2019. We sought comment on this proposal.

Comment: Several commenters supported the continued recognition for integration of Electronic Medical Records (EMRs) and the sharing of health information between providers and suppliers.

Response: We thank the commenters for their support.

Comment: A majority of commenters supported our proposal to replace ACO–

11—Use of Certified EHR Technology with a requirement that ACOs certify regarding the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers. In addition, many commenters urged CMS to clarify that MIPS eligible clinician participating in Shared Savings Program ACOs would not be required to report Promoting Interoperability (PI) and would instead see PI performance category weights redistributed equally to the Quality and Improvement Activities performance categories.

Response: As noted in the August 2018 proposed rule (83 FR 41909), the proposal to replace ACO–11: Use of Certified EHR Technology with a requirement that ACOs certify regarding the level of CEHRT use by eligible clinicians in the ACO would not affect any previously finalized requirements for MIPS eligible clinicians reporting on the PI performance category under MIPS. MIPS eligible clinicians who are participating in ACO tracks that are not Advanced APMs and/or who are not QPs would continue to report as usual on the PI performance category.

Comment: Several commenters asked CMS to clarify the proposals for Promoting Interoperability in the August 2018 proposed rule, in the final rule. Specifically, the commenters requested clarification on when complete implementation of the 2015 CEHRT edition was required for ACOs participating in the Shared Savings Program, as the proposal discussed in the August 2018 proposed rule would require an ACO to attest to the percentage of eligible clinicians utilizing CEHRT at the time of application and annually thereafter. The commenters stated that a requirement that they attest to meeting the CEHRT use threshold at the time of application would negatively impact ACOs whose participants make CEHRT decisions (such as upgrades) based on a minimum consecutive 90-day reporting period as set forth by the Quality Payment Program The commenters stated that clarification of the deadline for implementation was needed so healthcare organizations could have a clear understanding of the expectations, allowing them to plan accordingly, especially for those organizations that participate in more than one regulatory program. In addition, several commenters requested that CMS clarify its operational expectations with respect to the proposed new certification requirement, so that ACOs can confirm that they are able to confidently certify with respect to the level of CEHRT use in their ACO.

Response: We understand that ACOs need to know the deadline by which they must meet the proposed new requirements regarding the use of CEHRT and have an understanding of how they would be required to demonstrate that they have met the requirement. As we explained in the August 2018 proposed rule, we believe it is appropriate to ensure that ACOs new to participation in the Shared Savings Program not be excluded from the program due to a requirement that a high percentage of eligible clinicians participating in the ACO use CEHRT. At the same time, however, we also sought to align with the CEHRT use requirements under the Quality Payment Program to ensure that eligible clinicians in ACOs further along the risk continuum would have the opportunity to participate in an Advanced APM for purposes of the Quality Payment Program. While our proposal was intended to require that ACOs achieve the applicable CEHRT use threshold starting in the 2019 performance year, we understand from commenters that the requirement that ACOs certify that the percentage of eligible clinicians in the ACO that use CEHRT meets the applicable threshold at time of application could pose an operational challenge. For example, a commenter stated that, ACOs not yet operating on 2015 edition CEHRT may have implementation and cost barriers related to the upgrade of CEHRT that may place them in a non-complaint situation, given the short timeframe between the publication of the final rule and the start of performance year 2019.

Based on the comments received in response to the proposals in the August 2018 proposed rule and our desire to align with the Quality Payment Program, under which eligible clinicians must certify regarding their CEHRT use by the last day of the reporting period, we are not finalizing our proposal to require ACOs to certify at the time of application that they meet the applicable CEHRT requirements. However, we are finalizing our proposal to require ACOs to certify annually that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage during the current performance year. ACOs will be required to submit this certification in the form and manner specified by CMS for performance years starting on January 1, 2019, and all subsequent performance years. For performance years starting on January 1, 2019, the annual certification will occur in the spring of 2019 for ACOs extending their participation agreement for 6 months, and in the fall of 2019 for ACOs that have a 12-month performance year during 2019. We believe this final policy is not only responsive to commenters' concerns regarding the timing of the certification but also enables timely implementation of the requirement starting in 2019. As noted above, a majority of commenters supported our proposal to replace ACO–11—Use of Certified EHR Technology with a requirement that ACOs certify regarding the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers starting January 1, 2019. We also note that this new requirement aligns more closely with the requirements regarding CEHRT use imposed under the Next Generation ACO Model, which requires that participating ACOs certify compliance with the CEHRT use requirement in the fall of each performance year. As stated in the August 2018 proposed rule, we currently require that ACOs must have in place at the time of application a written plan to use enabling technologies, such as electronic health records and other health IT tools, to coordinate care (§ 425.112(b)(4)(i)(C)). Because this policy is already in place, we believe that our decision not to finalize the proposal to require ACOs to certify with respect to their use of CEHRT at time of application to the Shared Savings Program will not undermine the policies under the program designated to promote and encourage the use of CEHRT.

Although the comments requesting clarification of our CEHRT proposals were not specific regarding the Shared Savings Program track for which they were seeking clarification, in this final rule we are clarifying the CEHRT threshold requirement for ACOs participating in an Advanced APM. Our intent at the time we proposed this policy was to preserve a minimum threshold of 50 percent CEHRT use for all ACOs in the Shared Savings Program, even if the requirement at § 414.1415(a)(1)(i) were revised through future rulemaking to be below 50 percent. However, we now recognize that this proposed ''higher of'' policy generated undue complexity. In the unlikely event that the requirement for CEHRT use at § 414.1415(a)(1)(i) were to be reduced to below 50 percent in the future, we would have the opportunity

to revisit the Shared Savings Program threshold through future rulemaking. Accordingly, we are revising the proposed regulation at § 425.506(f)(2) to remove the reference to the 50 percent threshold and to indicate that ACOs participating in a Shared Savings Program track that meets the financial risk standard to be an Advanced APM, would be required to demonstrate that the percentage of eligible clinicians in the ACO using CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the percentage specified in the CEHRT use criterion for Advanced APMs under § 414.1415(a)(1)(i).

Comment: Several commenters suggested modifications to CMS' proposal to require ACOs to certify that the percentage of eligible clinicians in the ACO using CEHRT meets the applicable threshold. Several commenters suggested that CMS delay the implementation of the certification requirement attestation until performance year 2020 to avoid inadvertently penalizing Track 1 ACOs that may not have sufficient time to meet the new CEHRT requirement. Several other commenters expressed concern that meeting the 50 percent CEHRT threshold would be a hardship for ACOs in Track 1, especially ACOs composed of independent physician practices and rural practices. These commenters recommended that CMS not finalize this this new requirement, but if CMS were to finalize the 50 percent threshold, these commenters believed that CMS should extend exemptions to low-revenue ACOs or those ACOs in which the plurality of eligible clinicians qualify for a hardship exemption from the Promoting Interoperability performance category under the MIPS. Another commenter suggested that CMS require ACOs in a track (or payment model within a track) that meets the financial risk standard to be an Advanced APM to meet the 50 percent CEHRT requirement in the first performance year and then increase to 75 percent in the second performance year.

Response: We disagree with the suggestions that we delay implementation of the proposed new CEHRT use requirement or impose differential requirements for ACOs, depending on their performance year or other attributes. Since the inception of the Shared Savings Program in 2012, we have assessed the level of CEHRT use by certain clinicians in ACOs (ACO–11: Use of Certified EHR Technology) as part of the quality reporting requirements for each performance year. In the CY 2017 PFS final rule, we revised the ACO–11 measure to assess ACOs on the degree of CEHRT use by eligible clinicians participating in the ACO in order to align with the Quality Payment Program. Starting in 2017, performance on this measure has been determined by calculating the percentage of eligible clinicians participating in the ACO who successfully meet the Promoting Interoperability Category Base Score. We believe that this experience offers a foundation on which ACOs can build and create processes that allow them to determine the percentage of eligible clinicians participating in the ACO that use CEHRT during an applicable performance year. As noted in the August 2018 proposed rule (83 FR 41909 through 41910), average ACO performance on ACO–11: Use of Certified EHR Technology has substantially exceeded 50 percent, with ACOs reporting that on average roughly 80 percent of primary care physicians in their ACOs meet meaningful use requirements.[39] As a result, we do not believe it is unreasonable to expect Track 1 ACOs to meet the requirement that 50 percent or more of the eligible clinicians participating in the ACO use CEHRT beginning in the performance year starting on January 1, 2019. Furthermore, as noted above, our proposal to require ACOs to certify that they meet the applicable CEHRT threshold has no impact on the previously-finalized policy that MIPS eligible clinicians participating in ACOs will continue to report on the PI performance category. Under this policy, MIPS-eligible clinicians are required to use the 2015 version of CEHRT for purposes of reporting the promoting interoperability performance category (§ 414.1305). Accordingly, we believe our proposal to require this version to be used by eligible clinicians participating in Shared Savings Program ACOs aligns with existing requirements under the MIPS and does not impose a new requirement on ACOs. Further, we believe our decision not to finalize the requirement that ACOs certify with respect their level of CEHRT use as part of the application process, and to implement the requirement solely through the annual certification during the performance year, will allow additional time for ACOs to update any internal processes as needed in order to meet this requirement during the performance year starting on January 1, 2019. In addition, as noted above, over the years successful ACOs have provided feedback that it is important to ''hit the ground running'' on their first day of participation in the Shared Savings Program, rather than spending several years developing their care processes. Based on this feedback, as well as commenters who supported the CEHRT proposal, we believe it is important to implement the proposed CEHRT use thresholds starting January 1, 2019. We believe that the use of these thresholds to assess CEHRT use by ACOs participating in the Shared Savings Program aligns with existing requirements under the program and encourages participation by organizations that are more likely to meet the program goals.

We received no comments on our proposals to change the regulation at § 425.204(c) to establish the new application requirement and the regulation at § 425.302(a)(3)(iii) to establish the new annual certification requirement. We also received no comments on our proposal to amend § 425.20 to incorporate a definition of ''CEHRT'' consistent with the definition at § 414.1305, including any subsequent updates or revisions to that definition, and to incorporate the definition of ''eligible clinician'' at § 414.1305 that applies under the Quality Payment Program. In addition, we received no comments on our proposal to amend the separate Shared Savings Program CEHRT use criterion at § 414.1415(a)(1)(ii) so that it applies only for QP Performance Periods under the Quality Payment Program prior to 2019. Furthermore, we received no comments on our proposal to add a new provision to the regulation at § 425.506 to establish the CEHRT requirement for performance years starting on January 1, 2019, and subsequent performance years for ACOs in a track or payment model within a track that does not meet the financial risk standard to be an Advanced APM and ACOs in a track or payment model within a track that meets the financial risk standard to be an Advanced APM.

After considering the comments received, we are finalizing with modification our proposal that for performance years starting on January 1, 2019, and subsequent performance years, ACOs in a track that does not meet the financial risk standard to be an Advanced APM must certify that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT to document and communicate clinical care to their patients or other health care providers. Specifically, we are finalizing

[39] This estimate is based on calculations of CEHRT use by primary care physicians prior to the changes made to ACO–11 to align with the Quality Payment Program, which became effective for quality reporting for performance year 2017.

the requirement that ACOs make this certification annually in the form and manner specified by CMS, but, for the reasons discussed above, we are not finalizing the proposal to require ACOs to make this certification at the time of application. Accordingly, for performance years starting on January 1, 2019, and subsequent performance years, ACOs in a track that does not meet the financial risk standard to be an Advanced APM must certify annually that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT to document and communicate clinical care to their patients or other health care providers. We reiterate that this final policy does not affect the previously finalized requirements for MIPS eligible clinicians reporting on the Promoting Interoperability (PI) performance category under MIPS. Accordingly, MIPS eligible clinicians who are participating in ACOs under a payment track that is not an Advanced APM and/or who are not QPs would continue to report as usual on the Promoting Interoperability performance category.

Similarly, after considering the comments received, we are also finalizing with modification our proposal with respect to ACOs in Shared Savings Program tracks that meet the financial risk standard to be an Advanced APM. We proposed that these ACOs would be required to certify at the time of application and annually thereafter that they meet the higher of the 50 percent threshold proposed for ACOs in a track that does not meet the financial risk to be an advanced APM or the CEHRT use criterion for Advanced APMs under the Quality Payment Program at § 414.1415(a)(1)(i).

For the reasons discussed previously, we not finalizing the requirement that ACOs certify that they meet the higher of the 50 percent threshold or the applicable threshold under the Quality Payment Program. Rather, ACOs will be required to certify only that they meet the applicable threshold established under the Quality Payment Program. In addition, as also discussed, we are not finalizing our proposal that ACOs certify that they meet the CEHRT requirement at the time of application. Accordingly, for performance years starting on January 1, 2019, and subsequent years, ACOs in a track that meets the financial risk standard to be an Advanced APM must certify annually that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold established under the Quality Payment Program at § 414.1415(a)(1)(i).

We are finalizing the proposed new provision at § 425.506(f) with conforming modifications to reflect the policies we are finalizing in this final rule. As part of these modifications, we are omitting the reference to ''a payment model within a track'' because we are not addressing the proposal to create the BASIC track, with separate payment models at Levels A through E, at this time. We anticipate summarizing and responding to comments received on this proposal and other proposals related to the participation options under the Shared Savings Program in a forthcoming final rule. For the reasons discussed previously in this section, we are not finalizing the proposed changes to the regulation at § 425.204(c) to establish the new application requirement; but, we are finalizing the proposed changes to the regulation at § 425.302(a)(3)(iii) to establish the new annual certification requirement. In addition, we are finalizing our proposed amendments to § 425.20 to incorporate a definition of ''CEHRT'' consistent with the definition at § 414.1305, including any subsequent updates or revisions to that definition, and to incorporate the definition of ''eligible clinician'' at § 414.1305 that applies under the Quality Payment Program. We are also finalizing our proposal to amend the separate Shared Savings Program CEHRT use criterion at § 414.1415(a)(1)(ii) so that it applies only for QP Performance Periods under the Quality Payment Program prior to 2019.

As noted in the August 2018 proposed rule (83 FR 41910), CMS reserves the right to monitor, assess, and/or audit an ACO's compliance with respect to its certification of CEHRT use among its participating eligible clinicians, consistent with §§ 425.314 and 425.316, and to take compliance actions (including warning letters, corrective action plans, and termination) as set forth at §§ 425.216 and 425.218 when ACOs fail to meet or exceed the required CEHRT use thresholds.

Finally, after considering the comments received in response to the proposal to remove ACO–11: Use of Certified EHR Technology measure from the Shared Savings Program quality measure set, we are finalizing our proposal effective with quality reporting for performance years starting on January 1, 2019, and subsequent performance years. We are also finalizing the corresponding revisions to the regulation at § 425.506 to reflect this change.

3. Applicability of Final Policies to Track 1+ Model ACOs

a. Background

In the August 2018 proposed rule (83 FR 41912), we discussed the applicability of proposed policies to Track 1+ Model ACOs. We explained that the Track 1+ Model was established under the Innovation Center's authority at section 1115A of the Act, to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care for Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. We noted that 55 Shared Savings Program Track 1 ACOs entered into the Track 1+ Model beginning on January 1, 2018. This includes 35 ACOs that entered the model within their current agreement period (to complete the remainder of their agreement period under the model) and 20 ACOs that entered into a new 3-year agreement period under the model.

To enter the Track 1+ Model, ACOs must be approved to participate in the model and are required to agree to the terms and conditions of the model by executing a Track 1+ Model Participation Agreement available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/track-1plus-model-par-agreement.pdf*. Track 1+ Model ACOs are also required to have been approved to participate in the Shared Savings Program (Track 1) and to have executed a Shared Savings Program Participation Agreement. As indicated in the Track 1+ Model Participation Agreement, in accordance with its authority under section 1115A(d)(1) of the Act, CMS has waived certain provisions of law that otherwise would be applicable to ACOs participating in Track 1 of the Shared Savings Program, as necessary for purposes of testing the Track 1+ Model, and established alternative requirements for the ACOs participating in the Track 1+ Model.

We explained that, unless stated otherwise in the Track 1+ Model Participation Agreement, the requirements of the Shared Savings Program under 42 CFR part 425 continue to apply. Consistent with § 425.212, Track 1+ Model ACOs are subject to all applicable regulatory changes, including but not limited to changes to the regulatory provisions referenced within the Track 1+ Model Participation Agreement, that become effective during the term of the ACO's Shared Savings Program Participation Agreement and Track 1+ Model

Participation Agreement, unless otherwise specified through rulemaking or amendment to the Track 1+ Model Participation Agreement. We noted that the terms of the Track 1+ Model Participation Agreement permit the parties (CMS and the ACO) to amend the agreement at any time by mutual written agreement.

b. Unavailability of Application Cycles for Entry Into the Track 1+ Model in 2019

In the August 2018 proposed rule (83 FR 41912 through 41913), we discussed the unavailability of application cycles for entry into the Track 1+ Model in 2019 and 2020. We explained that an ACO's opportunity to join the Track 1+ Model aligns with the Shared Savings Program's application cycle. The original design of the Track 1+ Model included 3 application cycles for ACOs to apply to enter or, if eligible and if applicable, to renew their participation in the Track 1+ Model for an agreement period start date of 2018, 2019, or 2020. The 2018 application cycle is closed, and as discussed elsewhere in the August 2018 proposed rule, 55 ACOs began participating in the Track 1+ Model on January 1, 2018. As discussed in section II.A.7 of the August 2018 proposed rule (83 FR 41847) and section V.B.1.a of this final rule, we are not offering an application cycle for a January 1, 2019 start date for new agreement periods under the Shared Savings Program. Therefore, we similarly are not offering a start date of January 1, 2019, for participation in the Track 1+ Model.

We explained that existing Track 1+ Model ACOs would be able to complete the remainder of their current agreement period in the model. Additionally, as discussed in section II.A.7.c.(1) of the August 2018 proposed rule (83 FR 41854 through 41855) and section V.B.1.c.(1) of this final rule, ACOs currently participating in the Track 1+ Model will not have the opportunity to apply to use a SNF 3-day rule waiver starting on January 1, 2019, under our decision to forgo an annual application cycle for a January 1, 2019 start date in the Shared Savings Program. We proposed that, if finalized, the next available application cycle for a SNF 3-day rule waiver would occur in advance of a July 1, 2019 start date. We will address proposals related to future application cycles in subsequent rulemaking.

c. Applicability of Proposed Policies to Track 1+ Model ACOs Through Revised Program Regulations or Revisions to Track 1+ Model Participation Agreements

In section II.F of the August 2018 proposed rule (83 FR 41913 through 41914), we provided a comprehensive discussion of the applicability of the proposed policies to Track 1+ Model ACOs to allow these ACOs to better prepare for their future years of participation in the program and the Track 1+ Model. We explained that there are two ways in which the proposed policies would become applicable to Track 1+ Model ACOs: (1) Through revisions to existing regulations that currently apply to Track 1+ Model ACOs; and (2) through revisions to the ACO's Track 1+ Model Participation Agreement.

We sought comment on these considerations, and any other issues that we may not have discussed related to the effect of the proposed policies on ACOs that entered the Track 1+ Model beginning in 2018. We note that these ACOs will complete their participation in the Track 1+ Model by no later than December 31, 2020 (for ACOs that entered the model at the start of a 3-year agreement period), or sooner in the case of ACOs that entered the model at the start of their second or third performance year within their current 3-year agreement period.

Generally, comments regarding the application of specific proposals to Track 1+ Model ACOs have been addressed as part of the discussion of comments in the relevant section of this final rule. Accordingly, in this section of this final rule, we are not repeating comments related to the applicability of the proposed policies to ACOs participating in the Track 1+ Model.

Therefore, unless specified otherwise, the changes to the program's regulations finalized in this final rule that are applicable to Shared Savings Program ACOs within a current agreement period will apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 1, so long as the applicable regulation has not been waived under the Track 1+ Model. Similarly, to the extent that certain requirements of the regulations that apply to ACOs under Track 2 or Track 3 have been incorporated for ACOs in the Track 1+ Model under the terms of the Track 1+ Model Participation Agreement, changes to the regulations as finalized in this final rule will also apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 2 or Track 3. For example, the following policies apply to Track 1+ Model ACOs:

- Revisions to voluntary alignment policies (section V.B.2.b. of this final rule), applicable for the performance year beginning on January 1, 2019, and subsequent performance years.
- Revisions to the definition of primary care services used in beneficiary assignment (section V.B.2.c. of this final rule), applicable for the performance year beginning on January 1, 2019, and subsequent performance years.
- Discontinuation of quality measure ACO–11; requirement to attest as part of the annual certification that a specified percentage of the ACO's eligible clinicians use CEHRT (section V.B.2.f. of this final rule), applicable for the performance year beginning on January 1, 2019, and subsequent performance years.

We will also apply the following policies finalized in this final rule to Track 1+ Model ACOs through an amendment to the Track 1+ Model Participation Agreement executed by CMS and the ACO:

- Annual certification that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold established under § 414.1415(a)(1)(i) (section V.B.2.f. of this final rule). This certification is required to ensure the Track 1+ Model continues to meet the CEHRT criterion to qualify as an Advanced APM for purposes of the Quality Payment Program.
- For ACOs that started a first or second Shared Savings Program participation agreement on January 1, 2016, and entered the Track 1+ Model on January 1, 2018, and that elect to extend their Shared Savings Program participation agreement for the 6-month performance year from January 1, 2019 through June 30, 2019 (as described in section V.B.1 of this final rule):

++ As described in section V.B.1.c.(3) of this final rule, the ACO should extend its repayment mechanism so that it remains in effect for 24 months after the end of the agreement period (June 30, 2021).

++ As described in section V.B.1.c.(10) of this final rule, the ACO is eligible for shared savings if the following conditions are met: The ACO completed the 6-month performance year starting on January 1, 2019; the ACO has completed all close-out procedures specified in § 425.221(a) by the deadline specified by CMS (if applicable); and the ACO has satisfied

the criteria for sharing in savings for the performance year.

++ We will determine performance for the 6-month performance year from January 1, 2019 through June 30, 2019, according to the approach specified in a new section of the regulations at § 425.609(b), applying the financial methodology for calculating shared losses specified in the ACO's Track 1+ Model Participation Agreement.

++ We will continue to share aggregate report data with the ACO for the entire CY 2019, consistent with the approach described in section V.B.1.c.(8) of this final rule, and the terms of the ACO's Track 1+ Model Participation Agreement.

• Extreme and uncontrollable circumstances policies for determining shared losses for performance years 2018 and subsequent years, consistent with the policies specified in § 425.610(i) (section V.B.2.d. of this final rule) and, for ACOs that elect to extend their Shared Savings Program participation agreement for the 6-month performance year from January 1, 2019 through June 30, 2019, in § 425.609(d) (section V.B.1.c.(5) of this final rule).

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. chapter 35), we are required to publish a 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

We solicited comments in the notice of proposed rulemaking that published in the July 27, 2018 **Federal Register** (83 FR 35704). For the purpose of transparency, we are republishing the discussion of the information collection requirements along with a reconciliation of the public comments we received.

A. Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 60 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

Private Sector Wages: The adjusted hourly wage is used to calculate the labor costs associated with our finalized requirements.

TABLE 60—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead costs ($/hr)	Adjusted hourly wage ($/hr)
All Occupations (for Individuals' Wages)	00–0000	24.34	n/a	n/a
Billing and Posting Clerks	43–3021	18.49	18.49	36.98
Computer Systems Analysts	15–1121	44.59	44.59	89.18
Family and General Practitioner	29–1062	100.27	100.27	200.54
Licensed Practical Nurse (LPN)	29–2061	21.98	21.98	43.96
Medical Assistant	31–9092	16.15	16.15	32.30
Medical Secretary	43–6013	17.25	17.25	34.50
Physicians	29–1060	103.22	103.22	206.44
Practice Administrator (Medical and Health Services Managers)	11–9111	53.69	53.69	107.38
Registered Nurse	29–1141	35.36	35.36	70.72

As indicated, we adjusted our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Wages for Individuals: For beneficiaries who elect to complete the CAHPS for MIPS survey, we believe that the burden will be addressed under All Occupations (see Table 60) at $24.34/hr since the group of individual respondents varies widely from working and nonworking individuals and by respondent age, location, years of employment, and educational attainment, etc. Unlike our private sector adjustment to the respondent hourly wage, we did not adjust this figure for fringe benefits and overhead since the individuals' activities will occur outside the scope of their employment.

B. Information Collection Requirements (ICRs)

1. ICRs Regarding the Clinical Laboratory Fee Schedule (CLFS) (Section III.A. of This Final Rule)

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for clinical diagnostic laboratory test (CDLTs) under the CLFS. The CLFS final rule, titled ''Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule'' (CLFS final rule), was published in the **Federal Register** on June 23, 2016, and implemented section 1834A of the Act. Under that rule (81 FR 41036), ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' (that is, certain private payor data) collected during a ''data collection period'' for their component ''applicable laboratories.'' In general, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the 6-month data collection period and reported to us during the 3-month data reporting period, and is equal to the weighted median of the private payor rates for the CDLT.

An applicable laboratory is defined at § 414.502, in part, as an entity that is a laboratory (as defined under the Clinical Laboratory Improvement Amendments (CLIA) definition at § 493.2) that bills Medicare Part B under its own National Provider Identifier (NPI). In addition, an applicable laboratory is an entity that receives more than 50 percent of its Medicare revenues during a data collection period from the CLFS and/or the PFS. We refer to this component of the applicable laboratory definition as the ''majority of Medicare revenues threshold.'' The definition of applicable laboratory also includes a ''low expenditure threshold'' component, which requires an entity to receive at least $12,500 of its Medicare revenues

from the CLFS during a data collection period for its CDLTs that are not advanced diagnostic laboratory tests (ADLTs).

In determining payment rates under the private payor rate-based CLFS, one of our goals is to obtain as much applicable information as possible from the broadest possible representation of the national laboratory market on which to base CLFS payment amounts, for example, from independent laboratories, hospital outreach laboratories, and physician office laboratories, without imposing undue burden on those entities. We believe it is important to achieve a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a CDLT, and minimizing the reporting burden for entities. In response to stakeholder feedback in the proposed rule (see section III.A.3 of this final rule for a discussion of this feedback) and in the interest of facilitating our goal, we are finalizing the revision to the majority of Medicare revenues threshold component of the definition of applicable laboratory at § 414.502(3) to exclude Medicare Advantage (MA) payments under Medicare Part C from the definition of total Medicare revenues (that is, the denominator of the majority of Medicare threshold equation). Specifically, this revision could allow additional laboratories of all types serving a significant population of beneficiaries enrolled in Medicare Part C to meet the majority of Medicare revenues threshold and potentially qualify as applicable laboratories (provided they meet all other requirements for applicable laboratory status) and report data to us.

In addition, in response to stakeholder feedback (see section III.A.4 of this final rule for a discussion of this feedback) in response to the comment solicitation in the proposed rule and in the interest of obtaining as much applicable information as possible, we are finalizing a revision to the definition of applicable laboratory at § 414.502 to include a hospital that bills Medicare on the Form CMS–1450 14x Type of Bill (OMB control number: 0938–0997) and its electronic equivalent.

As such, we believe the finalized changes may result in more applicable information being reported, which we will use to set CLFS payment rates. However, with regard to the CLFS-related requirements and burden, as we noted in the proposed rule, section 1834A(h)(2) of the Act provides that the Paperwork Reduction Act in chapter 35 of title 44 of the U.S.C. shall *not* apply to information collected under section 1834A of the Act (which is the new private payor rate-based CLFS).

For a complete discussion of our finalized revisions to the definition of applicable laboratory in § 414.502 related to the majority of Medicare revenues threshold and use of the Form CMS–1450 14X TOB, we refer readers to sections III.A.4.a of this final rule.

2. ICRs Regarding Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services (§ 414.94 and Section III.D. of this final rule)

Consultations: In the CY19 PFS proposed rule, we proposed to revise § 414.94(j) to allow the AUC consultation, when not performed personally by the ordering professional, to be performed by auxiliary personnel (as defined in § 410.26(a)(1)) under the direction of, and incident to, the ordering professional's services. In this final rule, we did not finalize this proposal but, instead, revised the regulation to specify that clinical staff acting under the direction of the ordering professional may perform the AUC consultation. The revised AUC consultation requirements and burden will be submitted to OMB for approval under control number 0938–1345 (CMS–10654).

General practitioners make up a large group of practitioners who order applicable imaging services and will be required to consult AUC under this program so we use ''family and general practitioner'' from the list of BLS occupation titles (see Table 60) to calculate the following cost estimates. While we proposed to modify the consultation requirement to allow auxiliary personnel, working under the direction of the ordering professional, to interact with the CDSM for AUC consultation, in this final rule we changed this estimate from using the ''registered nurse'' occupation to using the ''medical assistant'' occupation to calculate our revised cost estimates for our final policy to allow clinical staff acting under the direction of the ordering professional to perform the AUC consultation.

To derive the burden associated with the requirements under § 414.94(j), we estimate it will take 2 minutes (0.033 hr) at $70.72/hr for auxiliary personnel in the form of a registered nurse to consult with a qualified CDSM. The Medicare Benefit Policy Manual (Pub. 100–02), Chapter 15, Section 60.2 IOM 100–02, requires that an incidental service performed by the nonphysician practitioner must have followed from a direct, personal, professional service furnished by the physician. Therefore, to estimate the percentage of consultations available to be performed incident to, we analyzed 2014 Medicare Part B claims comparing evaluation and management visits for new (CPT codes 99201, 99202, 99203, 99204, and 99205) relative to established (CPT codes 99211, 99212, 99213, 99214, 99215) patients with place of service codes 11 (physician's office). We found that approximately 10 percent of all claims incurred were for new patients. Therefore, we also estimate that 90 percent or 38,863,636 of the total consultations (43,181,818 total consultations × 0.90) will be performed by such auxiliary personnel, with the remaining 10 percent (43,181,818 × 0.10) performed by the ordering professional. In this final rule and after review of public comments (see below), we revised § 414.94(j) to allow ordering professionals to delegate the AUC consultation to clinical staff acting under the direction of the ordering professional. To reflect this change, we updated our burden estimates to reflect the final policy and revised our estimates to replace a registered nurse with medical assistant to perform the AUC consultation. In aggregate, we estimate an annual burden of 1,282,500 hours (38,863,636.2 consultations × 0.033 hr/consultation) at a cost of $41,424,750 (1,282,500 hr × $32.30/hr) or $1.07 per consultation performed by clinical staff under the direction of the ordering professional. We will continue to monitor our burden estimates and, if necessary, adjust them for more precision once the program begins.

Additionally, the CY 2018 Physician Fee Schedule final rule (82 FR 52976) explicitly discussed and provided a voluntary period for ordering professionals to begin to familiarize themselves with qualified CDSMs. During the current 18-month voluntary participation period, we estimate there may be 10,230,000 consultations based on market research from current applicants for the qualification of their CDSMs for advanced diagnostic imaging services. Based on feedback from CDSMs with experience in AUC consultation, as well as standards recommended by the Office of the National Coordinator (ONC) [40] and the Healthcare Information Management Systems Society (HIMSS),[41] we estimate it will take 2 minutes (0.033 hr) at $200.54/hr for a family and general practitioner or 2 minutes at $32.30/hr for a medical assistant to use a qualified CDSM to consult specified applicable

[40] *https://ecqi.healthit.gov/cds#quicktabs-tabs_cds3.*

[41] *http://www.himss.org/improving-outcomes-cds-practical-pearls-new-himss-guidebook.*

AUC. The inclusion of a medical assistant in this calculation is reflective of our modifications in the final rule as discussed above. As mentioned previously, we estimate that as many as 90-percent of practices could use auxiliary personnel working under the direction of the ordering professional to interact with the CDSM for AUC consultation. Consequently, we estimate a total burden of 337,590 hours (10,230,000 consultations × 0.033 hr) at a cost of $16,583,771 ([337,590 hr × 0.10 × $200.54/hr] + [337,590 hr × 0.90 × $32.30/hr]). Annually, we estimate 112,530 hours (337,590 hr/3 yr) at a cost of $5,527,924 ($16,583,771/3 yr). We are annualizing the one-time burden (by dividing our estimates by OMB's 3-year approval period) since we do not anticipate any additional burden after the 18-month voluntary participation period ends.

Beginning January 1, 2020, we anticipate 43,181,818 responses in the form of consultations based on the aforementioned market research, as well as Medicare claims data for advanced diagnostic imaging services. As noted earlier, we estimate it will take 2 minutes (0.033 hr) at $200.54/hr for a family and general practitioner or 2 minutes at $32.30/hr for a medical assistant to use a qualified CDSM to consult specified applicable AUC. In aggregate, we estimate an annual burden of 1,425,000 hours (43,181,818 consultations × 0.033 hr/consultation) at a cost of $70,001,700 ([0.1 × 1,425,000 hr × $200.54/hr] + [0.9 × 1,425,000 hr × $32.30/hr]).

Annual Reporting: Consistent with section 1834(q)(4)(B) of the Act, we finalized at § 414.94(k) the reporting requirement of AUC consultation information and in the CY 2018 PFS final rule (82 FR 52976) we estimated the burden of implementing the one-time voluntary reporting period beginning in July 2018, and will be implementing the mandatory annual reporting requirement beginning January 1, 2020. Specifically, § 414.94(k) requires Medicare claims for advanced diagnostic imaging services, paid for under an applicable payment system (as defined in § 414.94(b)) and ordered on or after January 1, 2020, to include the following information: (1) Which qualified CDSM was consulted by the ordering professional; (2) whether the service ordered would adhere to specified applicable AUC, would not adhere to specified applicable AUC, or whether specified applicable AUC was not applicable to the service ordered; and (3) the NPI of the ordering professional (if different from the furnishing professional). The reporting requirement will not have any impact on any Medicare claim forms because the forms' currently approved data fields, instructions, and burden are not expected to change. Consequently, there is no need for review by OMB under the authority of the PRA; however, we have assessed the impact and include an analysis to this effect in the regulatory impact section of this final rule.

Significant Hardship Exception: We proposed and are finalizing revisions to § 414.94(i)(3) that provide for a significant hardship exception for ordering professionals who experience a significant hardship affecting their consultation of AUC when ordering an advanced diagnostic imaging service. The revisions establish a process whereby all ordering professionals can self-attest that they are experiencing a significant hardship at the time of placing an advanced diagnostic imaging order. Although this is not a certification being used as a substitute for a collection of AUC consultation information because no consultation is required by statute to take place, the significant hardship exception process consists of appending to the order for an applicable imaging service the significant hardship information for inclusion on the Medicare claim in lieu of the AUC consultation information. This imposes no burden beyond providing identifying information and attesting to the applicable information. In this regard, the use of this process is not ''information'' as defined under 5 CFR 1320.3(h), and therefore, is exempt from requirements of the PRA.

Recordkeeping: Section 1834(q)(4)(C) of the Act provides for certain exceptions to the aforementioned AUC consultation requirement; therefore we believe that some claims for advanced diagnostic imaging services will not contain AUC consultation information, such as in the case of an ordering professional with a significant hardship. However, ordering professionals will store documentation supporting the self-attestation of a significant hardship. Storage of this information could involve the use of automated, electronic, or other forms of information technology at the discretion of the ordering professional. We estimate that the average time for office clerical activities associated with this storage of information to be 10 minutes (0.167 hr) at $34.50/hr for a medical secretary to perform 6,699 recordkeeping actions, since consultation will not take place in the year when a hardship is incurred and 2016 data from the Medicare EHR Incentive Program and the first 2019 payment year MIPS eligibility and special status file suggests this estimate of those seeking hardship (OMB control number 0938–1314; CMS–10621). In aggregate we estimate an annual burden of 1,119 hours (6,699 recordkeeping activities × 0.167 hr/activity) at a cost of $38,596 (0.167 hr/activity × 6,699 recordkeeping activities × $34.50/hr). We solicited comments to inform these burden estimates.

The following is a summary of the comments we received regarding these burden estimates.

Comment: Commenters questioned the assumptions in CMS's calculations as part of the proposal to modify the AUC consultation requirement to allow auxiliary personnel, working under the direction of the ordering professional, to interact with the CDSM for AUC consultation. These commenters suggested using the ''medical assistant'' rather than the ''registered nurse'' occupation to calculate our revised cost estimates.

Response: As stated in this rule, we have finalized a change in the consulting requirement at 414.94(j) to allow ordering professionals to delegate the consultation to clinical staff acting under the direction of the ordering professional. In aggregate, we update our proposed estimate of an annual burden of 1,282,500 hours at a cost of $90,698,400 or $2.33 per consultation to an annual burden of 1,282,500 hours (38,863,636.2 consultations × 0.033 hr/consultation) at a cost of $41,424,750 (1,282,500 hr × $32.30/hr) or $1.07 per consultation using the medical assistant occupation code 31–9092 with mean hourly wage of $16.15 and 100 percent fringe benefits.

Comment: A few commenters disagreed that the reporting requirement will not have any impact on any Medicare claim forms. These commenters observed that the electronic claim standard for the institutional provider (837i) does not capture or have a placeholder for reporting the ordering physician's NPI.

Response: We appreciate the opportunity to clarify our analysis and the distinctions between reporting AUC consultation information and standardized communications on Medicare claims forms. The X12N insurance subcommittee develops and maintains standards for healthcare administrative transactions on professional (837p), institutional (837i), and dental (837d) transactions when submitting healthcare claims for a service or encounter. The current mandated version of 837 transactions is 5010™. While we have not finalized a process for implementing the reporting requirements at § 414.94(k), we clarify that implementation of changes to the

claim form transactions would not take place outside of the existing process we described.

After considering the comments, we are updating the proposed impact estimate of consultations by ordering professionals. First, we modified our calculation of the effort by a registered nurse to the effort of a 2-minute consultation with a qualified CDSM by a medical assistant (occupation code 31–9092) with mean hourly wage of $16.15 and 100 percent fringe benefits for 90 percent of consultations (1,282,500 hours) to be $41,424,750 (1,282,500 hours × $32.30/hour). Consequently, we have updated our estimated total burden during the voluntary period to 337,590 hours (10,230,000 consultations × 0.033 hr) at a cost of $16,583,771.16 ([337,590 hr × 0.10 × $200.54/hr] + [337,590 hr × 0.90 × $32.30/hr]). Annually, this estimate represents 112,530 hours (337,590 hr/3 yr) at a cost of $5,527,923.72 ($16,583,771.16/3 yr). Additionally, we update our aggregate estimate of annual burden beginning January 1, 2020 of 1,425,000 hours (43,181,818 consultations × 0.033 hr/consultation) at a cost of $70,001,700 ([0.1 × 1,425,000 hr × $200.54/hr] + [0.9 × 1,425,000 hr × $32.30/hr]).

3. ICRs Regarding the Medicare Shared Savings Program (Part 425 and Section III.F. of This Final Rule)

Section 1899(e) of the Act provides that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the PRA, shall not apply to the Shared Savings Program.

4. ICRs Regarding the Physician Self-Referral Law (42 CFR Part 411 and Section III.G. of This Final Rule)

Section 1877 of the Act, also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. The statute establishes a number of specific exceptions, and grants the Secretary the authority to create regulatory exceptions for financial relationships that pose no risk of program or patient abuse. Additionally, the statute mandates refunding any amount collected under a bill for an item or service furnished under a prohibited referral. Finally, the statute imposes reporting requirements and provides for sanctions, including civil monetary penalty provisions.

As discussed in section III.G. of this rule, we are finalizing regulatory updates to implement section 50404 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018), which added provisions to section 1877(h)(1) of the Act pertaining to the writing and signature requirements in certain compensation arrangement exceptions to the physician self-referral law's referral and billing prohibitions. Although we believe that the newly enacted provisions in section 1877(h)(1) of the Act are principally intended merely to codify in statute existing CMS policy and regulations with respect to compliance with the writing and signature requirements, we are finalizing revisions to our regulations at 42 CFR 411.354(e) and 411.353(g) to address any actual or perceived difference between the statutory and regulatory language, to codify in regulation our longstanding policy regarding satisfaction of the writing requirement found in many of the exceptions to the physician self-referral law, and to make the Bipartisan Budget Act of 2018 policies applicable to compensation arrangement exceptions issued using the Secretary's authority in section 1877(b)(4) of the Act. The burden associated with the writing and signature requirements is the time and effort necessary to prepare written documents and obtain signatures of the parties.

Although the writing and signature requirements are subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with the writing and signature requirements will be incurred by persons during the normal course of their activities and in the absence of federal regulation. Specifically, we believe that, for normal business operations purposes, health care providers and suppliers document their financial arrangements with physicians and others in order to identify and be able to enforce the legal obligations of the parties. Therefore, we believe that the writing and signature requirements should be considered usual and customary business practices.

We did not receive any public comments regarding our position that the burden associated with these requirements is a usual and customary business practice that is exempt from the PRA.

5. The Quality Payment Program (Part 414 and Section III.I. of This Final Rule)

Summary: For the PRA, the Quality Payment Program is comprised of a series of ICRs associated with MIPS and Advanced APMs. The MIPS ICRs consist of registration for virtual groups; qualified registry and QCDR self-nomination; CAHPS survey vendor applications; Quality Payment Program Identity Management Application Process; quality performance category data submission by Medicare Part B claims collection type, QCDR and MIPS CQM collection type, eCQM collection type, and CMS web interface submission type; CAHPS for MIPS survey beneficiary participation; group registration for CMS web interface; group registration for CAHPS for MIPS survey; call for quality measures; reweighting applications for Promoting Interoperability and other performance categories; Promoting Interoperability performance category data submission; call for Promoting Interoperability measures; improvement activities performance category data submission; nomination of improvement activities; and opt-out of Physician Compare for voluntary participants. ICRs for Advanced APMs consist of Partial Qualifying APM participant (QP) election; Other Payer Advanced APM identification: Payer Initiated and Eligible Clinician Initiated Processes; and submission of data for All-Payer QP determinations under the All-Payer Combination Option.

The following ICRs reflect this final rule's policies, as well as policies in the CY 2017 (81 FR 77008) and CY 2018 (82 FR 53568) Quality Payment Program final rules. In discussing each ICR, we reference the specific policies and whether they are finalized in this final rule or finalized in the CY 2017 or CY 2018 Quality Payment Program final rules. As described in this section in more detail, three ICRs (Quality: CMS Web Interface, Promoting Interoperability Performance Category: Data Submission, and Voluntary Participants Election to Opt-Out of Performance Data Display on Physician Compare) show a reduction in burden due to changes in policies that we are finalizing in this final rule. Most of the burden estimates discussed in this section are reductions in burden compared to currently approved estimates and reflect adjustments due to the use of data from the 2017 MIPS performance period or revised per-respondent burden assumptions. Finally, we added one ICR to incorporate a collection previously mentioned in the CY 2018 Quality

Payment Program final rule for which collection had not yet started: Submission of Data for All-Payer QP Determinations (82 FR 53886). See section V.B.5. of this final rule for a summary of the ICRs, the overall burden estimates, changes in burden estimates due to policies established in this final rule, and a summary of the policy and data changes affecting each ICR.

The revised requirements and burden estimates for all Quality Payment Program ICRs (except for CAHPS for MIPS and virtual groups election) will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). The revised CAHPS for MIPS ICRs will be submitted to OMB for approval under control number 0938–1222 (CMS–10450). The Virtual Groups Election is approved under OMB control number 0938–1343 (CMS–10652).

With regard to Quality Payment Program respondents, we selected BLS occupations Billing and Postal Clerks, Computer Systems Analysts, Physicians, Practice Administrator, and Licensed Practical Nurse (see Wage Estimates in section V.A. of this final rule) based on a study (Casalino et al., 2016) that collected data on the staff in physician's practices involved in the quality data submission process.[42] To calculate the cost for virtual groups to prepare their written formal agreements, we used wage estimates for Legal Support Workers, All Others.

Respondent estimates for the quality, Promoting Interoperability, and improvement activities performance categories are modeled using data from the 2017 MIPS performance period with the sole exception of 286 CMS Web Interface respondents, which is based on the number of groups who registered for using the CMS Web Interface during the 2018 MIPS performance period.

As discussed in section III.I.3.a. of this final rule, we are finalizing with modification our proposal to expand MIPS to additional clinician types starting with the 2019 MIPS performance period/2021 MIPS payment year; these new clinician types include physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals. In addition, in section III.I.3.c. of this final rule, we are finalizing the low-volume threshold in the following manner: If a MIPS eligible clinician meets or exceeds one, but not all, of the low-volume threshold criterion, including as defined by dollar amount ($90,000), beneficiary count (200), or covered professional services to Part-B enrolled individuals (minimum threshold of 200) then the clinician may elect to submit data and opt-in to MIPS. If a MIPS eligible clinician does not meet at least one of these low-volume determinations or meets at least one, but not all, of these low-volume determinations and elects not to opt-in, the clinician is not eligible and is excluded from MIPS. If the clinician is excluded and submits data, the clinician will be a voluntary reporter. These policies will expand the number of potential MIPS eligible clinicians, but we do not anticipate an incremental increase in the burden because the affected clinicians were assumed to be voluntary reporters in prior rules. In the CY 2018 Quality Payment Program final rule, clinicians who participated in 2016 PQRS, and who were not determined to be QPs based on their participation in Advanced APMs during CY 2017 and were not MIPS eligible, were assumed to be voluntary reporters in MIPS (82 FR 53908) with their burden accounted for within our estimates. Therefore, the finalized expansion in MIPS eligibility does not change the total number of respondents, but instead shifts a certain number of assumed voluntary reporters to MIPS eligible clinicians. Additionally, clinicians or groups agreeing to opt-in or voluntarily report will simply select the option of opt-in participation or to remain excluded and voluntarily report prior to submitting data; therefore, we do not believe a commensurate revision to the burden hours is necessary for any of our burden estimates. We realize that clinicians or groups in small practices who submit quality data via Medicare Part B claims do not have to log in the Quality Payment Program portal to submit data; however, we assume the clinicians or groups electing to opt-in would also submit data for the improvement activities performance category as well. Therefore, the effort to elect to opt-in is included in the burden estimate for the improvement activities performance category. We also note that third party intermediaries can be authorized to communicate this opt-in on behalf of clinicians.

Our participation estimates are reflected in Tables 64, 65, and 66 for the quality performance category, Table 77 for the Promoting Interoperability performance category, and Table 79 for the improvement activities performance category.

Due to data limitations, our burden estimates may overstate the total burden for data submission under the quality, Promoting Interoperability, and improvement activities performance categories. This is due to two primary reasons. First, we anticipate the number of QPs to increase because of total expected growth in Advanced APM participation. The additional QPs will be excluded from MIPS and likely not report. Second, it is difficult to predict what eligible clinicians who may report voluntarily will do in the 2019 MIPS performance period compared to the 2017 MIPS performance period and, therefore, the actual number of participants and how they elect to submit data may be different than our estimates. However, we believe our estimates are the most appropriate given the available data.

The following is a summary of general public comments received regarding our request for comment on our information collections and our responses. We received several general comments regarding the burden of data collection associated with the Quality Payment Program.

Comment: One commenter requested CMS provide a table in the Collection of Information section of the final rule consistent with the summary table provided in previous years' final rules which summarizes annual recordkeeping and submission requirements as well as the total burden estimate for the cost of reporting to the Quality Payment Program. The commenter stated its belief that this information is important for policymakers to consider the total cost of pay-for-performance programs in light of the utility of the information collected.

Response: We have provided total burden summary information by OMB control number including the total burden estimate for the cost of reporting to the Quality Payment Program in the table notes for Table 91. For more details, please refer to the Supporting Statement A of the Paperwork Reduction Act package for each OMB control number.

Comment: One commenter noted that based on the burden estimates provided in the proposed rule as well as the additional time spent analyzing feedback data and implementing care improvements, clinicians and their staff are spending too much time and money reporting data and not enough time on patient care. Further, the commenter requested that CMS continue finalizing policies that will reduce administrative burden and make the Quality Payment

[42] Lawrence P. Casalino et al., ''US Physician Practices Spend More than $15.4 Billion Annually to Report Quality Measures,'' Health Affairs, 35, no. 3 (2016): 401–406.

Program more cohesive, holistic, and simplified.

Response: We will continue refining the Quality Payment Program with the goal of reducing administrative, operational, and reporting burden while balancing the goal of improving quality of care.

After consideration of the public comments, we are not making any changes to our burden estimate methodology, but have updated the burden estimates to reflect the availability of participation data from the 2017 MIPS performance period.

Framework for Understanding the Burden of MIPS Data Submission: Because of the wide range of information collection requirements under MIPS, Table 61 presents a framework for understanding how the organizations permitted or required to submit data on behalf of clinicians vary across the types of data, and whether the clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, MIPS APM participant, or an Advanced APM participant. As shown in the first row of Table 61, MIPS eligible clinicians that are not in MIPS APMs and other clinicians voluntarily submitting data will submit data either as individuals, groups, or virtual groups for the quality, Promoting Interoperability, and improvement activities performance categories. Note that virtual groups are subject to the same data submission requirements as groups, and therefore, we will refer only to groups for the remainder of this section unless otherwise noted. Because MIPS eligible clinicians are not required to submit any additional information for assessment under the cost performance category, the administrative claims data used for the cost performance category is not represented in Table 61.

For MIPS eligible clinicians participating in MIPS APMs, the organizations submitting data on behalf of MIPS eligible clinicians will vary between performance categories and, in some instances, between MIPS APMs. For the 2019 MIPS performance period, the quality data submitted by Shared Savings Program ACOs, Next Generation ACOs, and other APM Entities on behalf of their participant MIPS eligible clinicians will fulfill any MIPS submission requirements for the quality performance category.

For the Promoting Interoperability performance category, group TINs may submit data on behalf of eligible clinicians in MIPS APMs, or eligible clinicians in MIPS APMs may submit data individually. For the improvement activities performance category, we will assume no reporting burden for MIPS APM participants. In the CY 2017 Quality Payment Program final rule, we describe that for MIPS APMs, we compare the requirements of the specific MIPS APM with the list of activities in the Improvement Activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77185). Although the policy allows for the submission of additional improvement activities if a MIPS APM receives less than the maximum improvement activities performance category score, to date all MIPS APM have qualified for the maximum improvement activities score. Therefore, we assume that no additional submission will be needed.

Advanced APM participants who are determined to be Partial QPs may incur additional burden if they elect to participate in MIPS, which is discussed in more detail in the CY 2018 Quality Payment Program final rule (82 FR 53841 through 53844), but other than the election to participate in MIPS, we do not have data to estimate that burden.

TABLE 61—CLINICIANS OR ORGANIZATIONS SUBMITTING MIPS DATA ON BEHALF OF CLINICIANS, BY TYPE OF DATA AND CATEGORY OF CLINICIAN *

Category of clinician	Type of data submitted			
	Quality performance category	Promoting interoperability performance category	Improvement activities performance category	Other data submitted on behalf of MIPS eligible clinicians
MIPS Eligible Clinicians (not in MIPS APMs) and Other Eligible Clinicians Voluntarily Submitting Data [a].	As group or individual clinicians.	As group or individual clinicians. Clinicians who are hospital-based, ambulatory surgical center-based, non-patient facing, physician assistants, nurse practitioners, clinician nurse specialists, certified registered nurse anesthetists, physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals are automatically eligible for a zero percent weighting for the Promoting Interoperability performance category. Clinicians who submit an application and are approved for significant hardship or other exceptions are also eligible for a zero percent weighting.	As group or individual clinicians.	Groups electing to use a CMS-approved survey vendor to administer CAHPS must register. Groups electing to submit via CMS Web Interface for the first time must register. Virtual groups must register via email.

TABLE 61—CLINICIANS OR ORGANIZATIONS SUBMITTING MIPS DATA ON BEHALF OF CLINICIANS, BY TYPE OF DATA AND CATEGORY OF CLINICIAN *—Continued

Category of clinician	Type of data submitted			
	Quality performance category	Promoting interoperability performance category	Improvement activities performance category	Other data submitted on behalf of MIPS eligible clinicians
Eligible Clinicians participating in the Shared Savings Program or Next Generation ACO Model (both MIPS APMs).	ACOs submit to the CMS Web Interface and CAHPS for ACOs on behalf of their participating MIPS eligible clinicians. [These submissions are not included in burden estimates for this final rule because quality data submission to fulfill requirements of the Shared Savings Program and for purposes of testing and evaluating the Next Generation ACO Model are not subject to the PRA].[b]	Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category through either group TIN or individual reporting. [Burden estimates for this final rule assume group TIN-level reporting].[c]	CMS will assign the improvement activities performance category score to each APM Entity group based on the activities involved in participation in the Shared Savings Program.[d] The burden estimates for this final rule assume no improvement activity reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity performance category score.].	Advanced APM Entities will make election for participating MIPS eligible clinicians.
Eligible Clinicians participating in Other MIPS APMs.	APM Entities submit to MIPS on behalf of their participating MIPS eligible clinicians. [These submissions are not included in burden estimates for this final rule because quality data submission for purposes of testing and evaluating Innovation Center models tested under Section 1115A of the Social Security Act (or Section 3021 of the Affordable Care Act) are not subject to the PRA].	Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category through either group TIN or individual reporting. [The burden estimates for this final rule assume group TIN-level reporting].	CMS will assign the same improvement activities performance category score to each APM Entity based on the activities involved in participation in the MIPS APM. [The burden estimates for this final rule assume no improvement activities performance category reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity score].	Advanced APM Entities will make election for participating eligible clinicians.

* Because the cost performance category relies on administrative claims data, MIPS eligible clinicians are not required to provide any additional information, and therefore, the cost performance category is not represented in this table.

[a] Virtual group participation is limited to MIPS eligible clinicians, specifically, solo practitioners and groups consisting of 10 eligible clinicians or fewer.

[b] Sections 1899 and 1115A of the Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a, respectively) state the Shared Savings Program and testing, evaluation, and expansion of Innovation Center models are not subject to the PRA.

[c] Both group TIN and individual clinician Promoting Interoperability data will be accepted. If both group TIN and individual scores are available for the same APM Entity, CMS will use the higher score for each TIN/NPI. The TIN/NPI scores are then aggregated for purposes of calculating the APM Entity score.

[d] APM Entities participating in MIPS APMs do not need to submit improvement activities data unless the CMS-assigned improvement activities scores are below the maximum improvement activities score.

The policies finalized in the CY 2017 and the CY 2018 Quality Payment Program final rules and this final rule create some additional data collection requirements not listed in Table 61. These additional data collections, some of which were previously approved by OMB under the control numbers 0938–1314 (Quality Payment Program) and 0938–1222 (CAHPS for MIPS), are as follows:

Additional approved ICRs related to MIPS third-party intermediaries

- Self-nomination of new and returning QCDRs (81 FR 77507 through 77508 and 82 FR 53906 through 53908) (OMB 0938–1314).
- Self-nomination of new and returning registries (81 FR 77507 through 77508 and 82 FR 53906 through 53908) (OMB 0938–1314).
- Approval process for new and returning CAHPS for MIPS survey vendors (82 FR 53908) (OMB 0938–1222).

Additional ICRs related to the data submission and the quality performance category

- CAHPS for MIPS survey completion by beneficiaries (81 FR 77509 and 82 FR 53916 through 53917) (OMB 0938–1222).
- Quality Payment Program Identity Management Application Process (82 FR 53914).

Additional ICRs related to the Promoting Interoperability performance category

- Reweighting Applications for Promoting Interoperability and other performance categories (82 FR 53918) (OMB 0938–1314).

Additional ICRs related to call for new MIPS measures and activities

- Nomination of improvement activities (82 FR 53922) (OMB 0938–1314).

• Call for new Promoting Interoperability measures (OMB 0938–1314).

• Call for new quality measures (OMB 0938–1314).

Additional ICRs related to MIPS

• Opt out of performance data display on Physician Compare for voluntary reporters under MIPS (82 FR 53924 through 53925) (OMB 0938–1314).

Additional ICRs related to APMs

• Partial QP Election (81 FR 77512 through 77513 and 82 FR 53922 through 53923) (OMB 0938–1314).

• Other Payer Advanced APM determinations: Payer Initiated Process (82 FR 53923 through 53924) (OMB 0938–1314).

• Other Payer Advanced APM determinations: Eligible Clinician Initiated Process (82 FR 53924) (OMB 0938–1314).

• Submission of Data for All-Payer QP Determinations (New data collection for the 2019 performance period) (OMB 0938–1314).

6. Quality Payment Program ICRs Regarding the Virtual Group Election (§ 414.1315)

This final rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the virtual group election. The virtual group election requirements and burden are currently approved by OMB under control number 0938–1343 (CMS–10652). Consequently, we have not made any virtual group election changes under that control number.

7. Quality Payment Program ICRs Regarding Third-Party Intermediaries (§ 414.1400)

Under MIPS, the quality, Promoting Interoperability, and improvement activities performance category data may be submitted via relevant third-party intermediaries, such as qualified registries, QCDRs, and health IT vendors. Data on the CAHPS for MIPS survey, which counts as one quality performance category measure, or can be used for completion of an improvement activity, can be submitted via CMS-approved survey vendors. In the CY 2018 Quality Payment Program final rule, we combined the burden for self-nomination of qualified registries and QCDRs (82 FR 53906). For this final rule, we determined that requirements for self-nomination for qualified registries were sufficiently different from QCDRs that it is necessary to estimate the two independently. The change will align the burden more closely to the requirements for QCDRs and qualified registries to self-nominate, not because of any change in policy in this final rule, but because of changes in our initial assumptions. Specifically, while the processes for self-nomination are similar, QCDRs have the option to submit QCDR measures for the quality performance category. Therefore, differences between QCDRs and registries self-nomination are associated with the preparation of QCDR measures for approval. The burden associated with qualified registry self-nomination, QCDR self-nomination, and the CAHPS for MIPS survey vendor applications follow:

Qualified Registry Self-Nomination: The requirements and burden associated with qualified registry self-nomination will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Qualified registries interested in submitting MIPS data to us on their participants' behalf need to complete a self-nomination process to be considered qualified to submit on behalf of MIPS eligible clinicians or groups (82 FR 53815).

In the CY 2018 Quality Payment Program final rule, previously approved qualified registries in good standing (that are not on probation or disqualified) that wish to self-nominate using the simplified process can attest, in whole or in part, that their previously approved form is still accurate and applicable (82 FR 53815). In the same rule, qualified registries in good standing that would like to make minimal changes to their previously approved self-nomination application from the previous year, may submit these changes, and attest to no other changes from their previously approved qualified registry application for CMS review during the self-nomination period, from September 1 to November 1 (82 FR 53815). This simplified self-nomination process will begin for the 2019 MIPS performance period.

The CY 2017 Quality Payment Program final rule provided the definition of a qualified registry to be a medical registry, a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties or other data intermediary that, with respect to a particular performance period, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the MIPS qualification criteria specified by CMS for that performance period (81 FR 77382).

For this final rule, we have adjusted the number of respondents (from 120 to 150) based on more recent data and a revised definition of ''respondent'' to account for self-nomination applications received but not approved. We have also adjusted our per respondent time estimate (from 10 hours to 3 hours) based on our review of the current burden estimates against the existing policy. Finally, we have provided a range of time estimates (from 10 hours to 0.5 hours) which reflect the availability of a simplified self-nomination process for previously approved qualified registries.

For the 2017 MIPS performance period, we received 138 applications for nomination to be a qualified registry and 145 applications for the 2018 MIPS performance period. In continuance of this trend for the 2019 MIPS performance period, we estimate 150 nomination applications will be received from qualified registries desiring approval to report MIPS data, an increase of 30 respondents from our currently approved estimate.

For this final rule, the burden associated with qualified registry self-nomination will vary depending on the number of existing qualified registries that will elect to use the simplified self-nomination process in lieu of the full self-nomination process as described in the CY 2018 Quality Payment Program final rule (82 FR 53815). The self-nomination form is submitted electronically using the web-based tool JIRA. For the 2018 MIPS performance period, 141 qualified registries were approved to submit MIPS data.

In section III.I.3.k.(3)(a) of this final rule, we have finalized our proposal to modify the definition of a QCDR to be an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. This revised definition of a QCDR may result in previously approved QCDRs who no longer meet the new definition to decide to instead seek approval as qualified registries. However, we have not received any notifications of intent and do not have data to support changing our estimate of 150 qualified registries who will submit applications during the self-nomination period for the CY 2020 performance period.

In the CY 2018 Quality Payment Program final rule, we estimated the burden associated with self-nomination of a qualified registry to be 10 hours, similar to PQRS (82 FR 53907). For this final rule, we reduced our estimate to 3 hours because registries no longer provide an XML submission, calculated measure, or measure flow as part of the

self-nomination process and are not subject to a mandatory interview, which were done previously as part of the PQRS qualified registry self-nomination process, upon which the previous assumption of 10 hours was based. As described in the CY 2017 Quality Payment Program final rule, the full self-nomination process requires the submission of basic information, a description of the process the qualified registry will use for completion of a randomized audit of a subset of data prior to submission, and the provision of a data validation plan along with the results of the executed data validation plan by May 31 of the year following the performance period (81 FR 77383 through 77384).

For the simplified self-nomination process, we have estimated 0.5 hours per qualified registry to submit a nomination, a reduction of 9.5 hours from currently approved estimates.

As shown in Table 62, we estimate that the staff involved in the qualified registry self-nomination process will be mainly computer systems analysts or their equivalent, who have an adjusted labor cost of $89.18/hour. Assuming that the time associated with the self-nomination process ranges from a minimum of 0.5 hours (for the simplified self-nomination process) to 3 hours (for the full self-nomination process) per qualified registry, we estimate that the annual burden will range from 97.5 hours ([141 qualified registries × 0.5 hr] + [9 qualified registries × 3 hr]) to 450 hours (150 qualified registries × 3 hr) at a cost ranging from $8,695 (97.5 hr × $89.18/hr) to $40,131 (450 hr × $89.18/hr), respectively (see Table 62).

Independent of the change to our per response time estimate, the increase in the number of respondents results in an adjustment of 300 hours and $26,754 (30 registries × 10 hr × $89.18/hr). Accounting for the change in the number of qualified registries, the change in time per qualified registry to self-nominate results in an adjustment of between −1,402.5 hours and −125,075 ([(141 registries × −9.5 hr)] + [(9 registries × −7 hr)] at $89.18/hr) and −1,050 hours and −$93,639 (150 registries × −7 hr × $89.18/hr). When these two adjustments are combined, the net impact ranges between −1,102.5 (−1,402.5 + 300) and −750 (−1,050 + 300) hours and −$98,321 (−$125,075 + $26,754) and −$66,885 (−$93,639 + $26,754).

Qualified registries must comply with requirements on the submission of MIPS data to CMS. The burden associated with the qualified registry submission requirements will be the time and effort associated with calculating quality measure results from the data submitted to the qualified registry by its participants and submitting these results, the numerator and denominator data on quality measures, the Promoting Interoperability performance category, and improvement activities data to us on behalf of their participants. These requirements are currently approved by OMB under control number 0938–1314 (CMS–10621).

We expect that the time needed for a qualified registry to accomplish these tasks will vary along with the number of MIPS eligible clinicians submitting data to the qualified registry and the number of applicable measures. However, we believe that qualified registries already perform many of these activities for their participants. We believe the estimates discussed earlier and shown in Table 62 represents the upper bound of registry burden, with the potential for less additional MIPS burden if the registry already provides similar data submission services.

Based on the assumptions previously discussed, we provide an estimate of the total annual burden associated with a qualified registry self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 62—ESTIMATED BURDEN FOR QUALIFIED REGISTRY SELF-NOMINATION

	Minimum burden	Maximum burden
Number of Qualified Registry Simplified Self-Nomination Applications submitted (a)	141	0
Number of Qualified Registry Full Self-Nomination Applications submitted (b)	9	150
Total Annual Hours Per Qualified Registry for Simplified Process (c)	0.5	0.5
Total Annual Hours Per Qualified Registry for Full Process (d)	3	3
Total Annual Hours for Qualified Registries (e) = (a) * (c) + (b) * (d)	97.5	450
Cost Per Simplified Process Per Registry (@computer systems analyst's labor rate of $89.18/hr.) (f)	$44.59	$44.59
Cost Per Full Process Per Registry (@computer systems analyst's labor rate of $89.18/hr.) (g)	$267.54	$267.54
Total Annual Cost for Qualified Registries (h) = (a) * (f) + (b) * (g)	$8,695	$40,131

Both the minimum and maximum burden shown in Table 62 will be submitted for approval to OMB under control number 0938–1314 (CMS–10621) and reflect adjustments due to review of self-nomination process and the number of respondents. For purposes of calculating total burden associated with the final rule as shown in Table 89, only the maximum burden is used.

We received no public comments related to the burden estimates for qualified registry self-nomination. The burden estimates have not been updated from the CY 2019 PFS proposed rule (83 FR 36016 through 36018).

QCDR Self-Nomination:[43] The requirements and burden associated with QCDR self-nomination will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

QCDRs interested in submitting quality, Promoting Interoperability, and improvement activities performance category data to us on their participants' behalf will need to complete a self-nomination process to be considered qualified to submit on behalf of MIPS eligible clinicians or groups.

In the CY 2018 Quality Payment Program final rule, previously approved QCDRs in good standing (that are not on probation or disqualified) that wish to self-nominate using the simplified process can attest, in whole or in part, that their previously approved form is still accurate and applicable (82 FR 53808). Existing QCDRs in good standing that would like to make minimal changes to their previously approved self-nomination application

[43] We do not anticipate any changes in the CEHRT process for health IT vendors as we transition to MIPS. Hence, health IT vendors are not included in the burden estimates for MIPS.

from the previous year, may submit these changes, and attest to no other changes from their previously approved QCDR application, for CMS review during the self-nomination period, from September 1 to November 1 (82 FR 53808). This simplified self-nomination process will begin for the 2019 MIPS performance period.

For this final rule, the burden associated with QCDR self-nomination will vary depending on the number of existing QCDRs that will elect to use the simplified self-nomination process in lieu of the full self-nomination process as described in the CY 2018 Quality Payment Program final rule (82 FR 53808 through 53813). The self-nomination form is submitted electronically using the web-based tool JIRA. For the 2018 MIPS performance period, 150 QCDRs were approved to submit MIPS data.

For this CY 2019 Quality Payment Program final rule, we have adjusted the number of respondents (from 113 to 200) based on more recent data and a revised definition of ''respondent'' to account for self-nomination applications received but not approved. We have also adjusted the time burden estimates per respondent based on our review of the current burden estimates against the existing policy as well as provided a range of time burden estimates which reflect the availability of a simplified self-nomination process for previously approved QCDRs.

For the 2017 MIPS performance period, we received 138 self-nomination applications from QCDRs and for the 2018 MIPS performance period, we received 176 self-nomination applications. In continuance of this trend for the 2019 MIPS performance period, we estimate 200 self-nomination applications will be received from QCDRs desiring approval to report MIPS data, an increase of 87 respondents.

In section III.I.3.k.(3)(a) of this final rule, we have finalized our proposal to modify the definition of a QCDR to be an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. This revised definition of a QCDR may result in previously approved QCDRs who no longer meet the new definition to decide to instead seek approval as qualified registries or collaborate with another previously approved QCDR to meet the requirements of the new definition. However, we have not received any notifications of intent and do not have data to support changing our estimate of 200 QCDRs who will submit applications during the self-nomination period for the CY 2020 performance period. In addition, we have not accounted for any costs associated with QCDRs collaborating to meet the requirements of the new definition as electing to do so would be a business decision made by individual entities which is not required or endorsed by CMS and considering the alternate path of seeking to be a qualified registry would be available for entities seeking to continue participating in MIPS.

We estimate that the self-nomination process for QCDRs to submit on behalf of MIPS eligible clinicians or groups for MIPS will involve approximately 3 hours per QCDR to submit information required at the time of self-nomination as described in the CY 2017 Quality Payment Program final rule including basic information about the QCDR, describing the process it will use for completion of a randomized audit of a subset of data prior to submission, providing a data validation plan, and providing results of the executed data validation plan by May 31 of the year following the performance period (81 FR 77383 through 77384). However, for the simplified self-nomination process, we estimate 0.5 hours per QCDR to submit this information. The aforementioned modification to the definition of a QCDR is not expected to affect the estimated time for submitting the full or simplified self-nomination. The self-nomination form is submitted electronically using the web-based tool JIRA.

In addition, QCDRs calculate their measure results. QCDRs must possess benchmarking capabilities (for QCDR measures) that compare the quality of care a MIPS eligible clinician provides with other MIPS eligible clinicians performing the same quality measures. For QCDR measures, the QCDR must provide to us, if available, data from years prior (for example, 2017 data for the 2019 MIPS performance period) before the start of the performance period. In addition, the QCDR must provide to us, if available, the entire distribution of the measure's performance broken down by deciles. As an alternative to supplying this information to us, the QCDR may post this information on their website prior to the start of the performance period, to the extent permitted by applicable privacy laws. The time it takes to perform these functions may vary depending on the sophistication of the entity, but we estimate that a QCDR will spend an additional 1 hour performing these activities per measure and assume that each QCDR will submit information for 9 QCDR measures, for a total burden of 9 hours per QCDR (1 hr per measure $\times$ 9 measures). The estimated average of 9 measures per QCDR is based on the number of QCDR measure submissions received in the 2017 and 2018 MIPS performance periods and is the same for each QCDR regardless of whether they elect to use the simplified or full self-nomination process.

In the 2017 MIPS performance period, we received over 1,000 QCDR measure submissions. In the 2018 MIPS performance period, we received over 1,400 QCDR measure submissions. For the 2019 MIPS performance period, we anticipate this trend will continue, and therefore, estimate we will receive a total of approximately 1,800 QCDR measure submissions, resulting in an average of 9 measure submissions per QCDR (1,800 measure submissions/200 QCDRs).

In the CY 2018 Quality Payment Program final rule, the burden associated with self-nomination of a QCDR was estimated to be 10 hours (82 FR 53907). For this final rule, we are increasing the burden associated with self-nomination to 12 hours. Because QCDRs are no longer required to provide an XML submission and are not subject to a mandatory interview; both of which were completed as part of the PQRS QCDR self-nomination process upon which the previous assumption of 10 hours was based, we are eliminating 1 hour from our previous burden assumption. Simultaneously, we are increasing our burden assumption by 3 hours to account for an increase in the number of QCDR measure submissions being submitted. These two adjustments result in a net increase of 2 hours per respondent from our previously approved burden estimates.

As shown in Table 63, we estimate that the staff involved in the QCDR self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor cost of $89.18/hr. Assuming that the hours per QCDR associated with the self-nomination process ranges from a minimum of 9.5 hours (for the simplified self-nomination process) to 12 hours (for the full self-nomination process), we estimate that the annual burden will range from 2,025 hours ([150 QCDRs $\times$ 9.5 hr] + [50 QCDRs $\times$ 12 hr]) to 2,400 hours (200 QCDRs $\times$ 12 hr) at a cost ranging between $180,590 (2,025 hr $\times$ $89.18/hr) and $214,032 (2,400 hr $\times$ $89.18/hr), respectively (see Table 63).

Independent of the change to our per response time estimate, the increase in the number of respondents results in an

adjustment of 870 hours and $77,587 (87 registries × 10 hr × $89.18/hr). Accounting for the change in the number of qualified registries, the change in time per QCDR to self-nominate results in an adjustment of between 25 hours and $2,230 ([150 registries × −0.5 hr] + [50 registries × 2 hr] at $89.18/hr) and 400 hours and $35,672 (200 registries × 2 hr × $89.18/hr). When these two adjustments are combined, the net impact ranges between 895 (870 + 25) hours at $79,817 ($77,587 + $2,230) and 1,270 (870 + 400) hours at $113,259 ($77,587 + $35,672).

QCDRs must comply with requirements on the submission of MIPS data to CMS. The burden associated with the QCDR submission requirements will be the time and effort associated with calculating quality measure results from the data submitted to the QCDR by its participants and submitting these results, the numerator and denominator data on quality measures, the Promoting Interoperability performance category, and improvement activities data to us on behalf of their participants. These requirements are currently approved by OMB under control number 0938–1314 (CMS–10621). We expect that the time needed for a QCDR to accomplish these tasks will vary along with the number of MIPS eligible clinicians submitting data to the QCDR and the number of applicable measures. However, we believe that QCDRs already perform many of these activities for their participants. We believe the estimate noted in this section represents the upper bound of QCDR burden, with the potential for less additional MIPS burden if the QCDR already provides similar data submission services.

We finalized in the CY 2018 Quality Payment Program final rule that QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR (82 FR 53813). However, some QCDR measure stewards charge a fee for the use of their QCDR measures. We have not accounted for QCDR measure licensing costs as part of our burden estimate due to the election to license a QCDR measure being a business decision made by individual QCDRs which is not required or endorsed by CMS for participation in MIPS.

Based on the assumptions previously discussed, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 63—ESTIMATED BURDEN FOR QCDR SELF-NOMINATION

	Minimum burden	Maximum burden
Number of QCDR Simplified Self-Nomination Applications submitted (a)	150	0
Number of QCDR Full Self-Nomination Applications submitted (b)	50	200
Total Annual Hours Per QCDR for Simplified Process (c)	9.5	9.5
Total Annual Hours Per QCDR for Full Process (d)	12	12
Total Annual Hours for QCDRs (e) = (a) * (c) + (b) * (d)	2,025	2,400
Cost Per Simplified Process Per QCDR (@computer systems analyst's labor rate of $89.18/hr.) (f)	$847.21	$847.21
Cost Per Full Process Per QCDR (@computer systems analyst's labor rate of $89.18/hr.) (g)	$1,070.16	$1,070.16
Total Annual Cost for QCDRs (h) = (a) * (f) + (b) * (g)	$180,590	$214,032

Both the minimum and maximum burden shown in Table 63 will be submitted for approval to OMB under control number 0938–1314 (CMS–10621) and reflect adjustments due to the review of self-nomination process and the number of respondents. For purposes of calculating total burden associated with the final rule as shown in Table 89, only the maximum burden will be used.

We received no public comments related to the burden estimates for QCDR self-nomination. The burden estimates have not been updated from the CY 2019 PFS proposed rule (83 FR 36018 through 36019), however we have provided additional elaboration on the updated requirements for QCDRs electing to self-nominate and our rationale for why the burden estimates do not require additional revision.

CMS-Approved CAHPS for MIPS Survey Vendors: This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to CMS-approved CAHPS for MIPS survey vendors. The CMS-approved CAHPS for MIPS survey vendor requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we have not made any MIPS survey vendor changes under that control number.

8. Quality Payment Program ICRs Regarding Data Submission (§§ 414.1325 and 414.1335)

Under our current policies, two groups of clinicians will submit quality data under MIPS: Those who submit as MIPS eligible clinicians and other eligible clinicians who opt to submit data voluntarily but will not be subject to MIPS payment adjustments. Although the finalized expansion of the definition of a MIPS eligible clinician to new clinician types and the opt-in process for MIPS participation discussed in sections III.I.3.a and III.I.3.c.(6) of this final rule could affect respondent counts, all of the new potential respondents had the opportunity to participate in PQRS and as a voluntary reporter in MIPS. Therefore, consistent with our assumptions in the CY 2017 and CY 2018 Quality Payment Program final rules that PQRS participants that are not QPs will have participated in MIPS as voluntary respondents (81 FR 77501 and 82 FR 53908, respectively), we anticipate that this rule's finalized expansion of the definition of a MIPS eligible clinician will not have any incremental effect on any of our currently approved burden estimates. For the purpose of the following analyses, we assume that clinicians who participated in MIPS and who are not QPs in Advanced APMs in the 2017 MIPS performance period will continue to submit quality data in the 2019 MIPS performance period. We assume that 100 percent of APM Entities in MIPS APMs will submit quality data to CMS as required under their models. We estimate a total of 964,246 clinicians participated as individuals or groups in the 2017 MIPS performance period; this number differs from the currently approved estimate (OMB 0938–1314, CMS–10621) of 758,267 due to the availability of updated data.

As discussed in section III.I.3.h.(1)(b) of this final rule, we are replacing the term ''submission mechanism'' with the terms ''collection type'' and ''submission type.'' ''Submission mechanism'' is presently used to refer not only to the mechanism by which data is submitted, but also to certain types of measures and activities on which data are submitted to the entities submitting such data in the Quality Payment Program.

We assume that clinicians and groups will continue to submit quality data for the same collection types they used during the CY 2017 performance period. In addition, we assume that the 80 TINs that elect to form 16 virtual groups will continue to collect and submit MIPS data using the same collection and submission types as they did during the 2017 MIPS performance period, but the submission will be at the virtual group, rather than group level. Our burden estimates for the quality performance category do not include the burden for the quality data that APM Entities submit to fulfill the requirements of their models. The burden is excluded as sections 1899(e) and 1115A(d)(3) of the Act (42 U.S.C. 1395jjj(e) and 1315a(d)(3), respectively) state the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models tested under section 1115A of the Act (or section 3021 of the Affordable Care Act) are not subject to the PRA.[44] Tables 64, 65, and 66 explain our revised estimates of the number of organizations (including groups, virtual groups, and individual MIPS eligible clinicians) submitting data on behalf of clinicians segregated by collection type.

Table 64 provides our estimated counts of clinicians that will submit quality performance category data as MIPS individual clinicians or groups in the 2019 MIPS performance period based on data from the 2017 MIPS performance period.

For the 2019 MIPS performance period, respondents will have the option to submit quality performance category data via Medicare Part B claims, direct, and log in and upload submission types, and CMS Web Interface. At the time of the CY 2019 PFS proposed rule, participation data by submission type and user research data to inform burden assumptions was not available to estimate burden by submission type. As a result, we estimate the burden for collecting data via collection type: Claims, QCDR and MIPS CQMs, eCQMs, and the CMS Web Interface. While we have more information about MIPS submissions, for this final rule, we believe it is important to continue to estimate burden by collection type because the public was able to comment on our assumptions using this framework. As we gain more experience with the program, we may revise this approach through future rulemaking.

For the Medicare Part B claims collection type, in section III.I.3.h.(1)(b) of this rule, we finalized limiting the Medicare Part B claims collection type to small practices beginning with the 2021 MIPS payment year and allowing clinicians in small practices to report Medicare Part B claims as a group or as individuals. We assumed in our currently approved burden analysis that any clinician that submits quality data codes to us for the Medicare Part B claims collection type is intending to do so for the Quality Payment Program. We made this assumption originally in the CY 2017 Quality Payment Program final rule to ensure that we fully accounted for any burden that may have resulted from our policies (81 FR 77501 through 77504). In some cases, however, clinicians may be submitting quality data codes not only for the Medicare Part B claims collection type, but also for MIPS CQM and QCDR collection types. Some registries and QCDRs utilize data from claims to populate their datasets when submitting on behalf of clinicians. We are not able to separate out when a clinician submits a quality data code solely for the Medicare Part B claim collection type or when a clinician is also submitting these codes for MIPS CQM or QCDR collection types. In addition, we see a large number of voluntary reporters for the Medicare Part B claims collection type. Approximately 70 percent of the 257,260 clinicians we estimate will submit quality data via Medicare Part B claims (see Table 64) are MIPS eligible clinicians while the other 30 percent are voluntary reporters which means our burden include estimates for a large number of voluntary reporters. Of these clinicians who are not scored as part of an APM, approximately 55 percent are in practices with more than 15 clinicians; however, over 91 percent of the number in practices larger than 15 clinicians are either voluntary reporters, group reporters, or are also reporting quality data through another collection type. Approximately 10,700 individual clinicians in non-small practices are both MIPS eligible and scored based only on Medicare Part B claims data and of these, 52 percent also qualify for facility-based reporting, and therefore, will not be required to submit quality data in order to receive facility-based quality and cost scores. It is unclear why many clinicians are submitting quality data via an alternate collection type, and we currently lack data to accurately estimate both the number of clinicians who will be impacted by these finalized policies and the potential behavioral response of those clinicians who will be required to switch to another collection type. As a result, we will continue using the assumption that all clinicians (except QPs) who submitted data via the Medicare Part B claims collection type in the 2017 MIPS performance period will continue to do so for MIPS in order to avoid overstating the impact of the change. We intend to update this burden estimate with additional data as it becomes available. We solicited comment on potential other assumptions for capturing the Medicare Part B claims burden, but no comments were received.

Using our revised terminology, clinicians who used a QCDR or Registry will now collect measures via QCDR or MIPS CQM collection type; clinicians who used the EHR submission type will elect the eCQM collection type, and groups that elected the CMS Web Interface for MIPS will continue to elect the CMS Web Interface for MIPS.

Table 64 shows that in the 2019 MIPS performance period, an estimated 257,260 clinicians will submit data as individuals for the Medicare Part B claims collection type; 324,693 clinicians will submit data as individuals or as part of groups for the MIPS CQM or QCDR collection types; 243,062 clinicians will submit data as individuals or as part of groups via eCQM collection types; and 139,231 clinicians will submit as part of groups via the CMS Web Interface.

Table 64 provides estimates of the number of clinicians to collect quality measures data via each collection type, regardless of whether they decide to submit as individual clinicians or as part of groups. Because our burden estimates for quality data submission assume that burden is reduced when clinicians elect to submit as part of a group, we also separately estimate the expected number of clinicians to submit as individuals or part of groups.

[44] Our estimates do reflect the burden on MIPS APM participants of submitting Promoting Interoperability performance category data, which is outside the requirements of their models.

TABLE 64—ESTIMATED NUMBER OF CLINICIANS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA BY COLLECTION TYPE

	Medicare Part B claims	QCDR/MIPS CQM	eCQM	CMS web interface	Total
Number of clinicians to collect data by collection type (as individual clinicians or groups) in Quality Payment Program Year 3 (excludes QPs) (a)	257,260	324,693	243,062	139,231	964,246
*Number of clinicians to collect data by collection type (as individual clinicians or groups) in Quality Payment Program Year 2 (excludes QPs) (b)	278,039	255,228	131,133	93,867	758,267
Difference between Year 3 and Year 2 (c) = (a) − (b)	−20,779	+69,465	+111,929	+45,364	+205,979

*Currently approved by OMB under control number 0938–1314 (CMS–10621).

In the CY 2018 Quality Payment Program final rule (82 FR 53625 through 53626), beginning with the 2019 MIPS performance period, we allowed MIPS eligible clinicians to submit data for multiple collection types for a single performance category. Therefore, we captured the burden of any eligible clinician that may have historically collected via multiple collection types, as we assume they will continue to collect via multiple collection types and that our MIPS scoring methodology will take the highest score where the same measure is submitted via multiple collection types. Hence, the estimated numbers of individual clinicians and groups to collect via the various collection types are not mutually exclusive and reflect the occurrence of individual clinicians or groups that collected data via multiple collection types during the MIPS 2017 performance period.

Table 65 uses methods similar to those described for Table 64 to estimate the number of clinicians that will submit data as individual clinicians via each collection type in the 2019 MIPS performance period. We estimate that approximately 257,260 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 71,439 clinicians will submit data as individuals using MIPS CQMs or QCDR collection types; and approximately 47,557 clinicians will submit data as individuals using eCQMs collection type.

TABLE 65—ESTIMATED NUMBER OF CLINICIANS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA AS INDIVIDUALS BY COLLECTION TYPE

	Medicare Part B claims	QCDR/MIPS CQM	eCQM	CMS web interface	Total
Number of Clinicians to submit data as individuals in Quality Payment Program Year 3 (excludes QPs) (a)	257,260	71,439	47,557	0	376,256
*Number of Clinicians to submit data as individuals in Quality Payment Program Year 2 (excludes QPs) (b)	278,039	104,281	52,709	0	435,029
Difference between Year 3 and Year 2 (c) = (a) − (b)	−20,779	−32,842	−5,152	0	−58,773

*Currently approved by OMB under control number 0938–1314 (CMS–10621).

To be consistent with the policy in the CY 2018 Quality Payment Program final rule that for MIPS eligible clinicians who collect measures via Medicare Part B claims, MIPS CQM, eCQM, or QCDR collection types and submit more than the required number of measures (82 FR 53735 through 54736), we will score the clinician on the required measures with the highest assigned measure achievement points. Therefore, our columns in Table 65 are not mutually exclusive.

Table 66 provides our estimated counts of groups or virtual groups that will submit quality data on behalf of clinicians for each collection type in the 2019 MIPS performance period and reflects our assumption that the formation of virtual groups will reduce burden. We assume that groups that submitted quality data as groups in the 2017 MIPS performance period will continue to submit quality data either as groups or virtual groups for the same collection types as they did as a group or TIN within a virtual group for the 2019 MIPS performance period. First, we estimated the number of groups or virtual groups that will collect data via each collection type during the 2019 MIPS performance period using data from the 2017 MIPS performance period. The second and third steps in Table 66 reflect our currently approved assumption that virtual groups will reduce the burden for quality data submission by reducing the number of organizations that will submit quality data on behalf of clinicians. We assume that 40 groups that previously collected on behalf of clinicians via QCDR or MIPS CQM collection types will elect to form 8 virtual groups that will collect via QCDR and MIPS CQM collection types. We assume that another 40 groups that previously collected on behalf of clinicians via eCQM collection types will elect to form another 8 virtual groups that will collect via eCQM collection types. Hence, the second step in Table 66 is to subtract out the estimated number of groups under each collection type that will elect to form virtual groups, and the third step in Table 66 is to add in the estimated number of virtual groups that will submit on behalf of clinicians for each collection type.

Specifically, we assume that 10,542 groups and virtual groups will submit data for the QCDR or MIPS CQM collection types on behalf of 253,254 clinicians; 4,304 groups and virtual groups will submit for eCQM collection types on behalf of 195,505 eligible clinicians; and 286 groups will submit data via the CMS Web Interface on behalf of 139,231 clinicians. Because we are using 2017 MIPS performance period participation data to estimate participation for the 2019 MIPS performance period, our estimates do not account for the finalized policy to allow only groups that meet the definition of a small practice to submit quality data via the Medicare Part B claims collection type. Due to a lack of

historic data identifying which clinicians in small practices would want to submit via the Medicare Part B claims collection type and elect to be measured as part of a group, we continue to assume these clinicians submitting Medicare Part B claims will participate as individuals but will review this assumption for future performance periods.

TABLE 66—ESTIMATED NUMBER OF GROUPS AND VIRTUAL GROUPS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA BY COLLECTION TYPE ON BEHALF OF CLINICIANS

	Medicare Part B claims	QCDR/MIPS CQM	eCQM	CMS web interface	Total
Number of groups to collect data by collection type (on behalf of clinicians) in Quality Payment Program Year 3 (excludes QPs) (a)	0	10,574	4,336	286	15,196
Subtract out: Number of groups to collect data by collection type on behalf of clinicians in Quality Payment Program Year 3 that will submit as virtual groups in Quality Payment Program Year 3 (b)	0	40	40	0	80
Add in: Number of virtual groups to collect data by collection type on behalf of clinicians in Quality Payment Program Year 3 (c)	0	8	8	0	16
Number of groups to collect data by collection type on behalf of clinicians in Quality Payment Program Year 3 (d) = (a) − (b) + (c)	0	10,542	4,304	286	15,132
*Number of groups to collect data by collection type on behalf of clinicians in Quality Payment Program Year 2 (e)	0	2,936	1,509	296	4,741
Difference between Year 3 and Year 2 (f) = (d) − (e)	0	+7,606	+2,795	−10	+10,391

*Currently approved by OMB under control number 0938–1314 (CMS–10621).

The burden estimates associated with submission of quality performance category data have some limitations. We believe it is difficult to quantify the burden accurately because clinicians and groups may have different processes for integrating quality data submission into their practices' work flows. Moreover, the time needed for a clinician to review quality measures and other information, select measures applicable to their patients and the services they furnish, and incorporate the use of quality measures into the practice workflows is expected to vary along with the number of measures that are potentially applicable to a given clinician's practice and by the collection type. For example, clinicians submitting data via the Medicare Part B claims collection type need to integrate the capture of quality data codes for each encounter whereas clinicians submitting via the eCQM collection types may have quality measures automated as part of their EHR implementation.

We believe the burden associated with submitting quality measures data will vary depending on the collection type selected by the clinician, group, or third-party. As such, we separately estimated the burden for clinicians, groups, and third parties to submit quality measures data by the collection type used. For the purposes of our burden estimates for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, we also assume that, on average, each clinician or group will submit 6 quality measures. In terms of the quality measures available for clinicians and groups to report for the 2019 MIPS performance period, the total number of quality measures will be 257. These measures are stratified by collection type in Table 67, as well as counts of new, removed, and substantively changed measures.

TABLE 67—SUMMARY OF QUALITY MEASURES FOR THE 2019 MIPS PERFORMANCE PERIOD

Collection type	Number of measures finalized as new	Number of measures finalized for removal	Number of measures finalized with a substantive change	Number of measures remaining for CY 2019
Medicare Part B Claims Specifications	0	7	1	64
MIPS CQMs Specifications	6	21	0	233
eCQM Specifications	2	6	0	50
Survey—CSV	0	0	0	1
CMS Web Interface Measure Specifications	0	1	4	10
Administrative Claims	0	0	0	1
Total	8	*26	5	*257

*A measure may be applicable to more than one collection type but will only be counted once in the total.

For the 2019 MIPS performance period, there is a net reduction of 18 quality measures across all collection types. We do not anticipate that removing these measures will increase or decrease the reporting burden on clinicians and groups.

Quality Payment Program Identity Management Application Process: The requirements and burden associated with the application process will be

submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In the CY 2018 Quality Payment Program final rule, the time associated with the Identity Management Application Process was described as ''Obtain Account in CMS-Specified Identity Management System'' and included in the ICR for Quality Data Submission by Clinicians and Groups: EHR Submission for a total burden of 54,218 hours (1 hr × 54,218 respondents) (82 FR 53914). After our review of the quality data submission process, we determined the burden associated with the application process (3,741 hours) should be accounted for in a separate ICR. Our per respondent burden estimate remains unchanged at 1 hour per response.

For an individual, group, or third-party to submit MIPS quality, improvement activities, or Promoting Interoperability performance category data using either the log in and upload or the log in and attest submission type or to access feedback reports, the submitter must have a CMS Enterprise Portal user account. Once the user account is created, registration is not required again for future years.

Based on the number of new TINs registered in the 2017 MIPS performance period, we estimate 3,741 eligible clinicians, groups, or third-parties will register for new accounts for the 2019 MIPS performance period. As shown in Table 68, it will take 1 hour at $89.18/hr for a computer systems analyst (or their equivalent) to obtain an account for the CMS Enterprise Portal. In aggregate, we estimate an annual burden of 3,741 hours (3,741 registrations × 1 hr/registration) at a cost of $333,622 (3,741 hr × $89.18/hr) or $89.18 per registration.

TABLE 68—ESTIMATED BURDEN FOR QUALITY PAYMENT PROGRAM IDENTITY MANAGEMENT APPLICATION PROCESS

	Burden estimate
Number of New TINs completing the Identity Management Application Process (a)	3,741
Total Hours Per Application (b)	1
Total Annual Hours for completing the Identity Management Application Process (c) = (a) * (b)	3,741
Cost Per Application @ computer systems analyst's labor rate of $89.18/hr.) (d)	$89.18
Total Annual Cost for completing the Identity Management Application Process (e) = (a) * (d)	$333,622

We received no public comments related to the burden estimates for the Identity Management Application Process. The burden estimates have not been updated from the CY 2019 PFS proposed rule (83 FR 36022 through 36023).

Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type: The requirements and burden associated with clinicians' Medicare Part B claims-based data submissions will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As noted in Table 64, based on 2017 MIPS performance period data, we assume that 257,260 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type. We continue to anticipate that the Medicare Part B claims submission process for MIPS is operationally similar to the way the claims submission process functioned under the PQRS. Specifically, clinicians will need to gather the required information, select the appropriate QDCs, and include the appropriate QDCs on the Medicare Part B claims they submit for payment. Clinicians will collect QDCs as additional (optional) line items on the CMS–1500 claim form or the electronic equivalent HIPAA transaction 837–P, approved by OMB under control number 0938–1197. This final rule's provisions do not necessitate the revision of either form.

In this final rule, we have adjusted the number of respondents based on more recent data and adjusted our per respondent time estimates so that they correctly align with the number of required measures for which MIPS data must be submitted (6 measures) in comparison to the number of measures previously required under PQRS (9 measures).

The total estimated burden of Medicare Part B claims-based submission will vary along with the volume of Medicare Part B claims on which the submission is based. Based on our experience with PQRS, we estimate that the burden for submission of MIPS quality data will range from 0.15 to 7.2 hours per clinician, a reduction from the range of 0.22 to 10.8 hours as set out in the CY 2018 Quality Payment Program final rule (82 FR 53912). In the same rule, the 33 percent reduction in the number of measures (from 9 to 6) was erroneously omitted from our burden calculations; it is reflected in this final rule's burden estimates. The wide range of estimates for the time required for a clinician to submit quality measures via Medicare Part B claims reflects the wide variation in complexity of submission across different clinician quality measures. As shown in Table 69, we estimate that the cost of quality data submission using Medicare Part B claims will range from $13.38 (0.15 hr × $89.18/hr) to $642.10 (7.2 hr × $89.18/hr). The burden will involve becoming familiar with MIPS data submission requirements. We believe that the start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of 3 hours at $107.38/hr for a practice administrator, 1 hour at $206.44/hr for a clinician, 1 hour at $43.96/hr for an LPN/medical assistant, 1 hour at $89.18/hr for a computer systems analyst, and 1 hour at $36.98/hr for a billing clerk.

The estimate for reviewing and incorporating measure specifications for the claims collection type is higher than that of QCDRs/Registries or eCQM collection types due to the more manual, and therefore, more burdensome nature of claims measures.

Considering both data submission and start-up requirements, the estimated time (per clinician) ranges from a minimum of 7.15 hours (0.15 hr + 7 hr) to a maximum of 14.2 hours (7.2 hr + 7 hr). In this regard the total annual burden ranges from 1,819,082 hours (7.15 hr × 254,417 clinicians) to 3,612,721 hours (14.2 hr × 254,417 clinicians). The estimated annual cost (per clinician) ranges from $712.08 ($13.38 + $322.14 + $89.18 + $43.96 + $36.98 + $206.44) to a maximum of $1,340.80 ($642.10 + $322.14 + $89.18 + $43.96 + $36.98 + $206.44). The total annual burden ranges from a minimum

of $183,189,701 (257,260 clinicians × $712.08) to a maximum of $344,934,208 (257,260 clinicians × $1,340.80).

Table 69 summarizes the range of total annual burden associated with clinicians submitting quality data via Medicare Part B claims.

Independent of the change in the number of respondents, the change in estimated time per clinician results in a burden adjustment of between −19,463 hours at −$1,860,081 (278,039 clinicians × −0.07 hr × $89.18/hr) and −1,000,941 hours at −$89,261,641 (278,039 clinicians × −3.6 hr × $89.18/hr). Accounting for the change in the time burden per respondent, the decrease in number of respondents results in a total adjustment of between −148,713 hours at −$14,810,552 (−20,799 respondents × $712.08/respondent) and −295,346 hours at −$27,887,299 (−20,779 respondents × $1,340.80/respondent). When these two adjustments are combined, the net adjustment ranges between −168,176 (−19,463 −148,713) hours at −$16,670,633 (−$1,860,081 −$14,810,552) and −1,296,287 (−1,000,941 −295,346) hours at −$117,148,940 (−$89,261,641 −$27,887,299).

TABLE 69—ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS USING THE MEDICARE PART B CLAIMS COLLECTION TYPE

	Minimum burden	Median burden	Maximum burden estimate
Number of Clinicians (a)	257,260	257,260	257,260
Hours Per Clinician to Submit Quality Data (b)	0.15	1.05	7.2
Number of Hours Practice Administrator Review Measure Specifications (c)	3	3	3
Number of Hours Computer Systems Analyst Review Measure Specifications (d)	1	1	1
Number of Hours LPN Review Measure Specifications (e)	1	1	1
Number of Hours Billing Clerk Review Measure Specifications (f)	1	1	1
Number of Hours Clinician Review Measure Specifications (g)	1	1	1
Annual Hours per Clinician (h) = (b) + (c) + (d) + (e) + (f) + (g)	7.15	8.05	14.2
Total Annual Hours (i) = (a) * (h)	1,839,409	2,070,943	3,653,092
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $89.18/hr.) (j)	$13.38	$93.64	$642.10
Cost to Review Measure Specifications (@ practice administrator's labor rate of $107.38/hr.) (k)	$322.14	$322.14	$322.14
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $89.18/hr.) (l)	$89.18	$89.18	$89.18
Cost to Review Measure Specifications (@ LPN's labor rate of $43.96/hr.) (m)	$43.96	$43.96	$43.96
Cost to Review Measure Specifications (@ billing clerk's labor rate of $36.98/hr.) (n)	$36.98	$36.98	$36.98
Cost to Review Measure Specifications (@ physician's labor rate of $206/44/hr.) (o)	$206.44	$206.44	$206.44
Total Annual Cost Per Clinician (p) = (j) + (k) + (l) + (m) + (n) + (o)	$712.08	$792.34	$1,340.80
Total Annual Cost (q) = (a) * (p)	$183,189,701	$203,837,388	$344,934,208

We received no public comments related to the burden estimates for quality performance category: Clinicians using the Medicare Part B claims collection type. However, the burden estimates have been updated from the CY 2019 PFS proposed rule to reflect availability of data from the 2017 MIPS performance period (83 FR 36023 through 36024).

Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types: This final rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to this CQM and QCDR collection types. However, we have adjusted the number of respondents based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As noted in Tables 64, 65, and 66, and based on 2017 MIPS performance period data, we assume that 324,693 clinicians will submit quality data as individuals or groups using MIPS CQM or QCDR collection types. Of these, we expect 71,439 clinicians, as shown in Table 65, will submit as individuals and 10,542 groups, as shown in Table 66, are expected to submit on behalf of the remaining 253,254 clinicians. Given that the number of measures required is the same for clinicians and groups, we expect the burden to be the same for each respondent collecting data via MIPS CQM or QCDR, whether the clinician is participating in MIPS as an individual or group.

Under the MIPS CQM and QCDR collection types, the individual clinician or group may either submit the quality measures data directly to us, log in and upload a file, or utilize a third-party intermediary to submit the data to us on the clinician's or group's behalf.

We estimate that the burden associated with the QCDR collection type is similar to the burden associated with the MIPS CQM collection type; therefore, we discuss the burden for both together below. For MIPS CQM and QCDR collection types, we estimate an additional time for respondents (individual clinicians and groups) to become familiar with MIPS submission requirements and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe that the burden for an individual clinician or group to review measure specifications and submit quality data total 9.083 hours at $858.86. This consists of 3 hours at $89.18/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $107.38/hr for a practice administrator, 1 hour at $89.18/hr for a computer systems analyst, 1 hour at $43.96/hr for a LPN/medical assistant, 1 hour at $36.98/hr for a billing clerk, and 1 hour at $206.44/hr for a clinician to review measure specifications. Additionally, clinicians and groups will need to authorize or instruct the qualified registry or QCDR to submit quality measures' results and numerator and denominator data on quality measures to us on their behalf. We

estimate that the time and effort associated with authorizing or instructing the quality registry or QCDR to submit this data will be approximately 5 minutes (0.083 hours) per clinician or group (respondent) for a cost of $7.40 (0.083 hr × $89.18/hr for a computer systems analyst).

In aggregate, we estimate an annual burden of 744,633 hours (9.083 hr/response × 81,981 groups plus clinicians submitting as individuals) at a cost of $71,016,861 (81,981 responses × $866.26/response). The decrease in number of respondents results in a total adjustment of −229,219 hours at −$21,860,937 (−25,236 respondents × $866.26/respondent). Based on these assumptions, we have estimated in Table 70 the burden for these submissions.

TABLE 70—ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (PARTICIPATING INDIVIDUALLY OR AS PART OF A GROUP) USING THE MIPS CQM/QCDR COLLECTION TYPE

	Burden estimate
Number of clinicians submitting as individuals (a)	71,439
Number of groups submitting via QCDR or MIPS CQM on behalf of individual clinicians (b)	10,542
Number of Respondents (groups plus clinicians submitting as individuals) (c) = (a) + (b)	81,981
Hours Per Respondent to Report Quality Data (d)	3
Number of Hours Practice Administrator Review Measure Specifications (e)	2
Number of Hours Computer Systems Analyst Review Measure Specifications (f)	1
Number of Hours LPN Review Measure Specifications (g)	1
Number of Hours Billing Clerk Review Measure Specifications (h)	1
Number of Hours Clinician Review Measure Specifications (i)	1
Number of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf (j)	0.083
Annual Hours Per Respondent (k) = (d) + (e) + (f) + (g) + (h) + (i) + (j)	9.083
Total Annual Hours (l) = (c) * (k)	744,633
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $89.18/hr.) (m)	$267.54
Cost to Review Measure Specifications (@ practice administrator's labor rate of $107.38/hr.) (n)	$214.76
Cost Computer System's Analyst Review Measure Specifications (@ computer systems analyst's labor rate of $89.18/hr.) (o)	$89.18
Cost LPN Review Measure Specifications (@ LPN's labor rate of $43.96/hr.) (p)	$43.96
Cost Billing Clerk Review Measure Specifications (@ clerk's labor rate of $36.98/hr.) (q)	$36.98
Cost Clinician Review Measure Specifications (@ physician's labor rate of $206.44/hr.) (r)	$206.44
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (@ computer systems analyst's labor rate of $89.18/hr.) (s)	$7.40
Total Annual Cost Per Respondent (t) = (m) + (n) + (o) + (p) + (q) + (r) + (s)	$866.26
Total Annual Cost (u) = (c) * (t)	$71,016,861

We received no public comments related to the burden estimates for quality performance category: Clinicians using the MIPS CQM/QCDR collection type. However, the burden estimates have been updated from the CY 2019 PFS proposed rule to reflect availability of data from the 2017 MIPS performance period (83 FR 36024 through 36025).

Quality Data Submission by Clinicians and Groups: eCQM Collection Type: This final rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the eCQM collection type. However, we have adjusted the number of respondents based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As noted in Tables 64, 65, and 66, based on 2017 MIPS performance period data, we assume that 243,062 clinicians will elect to use the eCQM collection type; 47,557 clinicians are expected to submit eCQMs as individuals; and 4,304 groups are expected to submit eCQMs on behalf of the remaining 195,505 clinicians. We expect the burden to be the same for each respondent using the eCQM collection type, whether the clinician is participating in MIPS as an individual or group.

In the CY 2018 Quality Payment Program final rule, the time required for users to obtain an account for the CMS Enterprise Portal was included in this Quality Data Submission by Clinicians and Groups: eCQM Collection Type ICR (82 FR 53914). However, in this final rule, we are finalizing a separate ICR for this activity (now described as the Quality Payment Program Identity Management Application Process; see Table 68) and therefore, reduce (by 1 hour) our per respondent burden estimate for this ICR commensurately. We have also adjusted the number of respondents based on more recent data.

Under the eCQM collection type, the individual clinician or group may either submit the quality measures data directly to us from their eCQM, log in and upload a file, or utilize a health IT vendor to submit the data to us on the clinician's or group's behalf.

To prepare for the eCQM collection type, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from eCQMs, select the appropriate quality measures, extract the necessary clinical data from their CEHRT, and submit the necessary data to the CMS-designated clinical data warehouse or use a health IT vendor to submit the data on behalf of the clinician or group. We assume the burden for collecting quality measures data via eCQM is similar for clinicians and groups who submit their data directly to us from their CEHRT and clinicians and groups who use a health IT vendor to submit the data on their behalf. This includes extracting the necessary clinical data from their CEHRT and submitting the necessary data to the CMS-designated clinical data warehouse.

We continue to estimate that it will take no more than 2 hours at $89.18/hr for a computer systems analyst to submit the actual data file. The burden

will also involve becoming familiar with MIPS submission. In this regard, we estimate it will take 6 hours for a clinician or group to review measure specifications. Of that time, we estimate 2 hours at $107.38/hr for a practice administrator, 1 hour at $206.44/hr for a clinician, 1 hour at $89.18/hr for a computer systems analyst, 1 hour at $43.96/hr for a LPN/medical assistant, and 1 hour at $36.98/hr for a billing clerk.

In aggregate we estimate an annual burden of 414,888 hours (8 hr × 51,861 groups and clinicians submitting as individuals) at a cost of $39,916,374 (51,861 responses × $769.68/response) (see Table 71).

Independent of the change in the number of respondents, removing the time burden associated with completing the Quality Payment Program Identity Management Application Process results in an adjustment to the total burden of −54,218 hours and −$4,835,161 (54,218 respondents × −1 hr × $89.18/hr). Accounting for the change in the per respondent time estimate, the decrease in number of respondents results in a total adjustment of −18,856 hours at −$1,814,136 (−2,357 respondents × $769.68/respondent). When these two adjustments are combined, the net adjustment is −73,074 (−54,218–18,856) hours at −$6,649,297 (−$4,835,161–$1,814,136).

TABLE 71—ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (SUBMITTING INDIVIDUALLY OR AS PART OF A GROUP) USING THE eCQM COLLECTION TYPE

	Burden estimate
Number of clinicians submitting as individuals (a)	47,557
Number of Groups submitting via EHR on behalf of individual clinicians (b)	4,304
Number of Respondents (groups and clinicians submitting as individuals) (c) = (a) + (b)	51,861
Hours Per Respondent to Submit MIPS Quality Data File to CMS (d)	2
Number of Hours Practice Administrator Review Measure Specifications (e)	2
Number of Hours Computer Systems Analyst Review Measure Specifications (f)	1
Number of Hours LPN Review Measure Specifications (g)	1
Number of Hours Billing Clerk Review Measure Specifications (h)	1
Number of Hours Clinicians Review Measure Specifications (i)	1
Annual Hours Per Respondent (j) = (d) + (e) + (f) + (g) + (h) + (i)	8
Total Annual Hours (k) = (c) * (j)	414,888
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $88.10/hr.) (l)	$178.36
Cost to Review Measure Specifications (@ practice administrator's labor rate of $105.16/hr.) (m)	$214.76
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $88.10/hr.) (n)	$89.18
Cost to Review Measure Specifications (@ LPN's labor rate of $43.12/hr.) (o)	$43.96
Cost to Review Measure Specifications (@ clerk's labor rate of $36.12/hr.) (p)	$36.98
Cost to D21Review Measure Specifications (@ physician's labor rate of $202.08/hr.) (q)	$206.44
Total Cost Per Respondent (r) = (l) + (m) + (n) + (o) + (p) + (q)	$769.68
Total Annual Cost (s) = (c) * (r)	$39,916,374

We received no public comments related to the burden estimates for quality performance category: Clinicians using the eCQM collection type. However, the burden estimates have been updated from the CY 2019 PFS proposed rule to reflect availability of data from the 2017 MIPS performance period (83 FR 36025 through 36026).

Quality Data Submission via CMS Web Interface: The finalized requirements and burden associated with CMS Web Interface data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As discussed in section III.I.3.h.(2)(a)(iii)(A)(bb) of this rule, we are finalizing a 33 percent reduction in the number of measures (from 15 to 10 measures) for which clinicians are required to submit quality data via the CMS Web Interface. To account for the decrease in measures, we are also finalizing a decrease to our per respondent time estimate.

We assume that 286 groups will submit quality data via the CMS Web Interface based on the number of groups who registered for using the CMS Web Interface during the 2018 MIPS performance period. This is a decrease of 10 groups from the currently approved number provided in the CY 2018 Quality Payment Program final rule (82 FR 53915) due to receipt of more current data. We estimate that approximately 91,757 clinicians will submit via this method.

The burden associated with the group submission requirements is the time and effort associated with submitting data on a sample of the organization's beneficiaries that is prepopulated in the CMS Web Interface. In the CY 2018 Quality Payment Program final rule, we estimated that it would take, on average, 74 hours for each group to submit quality measures data via the CMS Web Interface (82 FR 53915). Of those hours, approximately half (or 37 hr) are unaffected by the number of required measures while the other half (37 hr) are affected proportionately by the number of required measures (37 hr × 33 percent reduction = 24.67 hr). Accounting for the finalized reduction in required measures, our revised estimate for the time to submit data via the CMS Web Interface for the 2019 MIPS performance period is 61.67 hours (37 hr + 24.67 hr), a reduction of 12.33 hours or approximately 18 percent of the currently approved 74 hour time estimate. Considering only the time which varies based on the number of required measures, the process of entering or uploading data requires approximately 2.74 hours of a computer systems analyst's time per measure (24.67 hr/9 measures). Our estimate for submission includes the time needed for each group to populate data fields in the web interface with information on approximately 248 eligible assigned Medicare beneficiaries and submit the data (we will partially pre-populate the CMS Web Interface with claims data

from their Medicare Part A and B beneficiaries). The patient data either can be manually entered, uploaded into the CMS Web Interface via a standard file format, which can be populated by CEHRT, or submitted directly. Each group must provide data on 248 eligible assigned Medicare beneficiaries (or all eligible assigned Medicare beneficiaries if the pool of eligible assigned beneficiaries is less than 248) for each measure. In aggregate, we estimate an annual burden of 17,637 hours (286 groups × 61.67 hr) at a cost of $1,572,837 (17,637 hr × $89.18/hr).

Independent of the change in the number of respondents, the decrease in total burden resulting from the decrease in required measures is −3,650 hours at −$325,566 (296 groups × −12.33 hr × $89.18/hr). Accounting for the decrease in total time, the decrease in number of respondents results in a total adjustment of −616.7 hours at −$54,994 (−10 respondents × 61.67 hr × $89.18/hr). When these adjustments are combined, the net adjustment is −4,267 (−3,650–617) hours at −$380,560 (−$325,566–$54,994).

Based on the assumptions discussed in this section, Table 72 summarizes the burden for groups submitting to MIPS via the CMS Web Interface.

TABLE 72—ESTIMATED BURDEN FOR QUALITY DATA SUBMISSION VIA THE CMS WEB INTERFACE

	Burden estimate
Number of Eligible Group Practices (a)	286
Total Annual Hours Per Group to Submit (b)	61.67
Total Annual Hours (c) = (a) * (b)	17,637
Cost Per Group to Report (@ computer systems analyst's labor rate of $89.18/hr.) (d)	$5,499
Total Annual Cost (e) = (a) * (d)	$1,572,837

We received no public comments related to the burden estimates for quality data submission via the CMS Web Interface. However, the burden estimates have been updated from the CY 2019 PFS proposed rule to reflect the change in the number of required measures from 9 in the proposed rule to 10 in the final rule (83 FR 36026 through 36027).

Beneficiary Responses to CAHPS for MIPS Survey: This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the CAHPS for MIPS survey. However, we have adjusted our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1222 (CMS–10450).

In this final rule, we have adjusted the number of groups electing to report on the CAHPS for MIPS survey as well as the average number of beneficiaries per group based on more recent data.

Under MIPS, groups of 25 or more clinicians can elect to contract with a CMS-approved survey vendor and use the CAHPS for MIPS survey as one of their 6 required quality measures. Beneficiaries that choose to respond to the CAHPS for MIPS survey will experience burden.

The usual practice in estimating the burden on public respondents to surveys such as CAHPS is to assume that respondent time is valued, on average, at civilian wage rates. As explained in section V.A. of this final rule, BLS data sets out an average hourly wage for civilians in all occupations at $24.34/hr. Although most Medicare beneficiaries are retired, we believe that their time value is unlikely to depart significantly from prior earnings expense, and we have used the average hourly wage to compute our cost estimate for the beneficiaries' time.

For the 2019 MIPS performance period, we assume that 143 groups will elect to report on the CAHPS for MIPS survey, which is equal to the number of groups that have registered and have a sufficient beneficiary sample size to conduct the CAHPS for MIPS survey in the 2018 MIPS performance period; a decrease of 318 from the 461 groups currently approved by OMB. Table 73 shows the estimated annual burden for beneficiaries to participate in the CAHPS for MIPS Survey. Based on the number of complete and partially complete surveys for groups participating in CAHPS for MIPS survey administration for the 2018 MIPS performance period, we assume that an average of 273 beneficiaries will respond per group for the 2019 MIPS performance period. Therefore, the CAHPS for MIPS survey will be administered to approximately 39,039 beneficiaries per year (143 groups × an average of 273 beneficiaries per group responding). This is a decrease of 93,268 from our currently approved 132,307 beneficiary estimate.

The CAHPS for MIPS survey that will be administered in the 2019 MIPS performance period is unchanged from the survey administered in the 2018 MIPS performance period. In that regard, we continue to estimate an average administration time of 12.9 minutes (or 0.215 hr) at a pace of 4.5 items per minute for the English version of the survey. For the Spanish version, we estimate an average administration time of 15.5 minutes (assuming 20 percent more words in the Spanish translation). However, since less than 1 percent of surveys were administered in Spanish for reporting year 2016, our burden estimate reflects the time for administering the English version of the survey.

Given that we expect approximately 39,039 respondents, we estimate an annual burden of 8,393 hours (39,039 respondents × 0.215 hr/respondent) at a cost of $204,286 (8,393 hr × $24.34/hr).

The decrease in the number of beneficiaries responding to the CAHPS for MIPS survey results in an adjustment to the total time burden of −20,715 hours and −$503,556 (−93,268 beneficiaries × 0.215 hr × $24.34/hr).

TABLE 73—ESTIMATED BURDEN FOR BENEFICIARY PARTICIPATION IN CAHPS FOR MIPS SURVEY

	Burden estimate
Number of Eligible Group Practices Administering CAHPS for MIPS (a)	143
Number of Beneficiaries Per Group Responding to Survey (b)	273
Number of Total Beneficiary Respondents (c) = (a) * (b)	39,039
Number of Hours Per Beneficiary Respondent (d)	0.215
Cost (@ labor rate of $24.34/hr.) (e)	$24.34/hr
Total Annual Hours (f) = (c) * (d)	8,393
Total Annual Cost for Beneficiaries Responding to CAHPS for MIPS (g) = (c) * (e)	$204,286

We received no public comments related to the burden estimates for beneficiary participation in CAHPS for MIPS survey. However, the burden estimates have been updated from the CY 2019 PFS proposed rule to reflect availability of data from the 2018 MIPS performance period (83 FR 36027).

Group Registration for CMS Web Interface: This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the group registration for CMS Web Interface. However, we have adjusted our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1222 (CMS–10450).

In this final rule, we have adjusted the number of respondents based on more recent data and adjusted our per response time estimate based on our review of the currently approved estimates against the existing registration process.

Groups interested in participating in MIPS using the CMS Web Interface for the first time must complete an on-line registration process. After first time registration, groups will only need to opt out if they are not going to continue to submit via the CMS Web Interface. In Table 74, we estimate that the registration process for groups under MIPS involves approximately 0.25 hours at $89.18/hr for a computer systems analyst (or their equivalent) to register the group. Although the registration process remains unchanged from the CY 2018 Quality Payment Program final rule, a review of the steps required for registration warranted a reduction of 0.75 hours in estimated burden per group (82 FR 53917).

We assume that approximately 67 groups will elect to use the CMS Web Interface for the first time during the 2019 MIPS performance period based on the number of new registrations received during the CY 2018 registration period; an increase of 57 compared to the number of groups currently approved by OMB under control number 0938–1314 (CMS–10621). In aggregate, we estimate a burden of 16.75 hours (67 new registrations $\times$ 0.25 hr/registration) at a cost of $1,494 (16.75 hr $\times$ $89.18/hr).

Independent of the decrease in time burden per group, the increase in the number of groups registering to submit MIPS data via the CMS Web Interface results in an adjustment to the total time burden of 57 hours at $5,083 (57 groups $\times$ 1 hr $\times$ $89.18/hr). Accounting for the increase in the number of groups, the decrease in time burden per group to register results in an adjustment to the total burden of -50.25 hours at $-$4,481 (67 groups $\times$ -0.75 hrs $\times$ $89.18/hr). When these adjustments are combined, the net adjustment is 6.75 hours ($57-50.25$) at $602 ($5,083 $-$ $4,481).

TABLE 74—ESTIMATED BURDEN FOR GROUP REGISTRATION FOR CMS WEB INTERFACE

	Burden estimate
Number of New Groups Registering for CMS Web Interface (a)	67
Annual Hours Per Group (b)	0.25
Total Annual Hours (c) = (a) * (b)	16.75
Labor Rate to Register for CMS Web Interface @ computer systems analyst's labor rate) (d)	$89.18/hr
Total Annual Cost for CMS Web Interface Group Registration (e) = (a) * (d)	$1,494

We received no public comments related to the burden estimates for group registration for the CMS Web Interface. The burden estimates have not been updated from the CY 2019 PFS proposed rule (83 FR 36027 through 36028).

Group Registration for CAHPS for MIPS Survey: This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the group registration for the CAHPS for MIPS Survey. However, we have adjusted our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1222 (CMS–10450).

In this final rule, we have adjusted our currently approved number of respondents based on more recent data and adjusted our per respondent time estimate based on our review of the current burden estimates against the existing registration process.

Under MIPS, the CAHPS for MIPS survey counts for 1 measure toward the MIPS quality performance category and, as a patient experience measure, it also fulfills the requirement to submit at least one high priority measure in the absence of an applicable outcome measure. Groups that wish to administer the CAHPS for MIPS survey must register by June of the applicable 12-month performance period, and electronically notify CMS of which vendor they have selected to administer

the survey on their behalf. For the 2019 MIPS performance period, we assume that 282 groups will enroll in the MIPS for CAHPS survey based on the number of groups which elected to register during the CY 2018 registration period; a decrease of 179 compared to the number of groups currently approved by OMB under the aforementioned control number (82 FR 53917).

As shown in Table 75, we assume that the staff involved in the group registration for CAHPS for MIPS Survey will mainly be computer systems analysts (or their equivalent) who have an average labor cost of $89.18/hr. We assume the CAHPS for MIPS Survey registration burden consists of 0.25 hours to register for the survey as well as 0.5 hours to select the CAHPS for MIPS Survey vendor that will be used and electronically notifying CMS of this selection. In this regard, the total time for CAHPS for MIPS registration is 0.75 hours. Although the registration process remains unchanged from the CY 2018 Quality Payment Program final rule, after we reviewed the steps required for registration more thoroughly, we believe that the burden was less than we had originally estimated. Therefore, we have adjusted the estimated burden from 1.5 hours to 0.75 hours per respondent.

In aggregate, we estimate an annual burden of 211.50 hours (282 groups × 0.75 hr per group) at a cost of $18,862 (211.50 hr × $89.18/hr).

Independent of the change in time per group, the decrease in the number of groups registering results is an adjustment to the total burden of −268.5 hours at −$23,945 (−179 groups × 1.5 hrs × $89.18/hr). Accounting for the decrease in the number of groups registering, the decrease in time per group to register results in an adjustment to the total burden of −211.5 hours at −$18,862 (282 groups × −0.75 hr × $89.18/hr). When these adjustments are combined, the net adjustment is −480 hours (−268.5 − 211.5) at −$42,807 (−$23,945 − $18,862).

TABLE 75—ESTIMATED BURDEN FOR GROUP REGISTRATION FOR CAHPS FOR MIPS SURVEY

	Burden estimate
# of Groups Registering for CAHPS (a)	282
Total Annual Hours for CAHPS Registration (b)	0.75
Total Annual Hours for CAHPS Registration (c) = (a) * (b)	211.5
Labor Rate to Register for CAHPS (computer systems analyst) (d)	$89.18/hr
Total Annual Cost for CAHPS Registration (e) = (a) * (d)	$18,862

We received no public comments related to the burden estimates for group registration for the CAHPS for MIPS survey. However, the burden estimates have been updated from the CY 2019 PFS proposed rule to reflect availability of data from the 2018 MIPS performance period (83 FR 36028 through 36029).

9. Quality Payment Program ICRs Regarding the Nomination of Quality Measures

This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the nomination of quality measures. However, we have adjusted our currently approved burden estimates based on more recent data. We have also accounted for burden associated with policies that have been finalized but whose burden were erroneously excluded from our estimates. The new and adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As discussed in section III.I.3.h.(2)(b)(i) of this final rule, quality measures are selected annually through a call for quality measures under consideration, with a final list of quality measures being published in the **Federal Register** by November 1 of each year. Under section 1848(q)(2)(D)(ii) of the Act, the Secretary must solicit a ''Call for Quality Measures'' each year. Specifically, the Secretary must request that eligible clinician organizations and other relevant stakeholders identify and submit quality measures to be considered for selection in the annual list of MIPS quality measures, as well as updates to the measures. Under section 1848(q)(2)(D)(ii) of the Act, eligible clinician organizations are professional organizations as defined by nationally recognized specialty boards of certification or equivalent certification boards.

As we described in the CY 2017 Quality Payment Program final rule (81 FR 77137), we will accept quality measures submissions at any time, but only measures submitted during the timeframe provided by us through the pre-rulemaking process of each year will be considered for inclusion in the annual list of MIPS quality measures for the performance period beginning 2 years after the measure is submitted. This process is consistent with the pre-rulemaking process and the annual call for measures, which are further described at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rule-Making.html*.

To identify and submit a quality measure, eligible clinician organizations and other relevant stakeholders use a one-page online form that requests information on background, a gap analysis which includes evidence for the measure, reliability, validity, endorsement and a summary which includes how the proposed measure relates to the Quality Payment Program and the rationale for the measure. In addition, proposed measures must be accompanied by a completed Peer Review Journal Article form.

As shown in Table 76, we estimate that approximately 140 organizations, including clinicians, CEHRT developers, and vendors, will submit measures for the Call for Quality Measures process; an increase of 100 compared to the number of organizations currently approved by OMB. In keeping with the focus on clinicians as the primary source for recommending new quality measures, we are using practice administrators and clinician time for our burden estimates. We also estimate it will take 0.5 hours per organization to submit an activity to us, consisting of 0.3 hours at $107.38/hr for a practice administrator to make a strategic decision to nominate and submit a measure and 0.2 hours at $206.44/hr for clinician review time.

The 0.5 hour estimate assumes that submitters will have the necessary information to complete the nomination form readily available, which we believe is a reasonable assumption. Additionally, some submitters familiar

with the process or who are submitting multiple measures may require significantly less time, while other submitters may require more if the opposite is true; on average we believe 0.5 hours is a reasonable average across all submitters.

Consistent with the CY 2017 Quality Payment Program final rule, we also estimate it will take 4 hours at $206.44/hr for a clinician (or equivalent) to complete the Peer Review Journal Article Form (81 FR 77153 through 77155). This assumes that measure information is available and testing is complete in order to have the necessary information to complete the form, which we believe is a reasonable assumption. Although the requirement for completing the Peer Review Journal Article was previously included in the CY 2017 Quality Payment Program final rule, the time required for completing the form was erroneously excluded from our burden estimates.

As shown in Table 76, in aggregate we estimate an annual burden of 630 hours (140 organizations × 4.5 hr/response) at a cost of $125,896 (140 × [(0.3 hr × $107.38/hr) + (4.2 hr × $206.44/hr)].

Independent of the change in time per organization, the change in the number of organizations nominating new quality measures results in an adjustment of 50 hours at $7,350 (100 organizations × [(0.3 hr × $107.38/hr) + (0.2 hr x $206.44/hr)]). When accounting for the change in respondents, the change in burden to nominate a quality measure results in an adjustment of 560 hours at $115,606 (140 organizations × 4 hr × $206.44/hr). When these adjustments are combined, the total adjustment is 610 hours (560 + 50) at $122,956 ($7,350 + $115,606).

TABLE 76—ESTIMATED BURDEN FOR CALL FOR QUALITY MEASURES

	Burden estimate
# of Organizations Nominating New Quality Measures (a)	140
# of Hours Per Practice Administrator to Identify and Propose Measure (b)	0.30
# of Hours Per Clinician to Identify Measure (c)	0.20
# of Hours Per Clinician to Complete Peer Review Article Form (d)	4.00
Annual Hours Per Response (e) = (b) + (c) + (d)	4.50
Total Annual Hours (f) = (a) * (e)	630
Cost to Identify and Submit Measure (@ practice administrator's labor rate of $107.38/hr.) (g)	$32.21
Cost to Identify Quality Measure and Complete Peer Review Article Form (@ physician's labor rate of $206.44/hr.) (h)	$867.05
Total Annual Cost Per Respondent (i) = (g) + (h)	$899.26
Total Annual Cost (j) = (a) * (i)	$125,896

We received no public comments related to the burden estimates for the Call for Quality Measures. The burden estimates have not been updated from the CY 2019 PFS proposed rule (83 FR 36029 through 36030).

10. Quality Payment Program ICRs Regarding Promoting Interoperability Data (§§ 414.1375 and 414.1380)

The finalized requirements and burden discussed under this section will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

For the 2019 MIPS performance period, clinicians and groups can submit Promoting Interoperability data through direct, log in and upload, or log in and attest submission types. We have worked to further align the Promoting Interoperability performance category with other MIPS performance categories. With the exception of submitters who elect to use the log in and attest submission type for the Promoting Interoperability performance category which is not available for the quality performance category, we anticipate that most organizations will use the same data submission type for the both of these performance categories and that the clinicians, practice managers, and computer systems analysts involved in supporting the quality data submission will also support the Promoting Interoperability data submission process. Hence, the following burden estimates show only incremental hours required above and beyond the time already accounted for in the quality data submission process. Although this analysis assesses burden by performance category and submission type, we emphasize that MIPS is a consolidated program and submission analysis and decisions are expected to be made for the program as a whole.

Reweighting Applications for Promoting Interoperability and Other Performance Categories: As established in the CY 2017 and CY 2018 Quality Payment Program final rules, MIPS eligible clinicians who meet the criteria for a significant hardship or other type of exception may submit an application requesting a zero percent weighting for the Promoting Interoperability performance category in the following circumstances: insufficient internet connectivity, extreme and uncontrollable circumstances, lack of control over the availability of CEHRT, clinicians who are in a small practice, and decertified EHR technology (81 FR 77240 through 77243 and 82 FR 53680 through 53686). In addition, as finalized in the CY 2018 Quality Payment Program final rule, MIPS eligible clinicians and groups citing extreme and uncontrollable circumstances may also apply for a reweighting of the quality, cost, and/or improvement activities performance categories (82 FR 53783 through 53785). Respondents who apply for a reweighting for any of these performance categories have the option of applying for reweighting for the Promoting Interoperability performance category on the same online form. Since we do not have data on the number of reweighting applications submitted for the 2018 MIPS performance period for this rule, we assume that respondents applying for a reweighting of the Promoting Interoperability performance category due to extreme and uncontrollable circumstances will also request a reweighting of at least one of the other performance categories simultaneously and not submit multiple reweighting applications. As data availability allows, we will estimate the reporting burden for each reweighting application under separate ICRs in future rulemaking.

Table 77 summarizes the burden for clinicians to apply for reweighting the

Promoting Interoperability performance category to zero percent due to a significant hardship exception (including a significant hardship exception for small practices) or as a result of a decertification of an EHR. Based on the number of reweighting applications received for the 2017 MIPS performance period, we assume 6,041 respondents (eligible clinicians or groups) will submit a request to reweight the Promoting Interoperability performance category to zero percent due to a significant hardship (including clinicians in small practices) or EHR decertification. We estimate that 3,344 respondents (eligible clinicians or groups) will submit a request for reweighting the Promoting Interoperability performance category to zero percent due to extreme and uncontrollable circumstances, insufficient internet connectivity, lack of control over the availability of CEHRT, or as a result of a decertification of an EHR. An additional 2,697 respondents will submit a request for reweighting the Promoting Interoperability performance category to zero percent as a small practice experiencing a significant hardship. In total, this represents a decrease of 34,604 from the number of respondents currently approved by OMB. In the CY 2019 PFS proposed rule, we lacked the detailed data necessary to independently estimate the number of reweighting applications submitted by clinicians in a small practice who were of an eligible clinician type and are not eligible to have the Promoting Interoperability performance category reweighted for any other reason (for example, because they are hospital-based, ASC-based, or non-patient facing), and therefore, assumed all clinicians in small practices that met these criteria would apply for reweighting of the Promoting Interoperability performance category. Data from the 2017 MIPS performance period has sufficient detail to allow for this analysis, resulting in a decrease of 78,573 from the estimate of 81,270 clinicians in a small practice cited in the CY 2019 PFS proposed rule (83 FR 36030).

The total of 6,041 respondents represents a decrease of 34,604 from the number of respondents currently approved by OMB. The application to request a reweighting to zero percent only for the Promoting Interoperability performance category is a short online form that requires identifying the type of hardship experienced or whether decertification of an EHR has occurred and a description of how the circumstances impair the clinician or group's ability to submit Promoting Interoperability data, as well as some proof of circumstances beyond the clinician's control. The application for reweighting of the quality, cost, Promoting Interoperability, and/or improvement activities performance categories due to extreme and uncontrollable circumstances requires the same information with the exception of there being only one option for the type of hardship experienced. We estimate it will take 0.25 hours at $89.18/hr for a computer system analyst to submit the application. This is a reduction from the 0.5 hours estimated in the CY 2018 Quality Payment Program final rule due to a revised assessment of the application process (82 FR 53918). As shown in Table 77, in aggregate, we estimate an annual burden of 1,510.25 hours (6,041 applications × 0.25 hr/application) at a cost of $134,684 (1,510.25 hr × $89.18/hr).

Independent of the change to the number of respondents, the decrease in the amount of time to submit a reweighting application results in an adjustment of −10,161.25 hours at −$906,180 (40,645 respondents × −0.25 hr × $89.18/hr). Accounting for the decrease in time per respondent, the decrease in the number of respondents submitting reweighting applications results in an adjustment of −8,651 hours at −$771,496 (−34,604 respondents × 0.25 hr × $89.18hr). When these adjustments are combined, the total adjustment is −18,812.25 hours (−10,161.25 − 8,651) at $1,677,676 (−$906,180 − $771,496).

TABLE 77—ESTIMATED BURDEN FOR REWEIGHTING APPLICATIONS FOR PROMOTING INTEROPERABILITY AND OTHER PERFORMANCE CATEGORIES

	Burden estimate
# of Eligible Clinicians or Groups Applying Due to Significant Hardship and Other Exceptions (a)	3,344
# of Eligible Clinicians or Groups Applying Due to Significant Hardship for Small Practice (b)	2,697
Total Respondents Due to Hardships, Other Exceptions and Hardships for Small Practices (c)	6,041
Hours Per Applicant per application submission (d)	0.25
Total Annual Hours (e) = (a) * (c)	1,510.25
Labor Rate for a computer systems analyst (f)	$89.18/hr
Total Annual Cost (g) = (a) * (f)	$134,684

The following is a summary of the public comments received on the Quality Payment Program ICRs regarding reweighting applications for Promoting Interoperability and other performance categories:

Comment: One commenter noted that CMS's estimate of 15 minutes to complete and submit the Promoting Interoperability reweighting application is low and should be increased to an estimate of between 30 minutes and 1 hour.

Response: We understand that some respondents may require additional time to submit a reweighting application above the 15 minutes we estimate, but we believe this estimate is a reasonable average across all respondents as the application process requires limited basic information about the clinician or submitter, a small number of check boxes and drop-down selections, and a free text field to provide justification for the requested application. In addition, we believe increased familiarity with the process in its second year also reduces the average time across all respondents.

After consideration of public comments, we are making no changes to our estimates as a result of public comments received. However, the burden estimates have been updated from the CY 2019 PFS proposed rule to reflect availability of data from the 2017 MIPS performance period (83 FR 36030 through 36031).

Submitting Promoting Interoperability Data: In this final rule, we have adjusted the estimated number of respondents based on data from the 2017 MIPS performance period and the estimated per respondent time due to the net reduction of 3 measures (6 removed measures and 3 new measures) for which clinicians are required to submit data, which we are finalizing as discussed in section III.I.3.h.(5)(f) of this final rule.

A variety of organizations will submit Promoting Interoperability data on behalf of clinicians. Clinicians not participating in a MIPS APM may submit data as individuals or as part of a group. In the CY 2017 Quality Payment Program final rule (81 FR 77258 through 77260, 77262 through 77264), we established that eligible clinicians in MIPS APMS other than the Shared Savings Program may submit data for the Promoting Interoperability performance category as individuals or as part of a group, whereas eligible clinicians participating in the Shared Savings Program are limited to submitting data through the ACO participant TIN. In section III.I.3.h.(6)(d)(ii) of this final rule, we are finalizing our proposal to extend this flexibility to allow for both individual and group reporting by eligible clinicians participating in the Shared Savings Program.

As shown in Table 78, based on data from the 2017 MIPS performance period, we estimate that a total of 93,933 respondents consisting of 81,456 individual MIPS eligible clinicians and 12,413 groups will submit Promoting Interoperability data. Similar to the process shown in Table 66 for groups reporting via QCDR/MIPS CQM and eCQM collection types, we have adjusted the group reporting data from the 2017 MIPS performance period to account for virtual groups, as the option to submit data as a virtual group was not available until the 2018 MIPS performance period. These estimates reflect that under the policies in the CY 2017 Quality Payment Program final rule and in the CY 2018 Quality Payment Program final rule, certain MIPS eligible clinicians will be eligible for automatic reweighting of the Promoting Interoperability performance category to zero percent, including MIPS eligible clinicians that are hospital-based, ambulatory surgical center-based, non-patient facing clinicians, physician assistants, nurse practitioners, clinician nurse specialists, and certified registered nurse anesthetists (81 FR 77238 through 77245 and 82 FR 53680 through 53687). As discussed in section III.I.3.h.(5)(h)(ii) of this final rule, starting with the 2021 MIPS payment year, we are finalizing a policy to automatically reweight the Promoting Interoperability performance category for clinician types new to MIPS: Physical therapists; occupational therapists; qualified speech-language pathologists or qualified audiologist; clinical psychologists; and registered dieticians or nutrition professionals. These estimates also account for the reweighting policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules, including exceptions for MIPS eligible clinicians who have experienced a significant hardship (including clinicians who are in small practices), as well as exceptions due to decertification of an EHR.

Further, we assume that Shared Savings Program Track 1 ACOs will submit data at the ACO participant TIN-level, APM Entities electing the one-sided track in the CEC model will submit data at the group TIN-level, and APM Entities in the OCM (one-sided risk arrangement) will submit data at APM Entity level; these entities are included in our estimate of the number of groups submitting data. Our respondent estimate is based on existing data and does not consider policies finalized in section V of this final rule, as well as additional policies that were proposed in the August 2018 proposed rule and may be finalized in a future rule, which may change the number of Shared Saving Program ACOs that are required to submit Promoting Interoperability data for future years.[45]

TABLE 78—ESTIMATED NUMBER OF RESPONDENTS TO SUBMIT PROMOTING INTEROPERABILITY PERFORMANCE DATA ON BEHALF OF CLINICIANS

	Number of respondents
Number of individual clinicians to submit Promoting Interoperability (a)	81,456
Number of groups to submit Promoting Interoperability(b)	12,477
Subtract: Number of groups to submit Promoting Interoperability on behalf of clinicians in Quality Payment Program Year 3 that will submit as virtual groups in Quality Payment Program Year 3 (c)	80
Add in: Number of virtual groups to submit Promoting Interoperability on behalf of clinicians in Quality Payment Program Year 3 (d)	16
Number of groups to submit Promoting Interoperability on behalf of clinicians in Quality Payment Program Year 3 (e) = (b) − (c) + (d)	12,413
Total (f) = (a) + (e)	93,869

In the CY 2018 Quality Payment Program final rule, we estimated it takes 3 hours for a computer system analyst to collect and submit Promoting Interoperability performance category data (82 FR 53920). For this final rule, we estimate the time required to submit such data should be reduced by 20 minutes to 2.67 hours due to the reduction in the number of measures for which clinicians are required to submit data, which we are finalizing as discussed in section III.I.3.h.(5)(f) of this final rule. As shown in Table 78, the total time for an organization to submit data on the specified Promoting Interoperability objectives and measures is estimated to be 250,317 hours (93,869 respondents × 2.67 incremental hours for a computer analyst's time above and beyond the clinician, practice manager, and computer system's analyst time required to submit quality data) at a cost of $22,323,300 (250,317 hr × $89.18/hr).

Independent of the change in the number of respondents, the reduction in estimated time to submit Promoting Interoperability data results in a decrease in burden of −72,738.33 hours at −$6,486,805 (218,215 respondents × −0.33 hr × $89.18/hr). Accounting for the decreased per respondent time, the decrease in the number of respondents

[45] *https://www.gpo.gov/fdsys/pkg/FR-2018-08-17/pdf/2018-17101.pdf.*

results in an adjustment to the total burden of −331,589.33 hours at −$29,571,137 (−124,346 respondents × 2.67 hrs × $89.18/hr). When these adjustments are combined, the total adjustment is −404,327.67 hours (−72,738.33 −331,589.33) at −$36,057,941 (−$6,486,805 −$29,571,137).

TABLE 79—ESTIMATED BURDEN FOR PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY DATA SUBMISSION

	Burden estimate
Number of individual clinicians to submit Promoting Interoperability (a)	81,456
Number of groups to submit Promoting Interoperability (b)	12,413
Total (c) = (a) + (b)	93,869
Total Annual Hours Per Respondent (b)	2.67
Total Annual Hours (c) = (a) * (b)	250,317
Labor rate for a computer systems analyst to submit Promoting Interoperability data/hr.) (d)	$89.18/hr
Total Annual Cost (e) = (a) * (d)	$22,323,300

The following is a summary of the public comments received on the Quality Payment Program ICRs regarding Promoting Interoperability Data:

Comment: One commenter noted that CMS should consider and reduce the operational burden imposed on clinicians and medical practice staff by the required measures and reporting processes associated with the Quality Payment Program specifically and all quality reporting programs in general. The commenter cited the 20 minute reduction in burden associated with the proposed reduction in Promoting Interoperability measures as evidence of its belief that reducing the number of measures is not enough to reduce the total burden on respondents. The commenter also noted its belief that frustration and clinician burnout are increased due to the documentation requirements and workflow modifications associated with quality reporting programs.

Response: We thank the commenter for its input. We recognize there is additional burden on clinicians and practice staff beyond the reporting burden estimated in the Collection of Information section of this policy which only accounts for the time required for record keeping, reporting, and third-party disclosures associated with the policy. CMS does consider the operational burden imposed on clinicians and practice staff and weighs it against the goal of improving quality of care prior to finalizing policy decisions. On balance, we believe that any potential additional burden is outweighed by increased quality and improved patient outcomes. We will continue to monitor this balance and will continue to propose efficiencies and policies that will help to further reduce burden.

After consideration of public comments, we are making no changes to our estimates as a result of public comments received. However, the burden estimates have been updated from the CY 2019 PFS proposed rule to reflect availability of data from the 2017 MIPS performance period (83 FR 36031 through 36032).

11. Quality Payment Program ICRs Regarding the Nomination of Promoting Interoperability (PI) Measures

This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the nomination of Promoting Interoperability measures. However, we have adjusted our currently approved burden estimates based data from the 2017 MIPS performance period. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Consistent with our requests for stakeholder input on quality measures and improvement activities, we also request potential measures for the Promoting Interoperability performance category that measure patient outcomes, emphasize patient safety, support improvement activities and the quality performance category, and build on the advanced use of CEHRT using 2015 Edition standards and certification criteria. Promoting Interoperability measures may be submitted via a designated submission form that includes the measure description, measure type (if applicable), reporting requirement, and CEHRT functionality used (if applicable).

We estimate 47 organizations will submit Promoting Interoperability measures, based on the number of organizations submitting measures during the CY 2017 nomination period. This is an increase of 7 from the estimate currently approved by OMB under the aforementioned control number. We estimate it will take 0.5 hours per organization to submit an activity to us, consisting of 0.3 hours at $107.38/hr for a practice administrator to make a strategic decision to nominate that activity and submit an activity to us via email and 0.2 hours at $206.44/hr for a clinician to review the nomination. As shown in Table 80, in aggregate, we estimate an annual burden of 235 hours (47 organizations × 0.5 hr/response) at a cost of $3,455 (47 × [(0.3 h × $107.38/hr) + (0.2 hr × $206.44/hr)]. The increase in the number of respondents results in an adjustment of 3.5 hours and $514.50 (7 respondents × 0.5 hrs × $73.50 per respondent).

TABLE 80—ESTIMATED BURDEN FOR CALL FOR PROMOTING INTEROPERABILITY MEASURES

	Burden estimate
# of Organizations Nominating New Promoting Interoperability Measures (a)	47
# of Hours Per Practice Administrator to Identify and Propose Measure (b)	0.30
# of Hours Per Clinician to Identify Measure (c)	0.20

TABLE 80—ESTIMATED BURDEN FOR CALL FOR PROMOTING INTEROPERABILITY MEASURES—Continued

	Burden estimate
Annual Hours Per Respondent (d) = (b) + (c)	0.50
Total Annual Hours (e) = (a) * (d)	23.50
Cost to Identify and Submit Measure (@practice administrator's labor rate of $107.38/hr.) (f)	$32.21
Cost to Identify Improvement Measure (@physician's labor rate of $206.44/hr.) (g)	$41.29
Total Annual Cost Per Respondent (h) = (f) + (g)	$73.50
Total Annual Cost (i) = (a) * (h)	$3,455

We received no public comments related to the burden estimates for the Call for Promoting Interoperability Measures. The burden estimates have not been updated from the CY 2019 PFS proposed rule (83 FR 36032 through 36033).

12. Quality Payment Program ICRs Regarding Improvement Activities Submission (§§ 414.1305, 414.1355, 414.1360, and 414.1365)

This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the submission of Improvement Activities data. However, we have adjusted our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77511 through 77512) and the CY 2018 Quality Payment Program final rule (82 FR 53920 through 53922) for our previous burden estimates for improvement activities under the Quality Payment Program.

The CY 2018 Quality Payment Program final rule provides: (1) That for activities that are performed for at least a continuous 90 days during the performance period, MIPS eligible clinicians must submit a ''yes'' response for activities within the Improvement Activities Inventory (82 FR 53651); (2) that the term ''recognized'' is accepted as equivalent to the term ''certified'' when referring to the requirements for a patient-centered medical home to receive full credit for the improvement activities performance category for MIPS (82 FR 53649); and (3) that for the 2020 MIPS payment year and future years, to receive full credit as a certified or recognized patient-centered medical home or comparable specialty practice, at least 50 percent of the practice sites within the TIN must be recognized as a patient-centered medical home or comparable specialty practice (82 FR 53655).

In the CY 2017 Quality Payment Program final rule, we describe how we determine MIPS APM scores (81 FR 77185). We compare the requirements of the specific MIPS APM with the list of activities in the Improvement Activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77817 through 77831). If, by our assessment, the MIPS APM does not receive the maximum improvement activities performance category score, then the APM Entity can submit additional improvement activities, although, as we noted, we anticipate that MIPS APMs in the 2019 MIPS performance period will not need to submit additional improvement activities as the models will already meet the maximum improvement activities performance category score (81 FR 77185).

A variety of organizations and in some cases, individual clinicians, will submit improvement activity performance category data. For clinicians who are not part of APMs, we assume that clinicians submitting quality data as part of a group through direct, log in and upload submission types, and CMS Web Interface will also submit improvement activities data. As finalized in the CY 2017 Quality Payment Program final rule (81 FR 77264), APM Entities only need to report improvement activities data if the CMS-assigned improvement activities score is below the maximum improvement activities score. Our CY 2018 Quality Payment Program final rule burden estimates assumed that all APM Entities will receive the maximum CMS-assigned improvement activities score (82 FR 53921 through 53922).

As represented in Table 81, based on 2017 MIPS performance period data, we estimate that 125,713 clinicians will submit improvement activities as individuals during the 2019 MIPS performance period and 16,478 groups will submit improvement activities on behalf of clinicians. Similar to the process shown in Table 77 for groups submitting Promoting Interoperability data, we have adjusted the group reporting data from the 2017 MIPS performance period to account for virtual groups, as the option to submit data as a virtual group was not available until the 2018 MIPS performance period.

Our burden estimates assume there will be no improvement activities burden for MIPS APM participants. We will assign the improvement activities performance category score at the APM level. We also assume that the MIPS APM models for the 2019 MIPS performance period will qualify for the maximum improvement activities performance category score and the APM Entities will not need to submit any additional improvement activities.

TABLE 81: Estimated Numbers of Organizations Submitting Improvement Activities Performance Category Data on Behalf of Clinicians

	Count
# of clinicians to participate in improvement activities data submission as individuals during the 2019 MIPS performance period (a)	119,956
# of Groups to submit improvement activities on behalf of clinicians during the 2019 MIPS performance period (b)	16,112
Subtract: # of groups to submit improvement activities on behalf of clinicians in Quality Payment Program Year 3 that will submit as virtual groups during the 2019 MIPS performance period (c)	80
Add in: # of Virtual Groups to submit improvement activities on behalf of clinicians during the 2019 MIPS performance period (d)	16
# of Groups and Virtual Groups to submit improvement activities on behalf of clinicians during the 2019 MIPS performance period (e)	16,048
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2019 MIPS performance period (f) = (a) + (b) + (e)	136,004
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2018 MIPS performance period (g)	439,786
Difference between 2019 MIPS performance period and 2018 MIPS performance period (h)=(g)-(f)	-303,782

As described in section III.I.3.h.(4)(b) of this final rule, for purposes of the 2021 MIPS payment year, we have finalized § 414.1360(a)(1) to more accurately reflect the data submission process for the improvement activities performance category. In particular, instead of ''via qualified registries; EHR submission mechanisms; QCDR, CMS Web Interface; or attestation,'' as currently stated, we have revised the first sentence to state that data will be submitted ''via direct, log in and upload, and log in and attest.'' The revision will more closely align with the actual submission experience users have.

In the CY 2018 Quality Payment Program final rule, we estimated it would take 1 hour for a computer system analyst to submit data on the specified improvement activities (82 FR 53922). We are finalizing to decrease this burden estimate since the actual submission experience of the user is such that improvement activities data is submitted as part of the process for submitting quality and Promoting Interoperability data, resulting in less additional required time to submit improvement activities data. As a result, we estimate that the per response time required per individual or group is 5 minutes at $89.18/hr for a computer system analyst to submit by logging in and manually attesting that certain activities were performed in the form and manner specified by CMS with a set of authenticated credentials. Additionally, as stated in the CY 2018 Quality Payment Program final rule, the same improvement activity may be reported across multiple performance periods so many MIPS eligible clinicians will not have any additional information to submit for the 2019 MIPS performance period (82 FR 53921).

As discussed in section III.I.3.h.(4)(d)(ii) of this final rule, we are also finalizing for CY 2019 and future years to: Add 6 new improvement activities; modify 5 existing improvement activities; and remove 1 existing improvement activity. Because MIPS eligible clinicians are still required to submit the same number of activities, we do not expect these provisions to affect our collection of information burden estimates. In addition, in order for an eligible clinician or group to receive credit for being a patient-centered medical home or comparable specialty practice, the eligible clinician or group must attest in the same manner as any other improvement activity.

As shown in Table 82, we estimate an annual burden of 11,333.7 hours (136,004 responses × 5 minutes/60) at a cost of $1,010,736 (11,333.7 hr × $89.18/hr).

Independent of the change to our per response time estimate, the decrease in the number of respondents results in an adjustment of −303,782 hours at −$27,091,279 (−303,782 respondents × 1 hr × $89.18/hr). Accounting for the change in number of respondents, the decrease in the time to submit improvement activities data results in an adjustment of −124,670.33 hours at −$11,118,100.33 (136,004 respondents × 55 minutes/60 × $89.18/hr). When these adjustments are combined, the total adjustment is −428,452.33 hours (−303,782 − 124,670.33) hours at −$38,209,379.33 (−$27,091,279 − $11,118,100.33).

TABLE 82—ESTIMATED BURDEN FOR IMPROVEMENT ACTIVITIES SUBMISSION

	Burden estimate
Total Number of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2019 MIPS performance period (a)	136,004
Total Annual Hours Per Respondent (b)	5 minutes
Total Annual Hours (c)	11,333.7
Labor rate for a computer systems analyst to submit improvement activities (d)	$89.18/hr
Total Annual Cost (e) = (a) * (d)	$1,010,736

The following is a summary of the public comments received on the Quality Payment Program ICRs regarding Improvement Activities Submission:

Comment: One commenter noted that CMS's estimate of 5 minutes to submit data for the Improvement Activities performance category is low and should be increased to an estimate of between 15 and 30 minutes.

Response: We thank the commenter for its input. We understand that some respondents may require additional time to submit improvement activities data above the 5 minutes we estimate, but we believe this estimate is a reasonable average across all respondents as it reflects the actual submission experience of the user. User experiences from the 2017 MIPS performance period reflect that the majority of users submit improvement activities data as part of the login and upload or direct submission types which allow multiple performance categories (*i.e.,* quality and promoting interoperability) worth of data to be submitted at once. This results in less additional required time to submit improvement activities data which consists of manually attesting that certain activities were performed. In addition, as previously stated in the CY 2018 Quality Payment Program final rule, the same improvement activity may be reported across multiple performance periods so many MIPS eligible clinicians will not have any additional information to submit for the 2019 MIPS performance period, further reducing the average time spent reporting improvement activities data across all MIPS eligible clinicians (82 FR 53921).

After consideration of public comments, we are making no changes to our estimates as a result of public comments received. However, the burden estimates have been updated from the CY 2019 PFS proposed rule to reflect availability of data from the 2017 MIPS performance period (83 FR 36033 through 36034).

13. Quality Payment Program ICRs Regarding the Nomination of Improvement Activities (§ 414.1360)

The finalized requirements and burden discussed under this section will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). We refer readers to the CY 2018 Quality Payment Program final rule for our previous burden estimates for nomination of improvement activities under the Quality Payment Program (82 FR 53922). In this final rule, we have adjusted the number of respondents based on more recent data and adjusted our per response time estimate based on our review of our currently approved burden estimates against the existing process for nomination of improvement activities. As discussed in section III.I.3.h.(4)(d)(i)(A) of this final rule, we are also finalizing to adopt one new criteria and remove one existing criteria for nominating new improvement activities beginning with the CY 2019 performance period and future years. Furthermore, we have made clarifications to: (1) Considerations for selecting improvement activities for the CY 2019 performance period and future years; and (2) the weighting of improvement activities. We believe these policy changes will not affect our currently approved burden estimates since they do not substantively impact the level of effort previously estimated to nominate an Improvement Activity.

As discussed in section III.I.3.h.(4)(d)(i)(D) of this final rule, we are finalizing changing the performance year for which the nominations will apply, such that improvement activities nominations received in a particular year will be vetted and considered for the next year's rulemaking cycle for possible implementation in the following year. Also, as discussed in section III.I.3.h.(4)(d)(i)(D) of this final rule, we are finalizing changing the submission timeframe for the Call for Activities from February 1st through March 1st to February 1st through June 30th, providing approximately four additional months for stakeholders to submit nominations. We believe these policy changes will not affect our currently approved burden estimates since we believe that the number of nominations is unlikely to change, but the quality of the nominations is likely to increase given the additional time provided.

For the 2018 MIPS performance period, we provided opportunity for stakeholders to propose new activities formally via the Annual Call for Activities nomination form that was posted on the CMS website (82 FR 53657). The 2018 Annual Call for Activities lasted from March 2, 2017 through March 1, 2018, for which we received 72 nominations consisting of a total of 125 activities which were evaluated for the Improvement Activities Under Consideration (IAUC) list for possible inclusion in the CY 2019 Improvement Activities Inventory. Based on the number of activities being evaluated during the 2018 Annual Call for Activities (125 activities), we estimate that the total number of nominations we will receive for the 2019 Annual Call for Activities will continue to be 125, unchanged from the number of activities evaluated in CY 2018, which is a decrease from the 150 nominations currently approved by OMB.

In the CY 2018 Quality Payment Program final rule, we estimated that it takes 0.5 hours to nominate an improvement activity (82 FR 53922). As shown in Table 83, due to a review of the nomination process including the criteria required to nominate an improvement activity, we now estimate it will take 2 hours (per organization) to submit an activity to us. Of those hours, we estimate it will take 1.2 hours at $107.38/hr for a practice administrator or equivalent to make a strategic decision to nominate and submit that activity and 0.8 hours at $206.44/hr for a clinician's review. In aggregate, we estimate an annual burden of 250 hours (125 nominations × 2 hr/nomination) at a cost of $36,751 (125 × [(1.2 hr × $107.38/hr) + (0.8 hr × $206.44/hr)]).

The percentage of practice administrator and clinician labor in relation to the total is unchanged from the CY 2018 Quality Payment Program final rule (82 FR 53922).

Independent of the change to our per response time estimate, the decrease in the number of nominations results in an adjustment of −12.5 hours and −$1,837 (−25 activities × [(0.3 hr × $107.38/hr) + (0.2 hr × $206.44/hr)]). Accounting for the decrease in the number of nominated improvement activities, the increase in time per nominated improvement activity results in an adjustment of 187.5 hours and $27,563 (125 activities × [(0.9 hr × $107.38/hr) + (0.6 hr × $206.44/hr)]). When these adjustments are combined, the total adjustment is 175 hours (187.5 − 12.5) and $25,726 ($27,563 − $1,837).

TABLE 83—ESTIMATED BURDEN FOR NOMINATION OF IMPROVEMENT ACTIVITIES

	Burden estimate
Number of Organizations Nominating New Improvement Activities (a)	125
Number of Hours Per Practice Administrator to Identify and Propose Activity (b)	1.2
Number of Hours Per Clinician to Identify Activity (c)	0.8
Annual Hours Per Respondent (d) = (b) + (c)	2
Total Annual Hours (e) = (a) * (d)	250
Cost to Identify and Submit Activity (@practice administrator's labor rate of $107.38/hr.) (f)	$128.86
Cost to Identify Improvement Activity (@physician's labor rate of $206.44/hr.) (g)	$165.15
Total Annual Cost Per Respondent (h) = (f) + (g)	$294.01
Total Annual Cost (i) = (a) * (h)	$36,751

The following is a summary of the public comments received on the Quality Payment Program ICRs regarding Improvement Activities Submission:

Comment: One commenter noted that the burden estimate of 2 hours for nomination of Improvement Activities is low due to the time needed by clinicians and their staff to assess a need in their practice situation, formulate a creative solution, and determine how they would implement it in their practice in addition to documenting and submitting the improvement activity to CMS.

Response: We recognize there is additional burden on respondents associated with development of a new improvement activity beyond the reporting burden estimated in the Collection of Information section of this policy which only accounts for the time required for record keeping, reporting, and third-party disclosures associated with the policy. We understand that some respondents may require additional time above the 2 hours we estimate for completing the process for nominating an improvement activity, but given that we do not include development of an improvement activity in our burden estimate, we believe this estimate is a reasonable average across all respondents based on our review of the nomination process, the information required to complete the nomination form, and the criteria required to nominate an improvement activity.

After consideration of public comments, we are making no changes to our estimates as a result of public comments received. The burden estimates have not been updated from the CY 2019 PFS proposed rule (83 FR 36034 through 36035).

14. Quality Payment Program ICRs Regarding CMS Study on Factors Associated With Reporting Quality Measures

During each performance year, eligible clinicians are recruited to participate in the CMS study on the burden associated with reporting quality measures. Eligible clinicians who are interested in participating can sign up whereby an adequate sample size is then selected by CMS from this group of potential participants. This study is ongoing, and participants are recruited on a yearly basis. Current participants can sign up when the study year ends.

Section 1848(s)(7) of the Act, as added by section 102 of the MACRA (Pub. L. 114–10) states that Chapter 35 of title 44, United States Code, shall not apply to the collection of information for the development of quality measures. Consequently, we are not setting out such burden since the study shall inform us (and our contractors) on the root causes of clinicians' performance measure data collection and data submission burdens and challenges that hinders accurate and timely quality measurement activities. We refer readers to the discussion of this policy in section VII.F.7 of this final rule.

15. Quality Payment Program ICRs Regarding the Cost Performance Category (§ 414.1350)

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938–1197) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by CD or hardcopy. Moreover, the provisions of this final rule do not result in the need to add or revise or delete any claims data fields. Therefore, we do not anticipate any new or additional submission requirements and/or burden for MIPS eligible clinicians resulting from the cost performance category.

We received no public comments related to burden for the cost performance category.

16. Quality Payment Program ICRs Regarding Partial QP Elections (§ 414.1430)

This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to QP elections. However, we have adjusted our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

APM Entities may face a data submission burden under MIPS related to Partial QP elections. Advanced APM participants will be notified about their QP or Partial QP status as soon as possible after each QP determination. Where Partial QP status is earned at the APM Entity level, the burden of Partial QP election will be incurred by a representative of the participating APM Entity. Where Partial QP status is earned at the eligible clinician level, the burden of Partial QP election will be incurred by the eligible clinician. For the purposes of this burden estimate, we assume that all MIPS eligible clinicians determined to be Partial QPs will participate in MIPS.

Based on our predictive QP analysis for the 2019 QP performance period, we estimate that 6 APM Entities and 75 eligible clinicians will make the election to participate as a Partial QP in MIPS (see Table 84), an increase of 64 from the 17 elections currently approved by OMB under the aforementioned control number. We estimate it will take the APM Entity representative or eligible clinician 15 minutes (0.25 hr) to make this election. In aggregate, we estimate

an annual burden of 20.25 hours (81 respondents × .25 hr/election) at a cost of $1,805.90 (20.25 hours × $89.18/hr). The increase in the number of Partial QP elections results in an adjustment of 16 hours and $1,431 (64 elections × 0.25 hrs × $89.18/hr).

TABLE 84—ESTIMATED BURDEN FOR PARTIAL QP ELECTION

	Burden estimate
Number of respondents making Partial QP election (6 APM Entities, 75 eligible clinicians) (a)	81
Total Hours Per Respondent to Elect to Participate as Partial QP (b)	0.25 hours
Total Annual Hours (c) = (a) * (b)	20.25 hours
Labor rate for computer systems analyst (d)	$89.18/hr
Total Annual Cost (d) = (c) * (d)	$1,805.90

We received no public comments related to the burden estimates for Partial QP Election. The burden estimates have not been updated from the CY 2019 PFS proposed rule (83 FR 36036).

17. Quality Payment Program ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process (§ 414.1440) and Eligible Clinician Initiated Process (§ 414.1445)

As indicated below, the finalized requirements and burden discussed under this section will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Payer Initiated Process (§ 414.1440): This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the Payer Initiated Process. However, we have adjusted our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Beginning in Quality Payment Program Year 3, the All-Payer Combination Option will be an available pathway to QP status for eligible clinicians participating sufficiently in Advanced APMs and Other Payer Advanced APMs. The All-Payer Combination Option allows for eligible clinicians to achieve QP status through their participation in both Advanced APMs and Other Payer Advanced APMs. In order to include an eligible clinician's participation in Other Payer Advanced APMs in their QP threshold score, we will need to determine if certain payment arrangements with other payers meet the criteria to be Other Payer Advanced APMs. To provide eligible clinicians with advance notice prior to the start of a given performance period, and to allow other payers to be involved prospectively in the process, the 2018 CY Quality Payment Program final rule established a payer-initiated process for identifying payment arrangements that qualify as Other Payer Advanced APMs (82 FR 53844). The payer-initiated process for Other Payer Advanced APM determinations began in CY 2018 for Medicaid, Medicare Health Plans, and payers participating in CMS multi-payer models. Payers seeking to submit payment arrangement information for Other Payer Advanced APM determination through the payer-initiated process are required to complete a Payer Initiated Submission Form, instructions for which is available at *https://qpp.cms.gov/*. Determinations made in 2018 are applicable for the Quality Payment Program Year 3.

Also in the CY 2018 Quality Payment Program final rule we established our intent to finalize that the remaining other payers, including commercial and other private payers, may request that we determine whether other payer arrangements are Other Payer Advanced APMs starting prior to the 2020 QP performance period and each performance period thereafter (82 FR 53867). As a result, in this final rule, we finalized our proposal to eliminate the Payer Initiated Process that is specifically for CMS Multi-Payer Models. We believe that payers aligned with CMS Multi-Payer Models can submit their arrangements through the Payer Initiated Process for Remaining Other Payers in section III.I.4.e.(4)(c) of this final rule, or through the Medicaid or Medicare Health Plan payment arrangement submission processes.

As shown in Table 85, we estimate that in 2019 for the 2020 QP performance period 215 payer-initiated requests for Other Payer Advanced APM determinations will be submitted (15 Medicaid payers, 100 Medicare Advantage Organizations, and 100 remaining other payers), a decrease of 85 from the 300 total requests currently approved by OMB under the aforementioned control number. We estimate it will take 10 hours at $89.18/hr for a computer system analyst per arrangement submission. In aggregate, we estimate an annual burden of 2,150 hours (215 submissions × 10 hr/submission) at a cost of $191,737 (2,150 hr × $89.18/hr). The decrease in the number of payer-initiated requests results in an adjustment of −850 hours and −$75,803 (−85 requests × 10 hr × $89.18/hr).

TABLE 85—ESTIMATED BURDEN FOR OTHER PAYER ADVANCED APM IDENTIFICATION DETERMINATIONS: PAYER-INITIATED PROCESS

	Burden estimate
Number of other payer payment arrangements (15 Medicaid, 100 Medicare Advantage Organizations, 100 remaining other payers) (a)	215
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a) * (b)	2,150
Labor rate for a computer systems analyst (d)	$89.18/hr

TABLE 85—ESTIMATED BURDEN FOR OTHER PAYER ADVANCED APM IDENTIFICATION DETERMINATIONS: PAYER-INITIATED PROCESS—Continued

	Burden estimate
Total Annual Cost for Other Payer Advanced APM determinations (e) = (a) * (d)	$191,737

We received no public comments related to the burden estimates for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process. The burden estimates have been updated from the CY 2019 PFS proposed rule to reflect updated respondent estimates (83 FR 36036 through 36037).

Eligible Clinician Initiated Process (§ 414.1445): This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the Eligible Clinician Initiated Process. However, we have adjusted our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Beginning in Quality Payment Program Year 3, the All-Payer Combination Option will be an available pathway to QP status for eligible clinicians participating sufficiently in Advanced APMs and Other Payer Advanced APMs. The All-Payer Combination Option allows for eligible clinicians to achieve QP status through their participation in both Advanced APMs and Other Payer Advanced APMs. In order to include an eligible clinician's participation in Other Payer Advanced APMs in their QP threshold score, we will need to determine if certain payment arrangements with other payers meet the criteria to be Other Payer Advanced APMs. To provide eligible clinicians with advanced notice prior to the start of a given performance period, and to allow other payers to be involved prospectively in the process, the CY 2018 Quality Payment Program final rule provided a payer-initiated identification process for identifying payment arrangements that qualify as Other Payer Advanced APMs (82 FR 53854). In the same rule, under the Eligible Clinician Initiated Process, APM Entities and eligible clinicians participating in other payer arrangements will have an opportunity to request that we determine for the year whether those other payer arrangements are Other Payer Advanced APMs (82 FR 53857—53858). However, to appropriately implement the statutory requirement to exclude from the All Payer Combination Option QP threshold calculations certain Title XIX payments and patients, we determined it will be problematic to allow APM Entities and eligible clinicians to request determinations for Title XIX payment arrangements after the conclusion of the QP performance period because any late-identified Medicaid APM or Medicaid Medical Home Model that meets the Other Payer Advanced APM criteria could unexpectedly affect QP threshold calculations for every other clinician in that state (or county). Thus, the CY 2018 Quality Payment Program final rule provided that APM Entities and eligible clinicians may request determinations for any Medicaid payment arrangements in which they are participating at an earlier point, prior to the start of a given QP performance period (82 FR 53858). This will allow all clinicians in a given state or county to know before the beginning of the performance period whether their Title XIX payments and patients will be excluded from the all-payer calculations that are used for QP determinations for the year under the All-Payer Combination Option. This Medicaid specific eligible clinician-initiated determination process for Other Payer Advanced APMs also began in CY 2018, and determinations made in 2018 are applicable for the Quality Payment Program Year 3. Eligible clinicians or APM Entities seeking to submit payment arrangement information for Other Payer Advanced APM determination through the Eligible Clinician-Initiated process are required to complete an Eligible Clinician Initiated Submission Form, instructions for which is available at *https://qpp.cms.gov/*.

As shown in Table 86, we estimate that 150 other payer arrangements will be submitted by APM Entities and eligible Other Payer Advanced APM determinations, an increase of 75 from the 75 total requests currently approved by OMB under the aforementioned control number.

We estimate it will take 10 hours at $89.18/hr for a computer system analyst per arrangement submission to submit this data. In aggregate, we estimate an annual burden of 1,500 hours (150 submissions × 10 hr/submission) at a cost of $133,770 (1,500 hr × $89.18/hr). The increase in the number of clinician-initiated requests results in an adjustment of 750 hours and $66,885 (75 requests × 10 hr × $89.18/hr).

TABLE 86—ESTIMATED BURDEN FOR OTHER PAYER ADVANCED APM DETERMINATIONS: ELIGIBLE CLINICIAN INITIATED PROCESS

	Burden estimate
Number of other payer payment arrangements from APM Entities and eligible clinicians	150
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a) * (b)	1,500
Labor rate for a computer systems analyst (d)	$89.18/hr
Estimated Total Annual Cost for Other Payer Advanced APM determinations (e) = (a) * (d)	$133,770

We received no public comments related to the burden estimates for Other Payer Advanced APM Identification Determinations: Eligible Clinician Initiated Process. The burden estimates have not been updated from the CY

2019 PFS proposed rule (83 FR 36037 through 36038).

Submission of Data for QP Determinations under the All-Payer Combination Option (§ 414.1440): The following reflects the burden associated with the first year of data collection resulting from policies set out in the CY 2018 Quality Payment Program final rule. Because no collection of data was required prior to the CY 2019 performance period, the requirements and burden were not submitted to OMB for approval. However, by virtue of this rulemaking, the requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

The CY 2017 Quality Payment Program final rule provided that either APM Entities or individual eligible clinicians must submit by a date and in a manner determined by us: (1) Payment arrangement information necessary to assess whether each other payer arrangement is an Other Payer Advanced APM, including information on financial risk arrangements, use of CEHRT, and payment tied to quality measures; (2) for each payment arrangement, the amounts of payments for services furnished through the arrangement, the total payments from the payer, the numbers of patients furnished any service through the arrangement (that is, patients for whom the eligible clinician is at risk if actual expenditures exceed expected expenditures), and (3) the total number of patients furnished any service through the arrangement (81 FR 77480). The rule also specified that if we do not receive sufficient information to complete our evaluation of another payer arrangement and to make QP determinations for an eligible clinician using the All-Payer Combination Option, we will not assess the eligible clinicians under the All-Payer Combination Option (81 FR 77480).

In the CY 2018 Quality Payment Program final rule, we explained that in order for us to make QP determinations under the All-Payer Combination Option using either the payment amount or patient count method, we will need to receive all of the payment amount and patient count information: (1) Attributable to the eligible clinician or APM Entity through every Other Payer Advanced APM; and (2) for all other payments or patients, except from excluded payers, made or attributed to the eligible clinician during the QP performance period (82 FR 53885). We also finalized that eligible clinicians and APM Entities will not need to submit Medicare payment or patient information for QP determinations under the All-Payer Combination Option (82 FR 53885).

The CY 2018 Quality Payment Program final rule noted that we will need this payment amount and patient count information for the periods January 1 through March 31, January 1 through June 30, and January 1 through August 31 (82 FR 53885). We noted that the timing may be challenging for APM Entities or eligible clinicians to submit information for the August 31 snapshot date. If we receive information for either the March 31 or June 30 snapshots, but not the August 31 snapshot, we will use that information to make QP determinations under the All-Payer Combination Option. This payment amount and patient count information is to be submitted in a way that allows us to distinguish information from January 1 through March 31, January 1 through June 30, and January 1 through August 31 so that we can make QP determinations based on the two finalized snapshot dates (82 FR 30203 through 30204).

The CY 2018 Quality Payment Program final rule specified that APM Entities or eligible clinicians must submit all of the required information about the Other Payer Advanced APMs in which they participate, including those for which there is a pending request for an Other Payer Advanced APM determination, as well as the payment amount and patient count information sufficient for us to make QP determinations by December 1 of the calendar year that is 2 years to prior to the payment year, which we refer to as the QP Determination Submission Deadline (82 FR 53886).

In section III.I.4.e.(5)(b) of this final rule, we are finalizing the addition of a third alternative to allow QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights to the TIN participate in a single (the same) APM Entity. This option will therefore be available to all TINs participating in Full TIN APMs, such as the Medicare Shared Savings Program. It will also be available to any other TIN for which all clinicians who have reassigned billing rights to the TIN participating in a single APM Entity. To make QP determinations under the All-Payer Combination Option at the TIN level as finalized using either the payment amount or patient count method, we will need to receive, by December 1 of the calendar year that is 2 years to prior to the payment year, all of the payment amount and patient count information: (1) Attributable to the eligible clinician, TIN, or APM Entity through every Other Payer Advanced APM; and (2) for all other payments or patients, except from excluded payers, made or attributed to the eligible clinician(s) during the QP performance period for the periods January 1 through March 31, January 1 through June 30, and January 1 through August 31.

As shown in Table 87, we assume that 4 APM Entities, 225 TINs, and 80 eligible clinicians will submit data for QP determinations under the All-Payer Combination Option in 2019. We estimate it will take the APM Entity representative, TIN representative, or eligible clinician 5 hours at $107.38/hr for a practice administrator to complete this submission. In aggregate, we estimate an annual burden of 1,545 hours (309 respondents × 5 hr) at a cost of $165,902 (1,545 hr × $107.38/hr).

TABLE 87—ESTIMATED BURDEN FOR THE SUBMISSION OF DATA FOR ALL-PAYER QP DETERMINATIONS

	Burden estimate
# of APM Entities submitting data for All-Payer QP Determinations (a)	4
# of TINs submitting data for All-Payer QP Determinations (b)	225
# of eligible submitting data for All-Payer QP Determinations (c)	80
Hours Per respondent QP Determinations (d)	5
Total Hours (g) = [(a) * (d)] + [(b) * (d)] + [(c) * (d)]	1,545
Labor rate for a Practice Administrator ($107.38) (h)	$107.38/hr
Total Annual Cost for Submission of Data for All-Payer QP Determinations (i) = (g) * (h)	$165,902

We received no public comments related to the burden estimates for the Submission of Data for All-Payer QP Determinations. The burden estimates have been updated from the CY 2019 PFS proposed rule to reflect updated respondent estimates (83 FR 36038 through 36039).

18. Quality Payment Program ICRs Regarding Voluntary Participants Election To Opt-Out of Performance Data Display on Physician Compare (§ 414.1395)

This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the election by voluntary participants to opt-out of public reporting on Physician Compare. However, we have adjusted our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We estimate that 10 percent of the total clinicians and groups who will voluntarily participate in MIPS will also elect not to participate in public reporting. This results in a total of 11,617 (10 percent × 116,174 voluntary MIPS participants), a decrease of 10,783 from the total respondents currently approved by OMB under the aforementioned control number due to the reduction in voluntary participation in MIPS overall. As we discussed earlier in this section of the final rule, voluntary respondents are clinicians that are not QPs and are expected to be excluded from MIPS after applying the eligibility requirements discussed in section III.I.3.a. of this final rule, but have elected to submit data to MIPS. In implementing the finalized opt-in policy, we estimate that 33 percent of clinicians that exceed 1 of the low-volume criteria, but not all 3, will elect to opt-in to MIPS, become MIPS eligible, and no longer be considered a voluntary reporter. This logic was also applied in the regulatory impact analysis of this rule. Table 88 shows that for these voluntary participants, we estimate it will take 0.25 hours at $89.18/hr for a computer system analyst to submit a request to opt-out. In aggregate, we estimate an annual burden of 2,904.25 hours (11,617 requests × 0.25 hr/request) at a cost of $259,001 (2,904.25 hr × $89.18/hr).

The decrease in the number of respondents due to policies finalized in this rule results in a decrease of −2,695.75 hours (−10,783 respondents × 0.25 hr) and −$240,407 (−2,695.75 hours × $89.18/hr).

TABLE 88—ESTIMATED BURDEN FOR VOLUNTARY PARTICIPANTS TO ELECT OPT OUT OF PERFORMANCE DATA DISPLAY ON PHYSICIAN COMPARE

	Burden estimate
# of Voluntary Participants Opting Out of Physician Compare (a)	11,617
Total Annual Hours Per Opt-out Requester (b)	0.25
Total Annual Hours for Opt-out Requester (c) = (a) * (b)	2,904.25
Labor rate for a computer systems analyst (d)	$89.18/hr
Total Annual Cost for Opt-out Requests (e) = (a) * (d)	$259,001

We received no public comments related to the burden estimates for voluntary participants to elect to opt out of performance data display on Physician Compare. However, the burden estimates have not been updated from the CY 2019 PFS proposed rule to reflect availability of data from the 2017 MIPS performance period (83 FR 36039).

19. Summary of Annual Quality Payment Program Burden Estimates

Table 89 summarizes this final rule's burden estimates for the Quality Payment Program. To understand the burden implications of the policies finalized in this rule, we have also estimated a baseline burden of continuing the policies and information collections set forth in the CY 2018 Quality Payment Program final rule into the 2019 MIPS performance period. Our baseline burden estimates reflect the recent availability of data sources to more accurately reflect the number of the respondents for the quality, Promoting Interoperability, and improvement activities performance categories and the number of organizations exempt from the Promoting Interoperability performance category.

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TABLE 89: Summary of Finalized Quality Payment Program Burden Estimates and Requirements

Requirement	Currently Approved Respondents	Finalized Respondents	Change in Respondents	Currently Approved Total Burden Hours	Finalized Total Burden Hours	Change in Total Burden Hours
ICRs Under OMB Control Number 0938-1314 (CMS-10621)						
§414.1400 Registry self- nomination*	120	150	30	1,200	450	-750
§414.1400 QCDR self-nomination*	113	200	87	1,130	2,400	1,270
§§414.1325 and 414.1335 CMS Enterprise Portal User Account Registration	0	3,741	3,741	0	3,741	3,741
§§414.1325 and 414.1335 (Quality Performance Category) Medicare Part B Claims Collection Type	278,039	257,260	-20,779	4,949,094	3,653,092	-1,296,002
§§414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type	107,217	81,981	-25,236	973,852	744,633	-229,219
§§414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type	54,218	51,861	-2,357	487,962	414,888	-73,074
§414.1325 and 414.1335 (Quality Performance Category) CMS Web Interface	296	286	-10	21,904	17,636.7	-4,267.3
§§414.1325 and 414.1335 (Quality Performance Category) Registration and Enrollment for CMS Web Interface	10	67	57	10	16.75	6.75
(Quality Performance Category) Call for Quality Measures	40	140	100	20	630	610
§414.1375 (Promoting Interoperability Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories	40,645	6,041	-34,604	20,323	1,510	-18,813
§§414.1375 and 414.1380 (Promoting Interoperability Performance Category) Data Submission	218,215	93,869	-124,346	654,645	250,317	-404,328
(Promoting Interoperability Performance Category) Call for Promoting Interoperability Measures	40	47	7	20	23.5	3.5
§414.1360 (Improvement Activities Performance Category) Data Submission	439,786	136,004	-303,782	439,786	11,334	-428,452
§414.1360 (Improvement Activities Performance Category) Nomination of Improvement Activities	150	125	-25	75	250	175
§414.1430 Partial Qualifying APM Participant (QP) Election	17	81	64	4.25	20.25	16
§414.1440 Other Payer Advanced APM Identification: Payer Initiated Process	300	215	-85	3,000	2,150	-850
§414.1445 Other Payer Advanced APM Identification: Eligible Clinician Initiated Process	75	150	75	750	1,500	750
§414.1440 Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option	0	309	309	0	1,545	1,545
§414.1395 (Physician Compare) Opt Out for Voluntary Participants	22,400	11,617	-10,783	5,600	2,904.25	-2,695.75
Subtotal	*1,161,681*	*644,144*	*-517,537*	*7,559,375*	*5,109,042*	*-2,350,334*
ICRs Under OMB Control Number 0938-1222 (CMS-10450)						
§§414.1325 and 414.1335 (CAHPS for MIPS Survey) Beneficiary Participation	132,307	39,039	-93,268	29,108	8,393	-20,715
§§414.1325 and 414.1335 (CAHPS for MIPS Survey) Group Registration	461	282	-179	691.5	211.5	-480
Subtotal	*132,768*	*39,321*	*-93,447*	*29,799.5*	*8,605*	*-21,195*
TOTAL	**1,294,449**	**683,465**	**-610,984**	**7,589,175**	**5,117,646**	**-2,371,529**

*These two ICRs were combined in a single ICR in the CY 2018 Quality Payment Program final rule (82 FR 53906 through 53907).

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Table 90 provides the reasons for changes in the estimated burden for information collections in this final rule. We have divided the reasons for

our change in burden into those related to new policies and those related to changes in the baseline burden of continued Quality Payment Program Year 2 policies that reflect updated data and methods.

TABLE 90—REASONS FOR CHANGE IN BURDEN COMPARED TO THE CURRENTLY APPROVED CY 2018 INFORMATION COLLECTION BURDENS

Table in collection of information	Changes in burden due to finalized Year 3 policies	Changes to "baseline" of burden continued Year 2 policy (*italics are changes in number of respondents' due to updated data*)
Table 62: Qualified Registry Self-Nomination.	None	After a review of the self-nomination process, we determined it is more accurate to separately assess the burden of Qualified Registry and QCDR self-nomination rather than aggregate them in the same ICR. Review of self-nomination process resulted in a decrease in estimated time needed to complete simplified self-nomination (−9.5 hr. computer system analyst time) and full self-nomination (−7 hr. computer system analyst time). *Increase in the number of respondents as the number of qualified registries enrolling increases and the basis for estimating the number of respondents is updated to reflect the number of self-nomination applications received in place of the number of qualified registries being approved.*
Table 63: QCDR Self-Nomination	None	After a review of the self-nomination process, we determined it is more accurate to separately assess the burden of Qualified Registry and QCDR self-nomination rather than aggregate them in the same ICR. Review of self-nomination process resulted in an increase in estimated time needed to complete simplified self-nomination (−0.5 hr. computer system analyst time) and full self-nomination (+2 hr. computer system analyst time). *Increase in the number of respondents as the number of QCDRs enrolling increases and the basis for estimating the number of respondents is updated to reflect the number of self-nomination applications received in place of the number of QCDRs being approved.*
Table 68: Quality Payment Program Identity Management Application Process.	None	*Decreased number of respondents due to updates to the identity management system being used for data submission in the 2018 MIPS performance period; only new respondents submitting quality data using the CMS Enterprise Portal need to create a new account, versus system where all respondents submitting via EHR needed to register for user account annually.*
Table 69: Quality Performance Category Medicare Part B Claims Collection Type.	None	*Decreased number of respondents due to updated data from 2017 MIPS performance period.* Correction to estimate to account for reduced number of required measures compared to PQRS (6 in MIPS; 9 in PQRS) reduced estimated time to submit data.
Table 70: Quality Performance Category QCDR/MIPS CQM Collection Type.	None	*Decreased number of respondents due to updated data from 2017 MIPS performance period.*
Table 71: Quality Performance Category eCQM Collection Type.	None	*Decreased number of respondents due to updated data from 2017 MIPS performance period.*
Table 72: Quality Performance Category CMS Web Interface.	Decrease in number of required measures resulted in reduction in estimated time needed to submit data (−12.33 hrs computer system analyst time).	*Decrease in the number of respondents due to updated data from the 2018 MIPS performance period as fewer eligible group practices elected to submit data using the CMS Web Interface.*
Table 73: Beneficiary Responses to CAHPS for MIPS Survey.	None	*Decrease in the number of respondents due to updated data from the 2018 MIPS performance period as fewer eligible group practices elect to have vendors administer the CAHPS for MIPS survey and fewer beneficiaries per group respond to the survey, on average.*
Table 74: Registration for CMS Web Interface.	None	*Increase in the number of respondents due to updated data from the 2018 MIPS performance period as more groups register to submit data using the CMS Web Interface.* Review of registration process resulted in decrease in estimated time to register. (−0.75 hr. computer system analyst time).
Table 75: Registration for CAHPS for MIPS Survey.	None	*Decrease in the number of respondents due to updated data from the 2018 MIPS performance period as fewer eligible group practices elect to have vendors administer the CAHPS for MIPS survey.* Review of registration process resulted in decrease in estimated time to register. (−0.75 hr. computer system analyst time).
Table 76: Call for Quality Measures	None	*Increase in the number of new quality measures being nominated.* Inclusion of time required to complete Peer Review Journal Article Form resulted in increase in time to nominate a quality measure. This was a requirement in the CY 2017 Quality Payment Program final rule (81 FR 77153 through 77155) but was not included in burden estimates. (+4 hrs Physician time).
Table 77: Reweighting Applications for Promoting Interoperability and Other Performance Categories.	None	*Decrease in the number of respondents due to updated data from 2017 MIPS performance period.* Review of application process resulted in decrease in estimated time to apply (−0.25 hr computer system analyst time).
Table 79: Promoting Interoperability Performance Category Data Submission.	Decrease in number of required measures resulted in reduction in estimated time needed to submit data (−.33 hr computer system analyst time).	*Decrease in the number of respondents due to updated data from 2017 MIPS performance period.*
Table 80: Call for Promoting Interoperability Measures.	None	*Increase in the number of new Promoting Interoperability measures being nominated.*
Table 82: Improvement Activities Submission.	None	*Decrease in the number of respondents due to updated data from 2017 MIPS performance period.*

TABLE 90—REASONS FOR CHANGE IN BURDEN COMPARED TO THE CURRENTLY APPROVED CY 2018 INFORMATION COLLECTION BURDENS—Continued

Table in collection of information	Changes in burden due to finalized Year 3 policies	Changes to "baseline" of burden continued Year 2 policy (*italics are changes in number of respondents' due to updated data*)
		Review of submission process resulted in decrease in estimated to submit (−0.92 hr computer system analyst time).
Table 83: Nomination of Improvement Activities.	None	Review of nomination process resulted in increase in estimated time to nominate a new improvement activity (+0.9 hrs Practice Administrator time; +0.6 hrs Physician time).
Table 84: Partial QP Election	None	*Increase in the number of respondents due to additional APM Entities and eligible clinicians electing to participate as a Partial QP in MIPS.*
Table 85: Other Payer Advanced APM Identification: Other Payer Initiated Process.	None	*Decrease in the number of anticipated other payer arrangements submitted for identification as Other Payer Advanced APMs.*
Table 86: Other Payer Advanced APM Identification: Eligible Clinician Initiated Process.	None	*Increase in the number of anticipated other payer arrangements submitted by APM Entities and eligible clinicians for identification as Other Payer Advanced APMs.*
Table 87: Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option.	Reflects new policy in this final rule.	None.
Table 88: Voluntary Participants to Elect to Opt Out of Performance Data Display on Physician Compare.	*Decrease in the number of respondents due to updated data from 2017 MIPS performance period.*	None.

C. Summary of Annual Burden Estimates for Finalized Requirements

TABLE 91—ANNUAL REQUIREMENTS AND BURDEN

Regulation section(s) under Title 42 of the CFR	OMB control No. ***	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($/hr)	Total cost ($) *
§ 414.94(j) (AUC consultations) Voluntary period.	0938–1345	10,230,000	3,410,000	0.033 (2 min)	112,530	Varies	5,527,924
§ 414.94(j) (AUC consultations) Beginning Jan 1, 2020.	0938–1345	586,386	43,181,818	0.033 (2 min)	1,425,000	Varies	70,001,700
§ 414.94 (AUC recordkeeping)	0938–1345	586,386	6,699	0.167 (10 min)	1,119	34.50	38,596
Quality Payment Program (See Subtotal Under Table 89).	0938–1314	(**)	(517,537)	varies	(2,450,334)	varies	(221,510,118)
Quality Payment Program (See Subtotal Under Table 89).	0938–1222	(93,447)	(93,447)	varies	(21,195)	varies	(546,362)
Total		10,722,939	45,987,533	Varies	(932,880)	Varies	(146,488,260)

* For the PRA, this rule will not impose any non-labor costs.

** We are unable to accurately calculate a total number of respondents for the Quality Payment Program. In many cases, individuals, groups, and entities have responded to multiple data collections and there is no unified way to identify unique respondents.

*** OMB and CMS' PRA package ID numbers: OMB 0938–1345 (CMS–10654), OMB 0938–1314 (CMS–10621), and OMB 0938–1222 (CMS–10450).

**** For OMB 0938–1314 (CMS–10621), the estimated total number of respondents across all ICRs for the CY 2019 performance period is 644,144 while estimated total burden hours are 5,109,042 at a cost of $482,416,597. (CMS–10450), the estimated total number of respondents across all ICRs for the CY 2019 performance period is 39,336 while estimated total burden hours are 8,755 at a cost of $236,525. For OMB 0938–1343 (CMS–10652), the estimated total number of respondents across all ICRs for the CY 2019 performance period is 16 while estimated total burden hours are 160 at a cost of $13,506.

VII. Regulatory Impact Analysis

A. Statement of Need

This final rule makes payment and policy changes under the Medicare PFS and implements required statutory changes under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the Achieving a Better Life Experience Act (ABLE), the Protecting Access to Medicare Act of 2014 (PAMA), section 603 of the Bipartisan Budget Act of 2015, the Consolidated Appropriations Act of 2016, the Bipartisan Budget Act of 2018, and section 2001(a) of the SUPPORT for Patients and Communities Act of 2018. This final rule also makes changes to payment policy and other related policies for Medicare Part B.

This final rule is necessary to make policy changes under Medicare fee-for-service. Therefore, we included a detailed regulatory impact analysis (RIA) to assess all costs and benefits of available regulatory alternatives and explained the selection of these regulatory approaches that we believe adhere to section 1834(q) of the Act and, to the extent feasible, maximize net benefits.

This final rule also makes payment and policy changes under the Medicare PFS and makes required statutory changes under the MACRA, as amended by section 51003 of the Bipartisan Budget Act of 2018.

The new policies for CY 2019 are detailed throughout this final rule. For example, the policies associated with modernizing Medicare physician payment by recognizing communication technology-based services are described in section II.D. of this final rule, while the policies associated with E/M visits are described in section II.I. of this final rule. Several policies addressing the use of innovative technology that enables remote services will expand access to care and create more opportunities for patients to access more personalized care management, as well as connect with their physicians more quickly. These policies support access to care using telecommunications technology by paying clinicians for virtual check-ins (brief, non-face-to-face appointments via communications technology), paying clinicians for evaluation of patient-submitted photos or videos, and

expanding Medicare-covered telehealth services to include prolonged preventive services.

Several policies in the final rule will also give physicians more time to spend with their patients, especially those with complex needs, rather than on paperwork. Specifically, there are provisions that simplify certain documentation requirements for E/M visits, which make up about 40 percent of allowed charges under the PFS and consume much of clinicians' time; reduce supervision requirements for radiologist assistants during diagnostic test services; and remove burdensome and overly complex functional reporting requirements for outpatient therapy. In addition, section VII.H. of this final rule, the RIA, details the economic effect of these policies on Medicare providers and beneficiaries.

B. Overall Impact

We examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). An RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimated, as discussed in this section, that the PFS policies included in this final rule would redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details see the SBA's website at *http://www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals and states are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this final rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

For example, the effects of changes to payment rates for practitioners, other providers, and suppliers are discussed in VII.C. of this final rule. Alternative options considered to the payment rates are discussed generally in section VII.F. of this final rule.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. The PFS does not reimburse for services provided by rural hospitals; the PFS pays for physicians' services, which can be furnished by physicians and non-physician practitioners in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on state, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately $150 million. This final rule will impose no mandates on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. This final rule is considered an E.O. 13771 deregulatory action because it is expected to result in regulatory cost savings. The estimated impact would be $71 million in cost savings in 2019, $3.986 billion in costs in 2020, $387 million in cost savings in 2021, $450 million cost savings in 2022, and $557 million in cost savings in 2023 and thereafter. Annualizing these costs and cost savings in perpetuity and discounting at 7 percent back to 2016, we estimated that this rule would generate $190 million in annualized net cost savings for E.O. 13771 accounting purposes. Details on the estimated cost savings of this rule can be found in the following analyses.

We prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this final rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this final rule, we are implementing a variety of changes to our regulations, payments, or payment policies to ensure that our payment

systems reflect changes in medical practice and the relative value of services, and implementing statutory provisions. We provided information for each of the policy changes in the relevant sections of this final rule. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this final rule. The relevant sections of this final rule contain a description of significant alternatives if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compared payment rates for CY 2018 with payment rates for CY 2019 using CY 2017 Medicare utilization. The payment impacts in this final rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and would depend on the mix of services he or she furnishes. The average percentage change in total revenues will be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are paid under the Clinical Laboratory Fee Schedule (CLFS).

The annual update to the PFS conversion factor (CF) was previously calculated based on a statutory formula; for details about this formula, we refer readers to the CY 2015 PFS final rule with comment period (79 FR 67741 through 67742). Section 101(a) of the MACRA repealed the previous statutory update formula and amended section 1848(d) of the Act to specify the update adjustment factors for CY 2015 and beyond. The update adjustment factor for CY 2019, as required by section 53106 of the Bipartisan Budget Act of 2018, is 0.25 percent before applying other adjustments.

To calculate the CF for this year, we multiplied the product of the current year CF and the update adjustment factor by the budget neutrality adjustment described in the preceding paragraphs. We estimated the CY 2019 PFS CF to be 36.0391 which reflects the budget neutrality adjustment under section 1848(c)(2)(B)(ii)(II) and the 0.25 percent update adjustment factor specified under section 1848(d)(18) of the Act. We estimate the CY 2019 anesthesia CF to be 22.2730, which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE 92—CALCULATION OF THE FINAL CY 2019 PFS CONVERSION FACTOR

CY 2018 Conversion Factor		35.9996
Statutory Update Factor	0.25 percent (1.0025)	
CY 2019 RVU Budget Neutrality Adjustment	−0.14 percent (0.9986)	
CY 2019 Conversion Factor		36.0391

TABLE 93—CALCULATION OF THE FINAL CY 2019 ANESTHESIA CONVERSION FACTOR

CY 2018 National Average Anesthesia Conversion Factor		22.1887
Statutory Update Factor	0.25 percent (1.0025)	
CY 2019 RVU Budget Neutrality Adjustment	−0.14 percent (0.9986)	
CY 2019 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment.	0.27 percent (1.0027)	
CY 2019 Conversion Factor		22.2730

Table 94 shows the payment impact on PFS services of the policies contained in this final rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues would be different from those shown in Table 94 (CY 2019 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 94.

- *Column A (Specialty):* Identifies the specialty for which data are shown.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2017 utilization and CY 2018 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- *Column C (Impact of Work RVU Changes):* This column shows the estimated CY 2019 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- *Column D (Impact of PE RVU Changes):* This column shows the estimated CY 2019 impact on total allowed charges of the changes in the PE RVUs.
- *Column E (Impact of MP RVU Changes):* This column shows the estimated CY 2019 impact on total allowed charges of the changes in the MP RVUs.
- *Column F (Combined Impact):* This column shows the estimated CY 2019 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

TABLE 94—CY 2019 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY

Specialty	Allowed charges (mil)	Impact of work RVU changes (%)	Impact of PE RVU changes (%)	Impact of MP RVU changes (%)	Combined impact (%)
(A)	(B)	(C)	(D)	(E)	(F)
Allergy/Immunology	$239	0	−1	0	−1
Anesthesiology	1,982	0	0	0	0
Audiologist	68	0	1	0	1
Cardiac Surgery	293	0	0	0	0
Cardiology	6,616	0	0	0	0
Chiropractor	754	0	−1	0	−1
Clinical Psychologist	776	0	3	0	3
Clinical Social Worker	728	0	3	0	2
Colon and Rectal Surgery	166	0	1	0	1
Critical Care	342	0	−1	0	−1
Dermatology	3,489	0	1	0	1
Diagnostic Testing Facility	734	0	−5	0	−5
Emergency Medicine	3,121	0	0	0	0
Endocrinology	482	0	0	0	0
Family Practice	6,207	0	0	0	0
Gastroenterology	1,754	0	0	0	0
General Practice	428	0	0	0	0
General Surgery	2,090	0	0	0	0
Geriatrics	197	0	0	0	0
Hand Surgery	214	0	0	0	0
Hematology/Oncology	1,741	0	−1	0	−1
Independent Laboratory	646	0	−2	0	−2
Infectious Disease	649	0	0	0	−1
Internal Medicine	10,766	0	0	0	0
Interventional Pain Mgmt	868	0	1	0	1
Interventional Radiology	384	1	1	0	2
Multispecialty Clinic/Other Phys	149	0	0	0	0
Nephrology	2,188	0	0	0	0
Neurology	1,529	0	0	0	0
Neurosurgery	802	0	0	0	0
Nuclear Medicine	50	0	−1	0	−1
Nurse Anes/Anes Asst	1,242	0	0	0	0
Nurse Practitioner	4,060	0	0	0	0
Obstetrics/Gynecology	637	0	0	0	0
Ophthalmology	5,451	0	−1	0	−1
Optometry	1,309	0	−1	0	−1
Oral/Maxillofacial Surgery	67	0	0	0	0
Orthopedic Surgery	3,741	0	0	0	0
Other	31	0	4	0	4
Otolarngology	1,222	0	0	0	0
Pathology	1,165	0	−1	0	−2
Pediatrics	61	0	0	0	0
Physical Medicine	1,107	0	0	0	0
Physical/Occupational Therapy	3,950	0	−1	0	−1
Physician Assistant	2,438	0	0	0	0
Plastic Surgery	376	0	0	0	0
Podiatry	1,974	0	2	0	2
Portable X-Ray Supplier	99	0	1	0	1
Psychiatry	1,187	0	1	0	1
Pulmonary Disease	1,714	0	0	0	0
Radiation Oncology and Radiation Therapy Centers	1,765	0	0	0	−1
Radiology	4,907	0	0	0	0
Rheumatology	541	0	0	0	0
Thoracic Surgery	357	0	0	0	0
Urology	1,738	0	1	0	1
Vascular Surgery	1,141	0	2	0	2
Total	92,733	0	0	0	0

*Column F may not equal the sum of columns C, D, and E due to rounding.

2. CY 2019 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. The estimated impacts for some specialties, including clinical psychologists, vascular surgery, interventional radiology, and podiatry, reflect increases relative to other physician specialties. These increases can largely be attributed to finalized increases in

value for particular services following the recommendations from the American Medical Association (AMA)'s Relative Value Scale Update Committee (RUC) and CMS review, increased payments as a result of finalized updates to supply and equipment pricing, and the implementation of new payment policies associated with communication technology-based services.

The estimated impacts for several specialties, including diagnostic testing facilities, independent labs, pathology, and ophthalmology, reflect decreases in payments relative to payment to other physician specialties. These decreases can largely be attributed to revaluation of individual procedures reviewed by the AMA's committee and CMS, decreased payments as a result of finalized updates to supply and equipment pricing, and continued implementation of previously finalized code-level reductions that are being phased-in over several years. We note that the estimated impacts for many specialties differ significantly relative to the estimates included in the proposed rule. These changes reflect changes between the proposed and final policies based on our consideration of public comments. We note that the most significant of these changes relates to the various elements of the proposed changes in coding and payment for office/outpatient E/M visits, none of which are being finalized for CY 2019. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the CLFS. As a result, the estimated 2 percent reduction for CY 2019 is only applicable to approximately 17 percent of the Medicare payment to these entities.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table (Table 94), including comments received in response to the proposed rates. We remind stakeholders that although the estimated impacts are displayed at the specialty level, typically the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentages in Table 94 are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty, and compared to the same summed total from the previous calendar year. Therefore, they are averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty.

b. Impact

Column F of Table 94 displays the estimated CY 2019 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under ''downloads'' on the CY 2019 PFS final rule website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*. We selected these procedures for sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

c. Estimated Impacts of Implementing the Payment and Coding Changes for Office/Outpatient E/M Services for CY 2021

Although we are not finalizing changes to E/M coding and payment for CY 2019, we are finalizing certain changes for CY 2021. We provide the following impact estimate only for illustrative purposes. Table 95 illustrates the estimated specialty level impacts associated with implementing our finalized policies for E/M coding and payment in CY 2019, rather than delaying until CY 2021. Table 24C shows the estimated impacts of adopting single payment rates for new and established patient E/M visit levels 2–4 (with the rates determined using input values that reflect the weighted average of 2018 inputs for codes describing those visit levels), keeping separate rates for new and established patient E/M visit level 5 (with the rates determined using the 2018 input values for level 5 visits), and adopting add-on codes with equal rates to adjust for the inherent visit complexity of primary care and non-procedural specialty care (with the rates determined using the input values from the proposed rule for the non-procedural specialty care complexity code).

TABLE 95—ESTIMATED SPECIALTY LEVEL IMPACTS OF FINAL E/M PAYMENT AND CODING POLICIES IF IMPLEMENTED FOR 2019

Specialty	Allowed charges (mil)	Impact of work RVU changes %	Impact of PE RVU changes %	Impact of MP RVU changes %	Combined impact %
(A)	(B)	(C)	(D)	(E)	(F)
Allergy/Immunology	$239	0	0	0	0
Anesthesiology	1,981	−1	0	0	−2
Audiologist	68	−1	1	0	0
Cardiac Surgery	294	−1	−1	0	−2
Cardiology	6,618	−1	−1	0	−2
Chiropractor	754	−1	0	0	−1
Clinical Psychologist	776	−1	1	0	0
Clinical Social Worker	728	−2	2	0	0
Colon and Rectal Surgery	166	0	1	0	0
Critical Care	342	−2	−1	0	−3
Dermatology	3,486	1	3	0	4
Diagnostic Testing Facility	733	0	−5	0	−5
Emergency Medicine	$3,121	−2	−1	0	−2
Endocrinology	482	−1	−1	0	−2
Family Practice	6,208	1	1	0	2
Gastroenterology	1,757	−2	−1	0	−3
General Practice	429	2	1	0	3
General Surgery	2,093	0	0	0	−1

TABLE 95—ESTIMATED SPECIALTY LEVEL IMPACTS OF FINAL E/M PAYMENT AND CODING POLICIES IF IMPLEMENTED FOR 2019—Continued

Specialty	Allowed charges (mil)	Impact of work RVU changes %	Impact of PE RVU changes %	Impact of MP RVU changes %	Combined impact %
(A)	(B)	(C)	(D)	(E)	(F)
Geriatrics	197	−1	−1	0	−1
Hand Surgery	214	1	1	0	3
Hematology/Oncology	1,741	0	−1	0	0
Independent Laboratory	646	−1	3	0	3
Infectious Disease	649	−1	−1	0	−1
Internal Medicine	10,767	0	0	0	0
Interventional Pain Mgmt	868	1	2	0	3
Interventional Radiology	386	0	−2	0	−2
Multispecialty Clinic/Other Phys	149	−1	−1	0	−2
Nephrology	2,190	−1	−1	0	−2
Neurology	1,529	−1	0	0	−1
Neurosurgery	804	−1	−1	0	−1
Nuclear Medicine	50	−1	−1	0	−3
Nurse Anes/Anes Asst	1,242	−2	0	0	−2
Nurse Practitioner	4,065	2	1	0	3
Obstetrics/Gynecology	638	2	2	0	5
Ophthalmology	5,448	−1	−2	0	−3
Optometry	$1,309	0	−1	0	−1
Oral/Maxillofacial Surgery	68	0	0	0	1
Orthopedic Surgery	3,743	0	1	0	1
Other	31	−1	3	0	2
Otolarngology	1,210	3	3	0	5
Pathology	1,165	−1	−1	0	−2
Pediatrics	61	1	0	0	1
Physical Medicine	1,107	−1	0	0	−2
Physical/Occupational Therapy	3,950	−1	−2	0	−3
Physician Assistant	2,457	2	1	0	4
Plastic Surgery	377	0	0	0	1
Podiatry	1,974	4	6	0	10
Portable X-Ray Supplier	99	0	0	0	0
Psychiatry	1,187	3	2	0	5
Pulmonary Disease	1,715	−1	−1	0	−2
Radiation Oncology and Radiation Therapy Centers	1,766	−1	−1	0	−1
Radiology	4,911	−1	−1	0	−2
Rheumatology	541	0	−1	0	−1
Thoracic Surgery	358	−1	−1	0	−2
Urology	1,738	2	3	0	4
Vascular Surgery	1,148	0	−2	0	−2
Total	92,771	0	0	0	0

Under our finalized policies, specialties that disproportionately report lower level visits, such as podiatry, and specialties that report office/outpatient visits in conjunction with minor procedures, such as dermatology, would see significant increases. Specialties that predominantly furnish higher level visits would have their negative redistribution significantly mitigated by the maintenance of the level 5 visit and the add-on codes for inherent visit complexity for primary and non-procedural specialty care.

We note that our original proposal was developed more generally to maintain overall RVUs within the codes describing office/outpatient visits, but, after consideration of public comments, we are not finalizing several elements of those proposals, including and especially the multiple procedure payment reduction. As a result, implementation with the values and policies as altered, would require off-setting reductions in overall PFS payments. Following our current methodology, these reductions, required by statute, would be applied through a budget neutrality adjustment in the PFS CF, consistent with our established methodology. As a result of such an adjustment, specialties that do not furnish office/outpatient visits generally would see overall reductions in payment of approximately 2.0 percent, as generally reflected in the Table 95. Given that overall payment for the office/outpatient E/M codes would increase, and because these services are reported by most specialities, the overall changes for most specialties are generally offsetting. However, for physician specialties and suppliers that do not report office/outpatient E/M services, the reduction would be approximately −2.0 percent.

As discussed in section II.H., of this final rule, based on the statements by commenters that the medical community, through the CPT process, has committed itself to considering revisions to the office/outpatient visit codes and given the history of collaboration between CMS and the medical community, we expect to consider any possible changes in CPT coding, as well as recommendations regarding valuation for services, from the RUC and other stakeholders, through our annual rulemaking process, between now and implementation for

CY 2021. We note that any potential coding changes, and recommendations in overall valuation for new or existing codes, could have significant impact on the actual change in overall RVUs for office/outpatient visits relative to the rest of the PFS. Given the various factors that will be considered by the variety of stakeholders involved in the CPT and RUC processes, we do not believe we can estimate with any degree of certainty what the impact of potential changes might be. We also, note, however, that any changes in coding and payment for these services would be subject to notice and comment rulemaking.

With regard to the documentation policies we are finalizing for CY 2021, our intent is to allow clinicians a choice in how levels 2 through 5 visits are documented—using current framework, MDM or time. Assuming the current code set for E/M office/outpatient visits is maintained for CY 2021, when a level 2 through 4 visit (which comprises the majority of visits currently furnished) is documented using the current framework or MDM, documentation will be simplified by applying a minimum level 2 documentation standard to level 2 through 4 visits. When a level 2 through 4 visit is documented using time, practitioners should report the appropriate code based on the time defined as typical under the CPT code descriptors for office/outpatient E/M visits. Practitioners will be required to document that the visit was medically necessary and the billing practitioner spent at least the amount of time included in the CPT as typical face-to-face with the patient. The extended visit code can be reported with a level 2 through 4 visit when the time of the overall visit is between 34 and 69 minutes (for established patients) and between 38 and 89 minutes (for new patients) of face-to-face time with the billing practitioner. (See section II.I. of this final rule. For example, a level 2 through 4 extended visit will require the billing practitioner to spend and document that he or she spent at least 35 minutes face-to-face with the patient. We are also finalizing a policy to require minimal documentation to support reporting of the add-on codes that we are finalizing for use with the level 2 through 4 visit codes. These add-on codes are to reflect the inherent complexity in E/M services for primary care, and for other non-procedural specialty care, and for extended visits).

For level 5 E/M visits, again assuming the current code set remains in place for CY 2021, we will allow the visit to be documented using the current framework, MDM or time. When documenting using MDM, the current definition of level 5 MDM will apply. When documenting a level 5 visit using time, we will require the billing practitioner to document that they spent at least the typical time for the reported level 5 CPT code, face-to-face with the patient (currently 40 minutes for an established patient and 60 minutes for a new patient). The add-on codes that we are finalizing for use with the level 2 through 4 visits (the inherent complexity add-on codes for primary care and other non-procedural specialty care and extended visits) will not be reportable with level 5 visits. We note that the current coding for prolonged visits would continue to be reportable with level 5 visits.

As discussed elsewhere in this section of the final rule, we estimate this approach would lead to significant burden reduction for practitioners, while allowing preparatory time and time for potential refinement over the next few years as we take into account any feedback from stakeholders on these changes, as well as any potential revisions to the E/M code set.

D. Effect of Changes Related to Telehealth

As discussed in section II.D. of this final rule, we are adding two new codes, HCPCS codes G0513 and G0514, to the list of Medicare telehealth services. Although we expect these changes to have the potential to increase access to care in rural areas, based on recent telehealth utilization of services already on the list, including services similar to the proposed additions, we estimate there will only be a negligible impact on PFS expenditures from these additions. For example, for services already on the list, they are furnished via telehealth, on average, less than 0.1 percent of the time they are reported overall. This addition was responsive to longstanding stakeholder interest in expanding Medicare payment for telehealth services. The restrictions placed on Medicare telehealth by the statute limit the magnitude of utilization; however, we believe there is value in allowing physicians and patients the greatest flexibility when appropriate.

E. Effect of Changes to Payment to Provider-Based Departments (PBDs) of Hospitals Paid Under the PFS

As discussed in section II.G. of this final rule, we are finalizing a PFS Relativity Adjuster of 40 percent for CY 2019, meaning that nonexcepted items and services furnished by nonexcepted off-campus PBDs will be paid under the PFS at a rate that is 40 percent of the OPPS rate. In finalizing our policy to maintain the PFS Relativity Adjuster at 40 percent, we updated our analysis to include a full year of claims data. We estimated site-specific PFS rates for the technical component of a service for the entire range of HCPCS codes furnished in nonexcepted off campus PBDs. Next we compared the sum of the site-specific payment rates under the PFS, weighted by OPPS claims volume, to the sum of payment rates under the OPPS, also weighted by OPPS claims volume. This calculation resulted in a relative rate of approximately 40 percent, supporting our policy to maintain the PFS Relativity Adjuster at 40 percent. We are finalizing the PFS Relativity Adjuster of 40 percent, as proposed. There will be no additional savings for CY 2019 relative to CY 2018 because we are maintaining the current PFS Relativity Adjuster of 40 percent, which was finalized for CY 2018.

F. Other Provisions of the Final Regulation

1. Part B Drugs: Application of an Add-On Percentage for Certain Wholesale Acquisition Cost (WAC)-Based Payments

In section II.M. of this final rule, we finalized the following policy: Effective January 1, 2019, Wholesale Acquisition Cost (WAC)-based payments for Part B drugs made under section 1847A(c)(4) of the Act will utilize a 3 percent add-on in place of the 6 percent add-on that is currently being used. We also will permit Medicare Administrative Contractors (MACs) to use an add-on percentage of up to 3 percent for WAC-based payments for new drugs.

We anticipate that the reduction to the add-on payment made for a subset of Part B drugs will result in savings to the Medicare program. The 3 percent add-on is consistent with MedPAC's analysis and recommendations, as well as discounts observed by MedPAC in their June 2017 Report to the Congress. We have also considered how CMS' experience with WAC-based pricing for recently marketed new drugs and biologicals compares to MedPAC's findings. Although the number of new drugs that are priced using WAC is very limited, the average difference between WAC and Average Sales Price (ASP)-based payment limits for a group of 3 recently approved drugs and biologicals that appeared on the ASP Drug Pricing Files (including one biosimilar biological product) was 9.0 percent. Excluding the biosimilar biological product results in a difference of 3.5 percent. The difference was determined by comparing a partial quarter WAC-based payment amount determined

under section 1847A(c)(4) of the Act to the next quarter's ASP-based payment amount. These findings are in general agreement with MedPAC's findings.

Although we are able to provide examples of the relative differences between ASP and WAC based payment limits, and we anticipate some savings from the change in policy, we cannot estimate the magnitude of savings over time because we cannot determine how many new drugs and biologicals subject to partial quarter pricing will appear on the ASP Drug Pricing files in the future or how many Part B claims for these products will be paid. This limitation also applies to contractor-priced drugs and biologicals that have HCPCS codes and are in their first quarter of sales. Finally, the claims volume for contractor-priced drugs and biologicals that are billed using miscellaneous or Not Otherwise Classified codes, such as J3490 and J3590, cannot be quantified. We would like to note that for the three drugs discussed in the preceding paragraph, Medicare Part B payments for individual doses of each drug range from approximately $3,000 to $10,000. The payment changes finalized in this rule would result in a little less than $100 to $300 savings in Medicare allowed charges for each dose.

Although we cannot estimate the overall savings to the Medicare Program or to beneficiaries, we would like to note that this change in policy is likely to decrease copayments for individual beneficiaries who are prescribed new drugs. Given that launch prices for single doses for some new drugs may range from tens to hundreds of thousands of dollars, a 3 percentage point reduction in the total payment allowance will reduce a patient's 20 percent Medicare Part B copayment. This reduction can result in savings to an individual beneficiary and can help Medicare beneficiaries particularly those without supplementary insurance, afford to pay for new drugs by reducing out of pocket expenses.

The 3 percent add-on is expected to reduce the difference between acquisition cost and certain WAC-based Part B drug payments. Based on MedPAC's June 2017 Report to Congress, and for reasons discussed in section II.M. of this rule, we do not anticipate that this change will result in payments amounts that are below acquisition cost or that the new policy will impair providers or patients' access to Part B drugs.

2. Changes to the Regulations Associated With the Ambulance Fee Schedule

As discussed in section III B.2. of this final rule, section 50203(a) of the Bipartisan Budget Act of 2018 amended section 1834(l)(12)(A) and (l)(13)(A) of the Act to extend the payment add-ons set forth in those subsections through December 31, 2022. The ambulance extender provisions are enacted through legislation that is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase and does not require any substantive exercise of discretion on the part of the Secretary. As a result, there were no policy proposals associated with these legislative provisions or associated impact in this rule. We are finalizing our proposal without modification to revise the dates in § 414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to these self-implementing statutory requirements.

In addition, as discussed in section III.B.3. of this final rule, section 53108 of the BBA amended section 1834(l)(15) of the Act to increase the payment reduction from 10 percent to 23 percent effective for ambulance services furnished on or after October 1, 2018 consisting of non-emergency basic life support services involving transports of an individual with end stage renal disease for renal dialysis services furnished other than on an emergency basis by a provider of services or a renal dialysis facility. The 10 percent reduction applies for such ambulance services furnished during the period beginning on October 1, 2013 and ending on September 30, 2018.

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate decrease and does not require any substantive exercise of discretion on the part of the Secretary. As a result, there were no policy proposals associated with these legislative provisions or associated impact in this rule. We are finalizing our proposal without modification to revise § 414.610(c)(8) to conform the regulations to this self-implementing statutory requirement.

3. Clinical Laboratory Fee Schedule: Change to the Majority of Medicare Revenues Threshold in Definition of Applicable Laboratory

As discussed in section III. A. of this final rule, section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for Clinical Diagnostic Laboratory Tests (CDLTs) under the Clinical Laboratory Fee Schedule (CLFS). The CLFS final rule titled, Medicare Clinical Diagnostic Laboratory Tests Payment System final rule, published in the **Federal Register** on June 23, 2016, implemented section 1834A of the Act. Under the CLFS final rule (81 FR 41036), ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' (that is, certain private payor data) collected during a ''data collection period'' for their component ''applicable laboratories.'' In general, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the 6-month data collection period and reported to us during the 3-month data reporting period, and is equal to the weighted median of the private payor rates for the CDLT.

An applicable laboratory is defined at § 414.502, in part, as an entity that is a laboratory (as defined under the Clinical Laboratory Improvement Amendments (CLIA) definition at § 493.2) that bills Medicare Part B under its own National Provider Identifier (NPI). In addition, an applicable laboratory is an entity that receives more than 50 percent of its Medicare revenues during a data collection period from the CLFS and/or the PFS. We refer to this component of the applicable laboratory definition as the ''majority of Medicare revenues threshold.'' The definition of applicable laboratory also includes a ''low expenditure threshold'' component which requires an entity to receive at least $12,500 of its Medicare revenues from the CLFS during a data collection period, for its CDLTs that are not advanced diagnostic laboratory tests (ADLTs).

In determining payment rates under the private payor rate-based CLFS, one of our objectives is to obtain as much applicable information as possible from the broadest possible representation of the national laboratory market on which to base CLFS payment amounts, for example, from independent laboratories, hospital outreach laboratories, and physician office laboratories, without imposing undue burden on those entities. We believe it is important to achieve a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a CDLT, and minimizing the reporting burden for entities. In response to stakeholder feedback and in the interest of facilitating this objective, we are finalizing the revision to the majority of

Medicare revenues threshold component in the third paragraph of the definition of applicable laboratory at § 414.502 to exclude Medicare Advantage (MA) payments under Medicare Part C from the definition of total Medicare revenues (that is, the denominator of the majority of Medicare threshold equation). We believe this change would increase the opportunity for laboratories with a significant Medicare Part C revenue component to meet the majority of Medicare revenues threshold and qualify as an applicable laboratory (provided all other requirements for applicable laboratory status are met). We believe this will result in a broader representation of the laboratory industry reporting applicable information from which to determine payment rates under the CLFS. For a complete discussion of this revision to the majority of Medicare revenues threshold component of the definition of applicable laboratory under the Medicare CLFS, we refer readers to section III A. of this final rule.

Therefore, in response to stakeholder feedback and in the interest of obtaining as much applicable information as possible, we are finalizing the revision of the definition of applicable laboratory at § 414.502 to include a hospital laboratory that bills Medicare on the Form CMS–1450 14x bill type and its electronic equivalent. For a complete discussion of this revision to the definition of applicable laboratory under the Medicare CLFS, we refer readers to section III.A. of this final rule.

a. Estimation of Increased Reporting

To estimate the potential impact of excluding MA plan payments from total Medicare revenues (that is, the denominator of the low expenditure threshold) on the number of laboratories meeting the majority of Medicare revenues threshold, using CY 2017 Medicare claims data, we compared the number of billing NPIs that would have met the majority of Medicare revenues threshold with MA plan revenues included in total Medicare revenues (which is the current requirement) versus the number of billing NPIs that would meet the majority of Medicare revenues threshold had MA plan payments been *excluded* from total Medicare revenues. We found that excluding MA plan payments from total Medicare revenues increased the level of laboratories meeting the majority of Medicare revenues threshold by approximately 49 percent. In other words, we estimate that excluding MA plan payments from total Medicare revenues (the denominator) of the majority of Medicare revenues threshold, and keeping the numerator constant (that is revenues from only the CLFS and or PFS) yields an increase of 49 percent in the number of laboratories meeting the majority of Medicare revenues threshold.

Our summary analysis of data reporting from the initial data reporting period under the Medicare CLFS private payor rate-based payment system, indicates that we received applicable information from 1,942 applicable laboratories and they reported over 4.9 million records. Applying the projected 49 percent increase to the number of applicable laboratories from the first data reporting period (1,942 × 1.49) yields an estimated 2,893 laboratories that would meet the majority of Medicare revenues threshold, which reflects an additional 951 laboratories. Provided all other requirements for applicable laboratory status are met (including the low expenditure threshold of receiving at least $12,500 in CLFS revenues during a data collection period) a laboratory would report applicable information for the next data reporting period.

To determine the estimated reporting burden for an applicable laboratory, we looked at the distribution of reported records that occurred for the first data reporting period. The average number of records reported for an applicable laboratory for the first data reporting period was 2,573. The largest amount of records reported for an applicable laboratory was 457,585 while the smallest amount reported was 1 record. A summary of the distribution of reported records from the first data collection period is illustrated in the Table 96.

TABLE 96—SUMMARY OF RECORDS REPORTED FOR FIRST DATA REPORTING PERIOD

[By applicable laboratory]

Total records	Average records	Min records	Max records	Percentile distribution of records				
				10th	25th	50th	75th	90th
4,995,877	2,573	1	457,585	23	79	294	1,345	4,884

Presuming that all of the additional laboratories that are projected to meet the majority of Medicare revenues threshold, that is approximately 951, also meet all of the criteria necessary to receive applicable laboratory status, as defined at § 414.502, they would be an applicable laboratory and report applicable information for the next data reporting period, January 1, 2020 through March 31, 2020. Using the mid-point of the percentile distribution of reported records from the initial data reporting period, that is approximately 300 records reported per applicable laboratory (50th percentile for the first data reporting period was 294), we estimate an additional 285,300 records would be reported for the next data reporting period (951 laboratories × 300 records per laboratory = 285,300). This represents an increase in data reporting of about 5 percent over the number of records reported for the initial data reporting period (285,300 additional records/4,995,877 = 0.05). In other words, using the approximate mid-point of reported records for the first data reporting period, we estimate that our proposed change to the majority of Medicare revenues threshold would increase the total amount of records reported by approximately 5 percent. As illustrated in Table 96, the number of records reported varies greatly, depending on the volume of services performed by a given laboratory. Laboratories with larger test volumes, for instance at the 90th percentile, should expect to report more records as compared to the midpoint used for this analysis. Laboratories with smaller test volume, for instance at the 10th percentile, should expect to report fewer records as compared to the midpoint.

We estimate that the inclusion of 14X type of bills would yield an increase of 39 percent in the total number of laboratories meeting the majority of Medicare revenues threshold. Applying the projected 39 percent increase to the number of applicable laboratories from the first data reporting period (1,942 × 1.39) yielded an estimated 2,699 laboratories that would meet the majority of Medicare revenues threshold, which reflects approximately

757 additional laboratories. Provided all other required criteria for applicable laboratory status are met (including the low expenditure threshold of receiving at least $12,500 in CLFS revenues during a data collection period) a laboratory would report applicable information for the next data reporting period. Using the mid-point of the percentile distribution of reported records from the initial data reporting period, that is approximately 300 records reported per applicable laboratory (50th percentile for the first data reporting period was 294), we estimated an additional 221,100 records would be reported for the next data reporting period (757 laboratories × 300 records per laboratory = 227,100). This represents an increase in data reporting of about 5 percent over the number of records reported for the initial data reporting period (227,100 additional records/4,995,877 = 0.05).

b. Minimal Impact Expected on CLFS Rates

We note that there would only be an associated Medicare cost or savings to the extent that the additional applicable laboratories are paid at a higher or lower private payor rate, as compared to other laboratories that reported previously, and only to the extent that the volume of services performed by these ''additional'' applicable laboratories is significant enough to make an impact on the weighted median of private payor rates. We have no reason to believe that increasing the level of participation, either by excluding MA plan payments from total Medicare revenues or including laboratories that bill Medicare Part B on the Form CMS–1450 14x bill type would result in a measurable cost difference under the CLFS. Given that the largest laboratories with the highest test volumes, by definition, dominate the weighted median of private payor rates, and that the largest laboratories reported data for the determination of CY 2018 CLFS rates and are expected to report again, we do not expect the additional reported data resulting from our proposed change to the majority of Medicare revenues threshold to have a predictable, direct impact on CLFS rates because of the reasons stated above. However, we believe that this proposal responds directly to stakeholder concerns regarding the number of applicable laboratories reporting applicable information for the initial data reporting period. Therefore, in an effort to increase the number of laboratories qualifying for applicable laboratory status, we are finalizing a change to the majority of Medicare revenues threshold so that laboratories furnishing tests to a significant level of Medicare Part C enrollees may qualify as applicable laboratories and report data to us. In addition, as part of the same effort to increase the number of laboratories qualifying for applicable laboratory status, we are finalizing a change in the definition of applicable laboratory to include an entity that bills Medicare Part B on the Form CMS–1450 14x bill type. We note that other laboratory types, such as independent laboratories and physician office laboratories, are required under the current definition of an applicable laboratory to determine applicable laboratory status and must report applicable information. The use of Form CMS–1450 14x TOB to define an applicable laboratory would assist hospital outreach laboratories to comply with their obligation to assess applicable laboratory status for any outreach laboratories and report applicable information if they meet the requirements to be an applicable laboratory. As such, the hospital could use the revenues from the CLFS and PFS as the numerator compared to the total revenues for the 14X TOB to determine applicable laboratory status. Alternatively, a hospital could get an NPI for its outreach laboratory.

Comment: One commenter disagreed with our using the number of laboratories reporting applicable information during the first data reporting period as a baseline for estimating the number of additional laboratories that would report applicable information as a result of excluding MA plan payments under Part C from total Medicare revenues. The commenter stated that because the OIG estimated that 5 percent of all laboratories paid under Medicare Part B, or about 12,500 laboratories, would qualify as applicable laboratories and would be required to report applicable information to CMS. The commenter stated that because the OIG's estimate is far greater than the number of laboratories that actually reported (that is 1,942), we should not have used the number of laboratories reporting applicable information during the first data reporting period as a baseline.

Response: We believe that it is more appropriate to use the actual reporting levels (1,942 laboratories) from the initial data reporting period as a baseline for projecting increased data reporting under our final policy rather than an estimation of laboratories determined as applicable. We acknowledge that the OIG estimated that 5 percent of all laboratories paid under Medicare Part B, or about 12,500 laboratories, would qualify as applicable laboratories. It is important to note that individual laboratories determine whether they meet the requirements to be an applicable laboratory and that neither OIG nor CMS had the benefit of experience with collecting private payor data before those estimates were made. We believe that using the actual number of laboratories that reported is the more reliable method to develop our estimates of future potential applicable laboratories. We believe that it is would be inappropriate here to estimate future changes using an estimate as a baseline when there is actual experience (for example, number of reporters) that can base used as a baseline.

4. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 1834(q)(2) of the Act, as added by section 218(b) of the PAMA, established a program to promote the use of AUC for applicable imaging services furnished in an applicable setting. The CY 2016 PFS final rule with comment period established an evidence-based process and transparency requirements for the development of AUC and stated that the AUC development process requirements, as well as the application process that organizations must comply with to become qualified provider-led entities (PLEs) did not impact CY 2016 physician payments under the PFS (80 FR 71362). The CY 2017 PFS final rule identified the requirements clinical decision support mechanisms (CDSMs) must meet for qualification and stated that the CDSM requirements, as well as the application process that CDSM developers must comply with for their mechanisms to be specified as qualified under this program, did not impact CY 2017 physician payments under the PFS (81 FR 80546). The CY 2018 PFS final rule established the effective date of January 1, 2020, on which the AUC consulting and reporting requirements will begin, and extended the voluntary consulting and reporting period to 18 months. Therefore, we stated these proposals did not impact CY 2018 physician payments under the PFS (82 FR 53349) and noted we would provide an impact statement when applicable in future rulemaking.

This final rule modifies the Medicare AUC Program and addresses the impacts related to the actions taken by ordering professionals who order advanced diagnostic imaging services and those who furnish the advanced diagnostic imaging services, including the professional and technical portions of the services. We finalized a modification to the AUC consultation requirement for ordering professionals

specified in our regulation at § 414.94(j) to allow clinical staff under the direction of the ordering professional to perform the AUC consultation; therefore, this analysis estimates the impact of AUC consultations. We also clarified the requirement that reporting AUC consultation information across claims for both the furnishing professional and furnishing facility is required in § 414.94(k), and this analysis estimates the impact of the statutorily required reporting AUC consultation information. In addition, we modified the significant hardship exceptions in § 414.94(i) as proposed, therefore this analysis estimates the impact of a self-attestation process for ordering professionals. We also estimated the further reaching impacts of the AUC program in the detailed analysis that follows, assuming that some ordering professionals will voluntarily choose to purchase a qualified CDSM integrated within their existing electronic health record (EHR) and others may voluntarily choose to purchase an EHR system in order to obtain an integrated qualified CDSM. We believe that in the beginning of this program due to the additional action required on the part of the ordering professional, it may take longer for a Medicare beneficiary to obtain an order for an advanced diagnostic imaging service, and therefore, we have calculated an estimated impact to Medicare beneficiaries.

This final rule includes a discussion of the proposed options along with the final policy to report the required claims-based AUC consultation information in the form of G-codes and HCPCS modifiers. We estimated the impact to use existing coding methods (G-codes and HCPCS modifiers) to report that information. Finally, we measured the estimated impact on furnishing professionals and facilities of the finalized proposal to include independent diagnostic testing facilities (IDTFs) as an applicable setting in § 414.94(b). While the AUC consultation and reporting requirements of this program are effective beginning January 1, 2020 with an educational and operations testing period, we attempt in this analysis to identify areas of potential qualitative benefits to both Medicare beneficiaries and the Medicare program.

a. Impact of Required AUC Consultations by Ordering Professionals

In this final rule, we modified the AUC program largely in response to public comments and recommendations as we believe these modifications are also important in minimizing burden of the AUC program on ordering professionals, furnishing professionals, and facilities. Specifically, we included a proposal regarding who, other than the ordering professional, may conduct the AUC consultation through a qualified CDSM and still meet the requirements of our regulations. In the CY 2018 PFS final rule (82 FR 53349), we based our estimate for the AUC consultation requirement on the 2 minute effort of a family and general practitioner resulting in an annual burden of 1,425,000 hours (43,181,818 consultations (Part B analytics 2014 claims data) × 0.033 hr/consultation) at a cost of $275,139,000.

An important difference from last year's analysis is that this year's analysis includes estimates for non-physician practitioners that order advanced diagnostic imaging services. For the purposes of this analysis, we assumed that orders for advanced diagnostic imaging services will be placed by ordering professionals that are non-physician practitioners in the same percent as the numbers of non-physician practitioners are relative to the total number of non-institutional providers. Therefore, this analysis assumed that 40 percent of all advanced diagnostic imaging services will be ordered by non-physician practitioners. While non-physician practitioners may not order advanced diagnostic imaging services in the same proportion as their numbers, we did not have other data to use for this estimate. We specifically solicited comment and data on alternative assumptions about the number of non-physician practitioners who order advanced imaging services. We did not receive comments on this aspect of our estimate.

In addition, we had proposed, but did not finalize, that auxiliary personnel may perform the AUC consultation when under the direction of, and incident to, the ordering professional's services. We finalized that the AUC consultation task may be delegated by the ordering professional to clinical staff under the direction of the ordering professional. The final estimate below, after taking into account public comments, is applicable given the change in policy from proposed rule to final rule. In the CY 2019 PFS proposed rule, we estimated that the majority, or as many as 90 percent, of practices will employ the use of auxiliary personnel, working under the direction of the ordering professional, to interact with the CDSM for AUC consultation for advanced diagnostic imaging orders. We also considered leaving the policy unchanged, and smaller modifications to that could expand who performs the consultation to a single type of non-physician practitioner. We originally proposed this modification because we believed it maximized burden reduction effort as illustrated in the following updated estimate of consultation burden.

To estimate the burden of this proposed policy, we calculated the effort of a 2-minute consultation with a qualified CDSM by a registered nurse (occupation code 29–1141) with mean hourly wage of $35.36 and 100 percent fringe benefits to be $2.33/consultation ($35.36/hour × 2 × 0.033 hour). If 90 percent of AUC consultations (1,282,500 hours) are performed by auxiliary personnel as proposed then annually the burden estimate would be $90,698,400 (1,282,500 hours × $70.72/hour) to consult. We acknowledged that some AUC consultations will be performed by the ordering professional, therefore the remaining total annual burden we estimated was $28,576,950 for the consultation requirement as it was proposed. As a result of these assumptions and calculations, we estimated a reduction in the burden of the statutorily required AUC consultation burden from $275,139,000 (as fully discussed in the CY 2018 PFS final rule) to $122,508,675, which resulted in a net burden reduction of $152,630,325.

The following is a summary of the comments we received on the proposed estimated impact of consultations by ordering professionals.

Comment: In general, several commenters found CMS' proposed estimate of the burden of the Medicare AUC program to be sensible. A few commenters disagreed with the proposed burden estimate of 2 minutes to consult a qualified CDSM. One commenter suggested the time was too short and noted that the Medicare Imaging Demonstration Evaluation Report to Congress [46] indicated 3.3 additional minutes to order an advanced diagnostic imaging service, while another commenter questioned whether the estimate of burden included calculations for the time and effort of the ordering professional to look up the CDSM username and password, wait for web pages to load, conduct the AUC consultation, and record the results. Additionally, a few commenters stated that more complex clinical situations will require additional time to perform an AUC consultation, as well as consultations involving new patients with new clinical scenarios. In contrast, a few other commenters suggested that

[46] Timbie JW, Hussey PS, Burgette L, et al. Medicare imaging demonstration evaluation report for the report to congress. April 2014. RR–706–CMMS.

the 2 minute estimate to perform AUC consultation overestimated the time and effort, stating that accessing one no fee website for a qualified CDSM to perform an AUC consultation takes a healthcare provider less than 50 seconds.

Response: Based on the average of two estimates provided ([3.3 min + 0.8 min]/2 = 2.1 min), we continue to believe that 2 minutes is a reasonable estimate of the time and effort to consult one of the currently qualified clinical decision support mechanisms available under this program. We will continue to supplement these estimates with published evidence as the AUC consultation and reporting requirements are implemented beginning January 1, 2020.

Comment: A few commenters agreed with our estimates that as many as 90 percent of practices would use other personnel working under the direction of the ordering professional to interact with the CDSM. One commenter noted that most family physicians and general practitioners would not employ a registered nurse for the purpose of AUC consultation and instead would rely upon a licensed practical nurse or medical assistant. The commenter also noted that we are likely overestimating the costs in question because if CMS anticipates a registered nurse is needed, then such a professional would be cost prohibitive for most family medicine practices.

Response: As a result of the finalized policy at § 414.94(j) and after reading the public comments, we have updated our estimate to account for the $16.15 mean hourly wage and fringe benefits of a medical assistant (BLS #31–9092) to perform the AUC consultation. If 90 percent of consultations (1,282,500 hours) are performed by such an individual then annually the burden estimate would be $41,424,750 (1,282,500 hours × $32.30/hour) to consult.

Comment: One commenter suggested that not all clinical situations will require the ordering professional to consult a CDSM and report the AUC adherence, but rather noted that first the ordering professional must determine if the patient's clinical scenario is within a priority clinical area. Additionally, one commenter stated that additional time and effort should be considered to estimate the interaction that will likely be required between the ordering professional and auxiliary personnel to complete the AUC consultation within the CDSM. Finally, one commenter suggested that CMS also estimate the time and effort for the furnishing professional to perform the AUC consultation on behalf of the ordering professional.

Response: We remind all commenters that an AUC consultation must take place for any applicable imaging service furnished in an applicable setting and paid for under an applicable payment system, regardless of whether the patient's clinical scenario falls within a priority clinical area. Therefore, we believe that there is not additional time and effort needed to make this determination as it does not change the estimation of burden for the AUC consultation requirement at § 414.94(j). As a result of the finalized policy at § 414.94(j), the furnishing professional cannot perform the AUC consultation on behalf of the ordering professional; therefore, we did not include this additional estimate. When the consultation and reporting requirements are implemented beginning January 1, 2020, we may have data to support additional time for other supportive consultations, such as that between clinical staff and the ordering professional. However, at this time we have no experience or data to suggest the type or time of these interactions, and did not receive estimates or experience from commenters to suggest the level of effort required to change this AUC consultation burden estimate further.

Comment: A few commenters requested that CMS consider situations where multiple consultations occur for the same advanced diagnostic imaging service for the same Medicare beneficiary, such as in the case of obtaining a second opinion. One commenter expected that the estimate of burden would include calculations for the time and effort required of the ordering professional to consult more than one CDSM. Another commenter noted situations resulting in the Medicare beneficiary being unable to receive an order during the encounter and forced to return to the practice such as in the case of technical issues with a CDSM. Finally, one commenter asked that CMS consider an assumption that some ordering professionals will decide not to use a qualified CDSM and instead refer the patient to a specialist for AUC consultation.

Response: If we can consider that a patient is referred to a specialist in lieu of receiving an order from their general practitioner, then we recognize that no second consultation would occur and that a specialist acting as an ordering professional may choose to delegate the AUC consultation to another individual such as someone on their clinical staff. If there are technical difficulties that result in a significant hardship for the ordering professional to consult specified applicable AUC, then no consultation is required and no additional time and effort to perform the consultation would take place. While multiple consultations may take place, such as in the case of consulting more than one CDSM, it is not a requirement. We will continue to look for published evidence on these experiences after the AUC consultation and reporting requirements are implemented beginning January 1, 2020.

Comment: A few commenters noted that additional costs should be considered on the part of the ordering professional and/or personnel under their supervision. One commenter asked that CMS consider the time and effort to educate ordering professionals and auxiliary personnel on how to use a CDSM.

Response: We agree with the commenter that we unintentionally excluded the time and effort to undertake educational training activities related to performing an AUC consultation. As a result we have included the time and effort of a general practitioner (occupation code 29–1062) with mean hourly wage of $100.27 plus 100-percent to account for fringe benefits to attend a one-time, 1.0 hour training. The hour is representative of training incurred by physicians for a single topic as part of the process of maintaining credentials. Some physicians may not need to undertake educational training activities related to this program. Others may undertake training activities in lieu of an alternative continuing education training resulting in no net increase to their training costs. If all 579,687 ordering professionals subject to this program attend a one-time, 1.0 hour training, then we estimate the total burden to be $116,250,431 ($100.27 × 2 × 1.0 hour × 579,687). We recognize that some ordering professionals may be specialists with higher mean hourly wage and other ordering professionals are not physicians (for example, nurse practitioners, physician assistants) with lower mean hourly wage, however without any additional evidence or specific estimates from commenters, we could not inform this burden estimate further.

After considering the comments, we are updating the proposed impact estimate of consultations by ordering professionals. First, we modified our calculation of the effort by a registered nurse to the effort of a 2-minute consultation with a qualified CDSM by a medical assistant (occupation code 31–9092) with mean hourly wage of $16.15 and 100 percent fringe benefits

for 90 percent of consultations (1,282,500 hours) to be $41,424,750 (1,282,500 hours × $32.30/hour). We acknowledged that some AUC consultations will not be performed by these individuals, therefore the remaining total annual burden we estimate is $28,576,950 (142,500 hours × $200.54/hour) for this proposed consultation requirement. As a result of these assumptions and calculations, we estimated a reduction in burden of the statutorily required consultation from cost of $275,139,000 to $70,001,700, which results in a net burden reduction of $205,137,300.

In section VII.G. of this RIA, Alternatives Considered, we provide a detailed estimate of the burden of an ordering professional voluntarily choosing to consult a second, free CDSM for 300,717 services annually. If 90 percent of those consultations (300,717 services × 90 percent × 0.033 hr/service) for 8,931.285 total hours were performed by a medical assistant at a rate of $32.30/hour for a total of $288,480.50 (8,931.285 × $32.30/hour) and 10 percent of consultations (300,717 services × 10 percent × 0.033 hr/service) for 992.376 total hours were performed by the ordering professional at a rate of $200.54/hour for a total of $199,011.08 then annually the burden estimate would be 9,923.661 total hours (8,931.285 hours + 992.376 hours) and $487,491.58 ($288,480.50 + $199,011.08) to perform the second consultation.

We also estimated the burden of this one-time effort to undertake educational training activities related to the impact of consultations by ordering professionals. As a result we have included the time and effort of a general practitioner (occupation code 29–1062) with mean hourly wage of $100.27 plus 100-percent to account for fringe benefits to attend a one-time, 1.0 hour training. Based on our proposed estimate in section VII.F.4.b. of this RIA, if 579,687 ordering professionals are subject to this program, and all attend training for the same amount of time, then we estimate the total one-time burden of education and training to be $116,250,431 ($200.54/hr × 1.0 hour × 579,687). Since not all physicians would undertake educational training activities, this estimate should be considered an upper bound.

b. Impact of Significant Hardship Exceptions for Ordering Professionals

We previously identified significant hardship exceptions to the requirement that ordering professionals consult specified applicable AUC when ordering applicable imaging services (81 FR 80170). Our original intention was to design the AUC hardship exception process in alignment with the EHR Incentive Program and then the MIPS ACI performance category (now Promoting Interoperability). However, in this final rule, we modified the significant hardship exception criteria under § 414.94(i)(3) to be specific to the Medicare AUC program and independent of other Medicare programs both in policy and process. Specifically, we finalized the policy that all ordering professionals self-attest if they are experiencing a significant hardship at the time of placing an advanced diagnostic imaging order. Since the Medicare EHR Incentive Program has ended and we are unable to continue referring to a regulation that is no longer in effect, we did not consider leaving this policy unchanged. We also considered using a significant hardship application submission process. However, we believe that the self-attestation process maximizes burden reduction effort as illustrated in the following updated estimate of ordering professionals subject to an AUC consultation burden.

To estimate the impact of our modification and create a hardship exception specific to this program we attempted to identify how many ordering professionals would be subject to this program.

Medicare non-institutional Part B claims for the first 6 months of 2014 shows that for claims for an advanced diagnostic imaging service that listed an NPI for the ordering/referring provider, up to 90-percent of claims include only 18 different provider specialties. These specialties include: Emergency Medicine; Internal Medicine; Family Practice; Cardiology; Hematology/Oncology; Orthopedic Surgery; Neurology; Urology; Physician Assistant; Nurse Practitioner; Pulmonary Disease; General Surgery; Neurosurgery; Medical Oncology; Gastroenterology; Radiation Oncology; Otolaryngology; and Diagnostic Radiology. We then used CMS data that served to create Table II.8 of the 2014 Medicare Statistics Book and were able to identify how many practitioners in each of those specialties were participating in Medicare program. Table II.8 of the 2014 Medicare Statistics Book combines many of these specialties into higher level groupings and displays the total number of practitioners participating in the Medicare program. However, we used more granular information that identifies the number of practitioners participating in the Medicare program by an individual specialty rather than higher level groupings (table available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/2016/Downloads/PROVIDERS/2016_CPS_MDCR_PROVIDERS_6.pdf*). For example, Table II.8 of the 2014 Medicare Statistics Book combines all surgeons into one category whereas we used detailed information for the individual surgical specialties of general surgery and orthopedic surgery for this estimate.

Using this more specific data for the 18 specialties, we estimate the count of practitioners that will be ordering professionals under the AUC program to be 586,386. There are limitations as we do not have data on the actual number of practitioners who order advanced diagnostic imaging services because information about the ordering professional is not currently required to be included on the Medicare claim form for advanced diagnostic imaging services.

In the absence of data on the breadth of professionals who would be required to consult AUC, we assumed that all professionals in the specialties listed earlier could potentially be subject to these requirements because some professionals within a specialty may order these imaging services. We specifically requested comments and data on the numbers of professionals in the specialties that actually order advanced imaging services. We did not receive comments on this estimate.

With respect to the significant hardship exceptions, based on 2016 data from the Medicare EHR Incentive Program and the 2019 payment year MIPS eligibility and special status file, we estimated that 6,699 respondents in the form of eligible clinicians, groups, or virtual groups will submit a request for a reweighting to zero for the advancing care information performance category due to extreme and uncontrollable circumstances or as a result of a decertification of an EHR. For the purposes of this analysis, we cautiously estimated that each of the 6,699 respondents represents a unique ordering professional and that all respondents who experience extreme and uncontrollable circumstances or have an EHR that is decertified are ordering professionals who would self-attest to a significant hardship exception under the AUC program. Nevertheless, we have used this information to update our estimate that there are 579,687 ordering professionals subject to this program.

We believe that the proposed significant hardship exception at

§ 414.94(i) would further reduce the burden of this program as finalized for four reasons. First, due to the availability of a significant hardship exception there will likely be fewer ordering professionals consulting specified applicable AUC. Second, the self-attestation process is a less burdensome proposal when compared to the alternative of a hardship application process that may have both regulatory impact and information collection requirements. We estimate the impact of a significant hardship exception application in section VII.G. of this RIA, Alternatives Considered.

Third, any application or case-by-case determination would necessitate immediate infrastructure development by CMS directly or through one or more MACs, which adds burden and impact to this program. Finally, the proposed self-attestation process requires no verification on the part of the furnishing professional or facility required to report AUC consultation information on the Medicare claim, thus minimizing burden for both ordering professionals, furnishing professionals and facilities. While some of the efficiencies gained from a self-attestation process are qualitative in nature and difficult to measure, such as the streamlined reporting, we believe that relative to other regulatory approaches this proposal uses a least burdensome approach.

We recognize that ordering professionals would store documentation supporting the self-attestation of a significant hardship. Storage of this information could involve the use of automated, electronic, or other forms of information technology at the discretion of the ordering professional. We estimated that the average time for office clerical activities associated with this task to be 10 minutes. To estimate the burden of this storage, we expected that a Bureau of Labor Statistics (BLS) occupation title 43–6013 Medical Secretary with a mean hourly rate of $17.25 and 100-percent fringe benefits would result in a calculated effort of 10 minutes of clerical work to be $5.76 ($17.25/hour × 2 × 0.167 hour). If 6,699 separate ordering professionals require that a Medical Secretary perform the same clerical activity on an annual basis, then this equates to a cost of approximately $38,596 per year. We solicited comment to inform these burden estimates. We did not receive comments on these burden estimates and have finalized these estimates as proposed.

c. Impact of Consultations Beyond the Impact To Ordering Professionals

Although we have already discussed the time and effort to consult specified applicable AUC through a qualified CDSM here and in previous rulemaking (81 FR 80170), we believe the impact of this program is extensive as it will apply to every advanced diagnostic imaging service (for example, magnetic resonance imaging (MRI), computed tomography (CT) or positron emission tomography (PET)). Therefore, we also have described in this detailed analysis the estimated impacts of AUC consultation beyond the act of consulting specified applicable AUC which would be an upper bound.

(1) Transfers From Ordering Professionals to Qualified CDSMs and EHR Systems

The first additional impact we identified is upstream in the workflow of the AUC consultation and represents the acquisition cost, training, and maintenance of a qualified CDSM. These tools may be modules within or available through certified EHR technology (as defined in section 1848(o)(4)) of the Act or private sector mechanisms independent from certified EHR technology or established by the Secretary. Currently, none are established by the Secretary. Additionally, for the purposes of this program, as required by statute, one or more of such mechanisms is available free of charge. For this impact analysis we will illustrate three potential scenarios as low, medium, and higher burden assessments of this consultation requirement. First, we assume that some number of ordering professionals consults a qualified CDSM available free of charge. Second, we assume that some number purchase a qualified CDSM to integrate within an existing EHR system. Third, we assume that some do not currently have an EHR system and, as a result of the statutory requirement to consult with AUC, would purchase an EHR system with an integrated qualified CDSM to consult specified applicable AUC for the purposes of this program.

In the lowest estimate of burden, every AUC consultation would take place using a qualified CDSM available free of charge integrated into an EHR system and add no additional cost to the requirement in § 414.94(j) of this final rule. While we did not base this estimate on absolute behaviors by all those who have ordered advanced diagnostic imaging services, we believe it is reasonable to estimate that as many as 75 percent of an assumed annual 40,000,000 orders for advanced diagnostic imaging services could occur at no additional cost beyond the time and effort to perform the consultation. This may be an underestimate of orders that occur at no additional cost beyond time and effort because multiple free qualified CDSMs are available.

In contrast, some ordering professionals may voluntarily choose to purchase a qualified CDSM that is integrated within their EHR. To estimate how many ordering professionals may choose to purchase an integrated qualified CDSM, we consulted the 2015 National Electronic Health Records Survey [47] (NEHRS), which is conducted by the National Center for Health Statistics (NCHS) and sponsored by the Office of the National Coordinator for Health Information Technology (ONC). NEHRS is a nationally representative mixed mode survey of office-based physicians that collects information on physician and practice characteristics, including the adoption and use of EHR systems. In the United States in 2015, 86.9 percent of office-based physicians used any EHR/EMR, with significantly higher adoption by general or family practice physicians (92.7 percent, p-value <0.05), and slightly lower for medical non-primary care physicians (84.4 percent). Given that approximately 87 percent of office-based physicians have adopted EHR systems, we believe it is likely that the majority will prefer a qualified CDSM integrated with EHR. While we note that qualified CDSMs available free of charge are also integrated within one or more EHR systems, the following illustrative exercise estimates the time and effort to purchase, install, train, and maintain a qualified CDSM integrated into an EHR system. Since section 1834(q)(1)(c)(iii) requires that one or more free CDSMs be available, this is an illustrative exercise rather than an estimate of the burden of the statutory requirement.

Again, as stated above, we do not have data on the number of clinicians who order advanced diagnostic imaging services, and we have made overarching assumptions to look at particular specialty areas that in our claims analysis order these advanced diagnostic imaging services. We assumed all individual clinicians in these specialty areas could potentially be subject to these requirements. Adding the number of clinicians in each of the specialty areas results in 586,386 ordering professionals. We also did not make a distinction between individual

[47] Jamoom E, Yang N. Table of Electronic Health Record Adoption and Use among Office-based Physicians in the U.S., by State: 2015 National Electronic Health Records Survey. 2016.

professionals and groups, as further explained below.

To calculate the impact of a single purchase, we believe based on market research that ordering professionals, either in groups or individually, would spend an estimated $15,000 for a one-time purchase of an integrated qualified CDSM, including installation and training. We assume that all of these costs are based on market research and incurred over the course of 5 years. We also assume that the $15,000 purchase would be made by each ordering professional and did not take into account the potential that a group practice might incur a discounted price per user based on the number of ordering professionals in the practice. These assumptions could significantly alter the impact estimate and we sought comment on such assumptions. Given the difficult nature of deriving these illustrative estimates based on limited data, we solicited comment and information on the preference that physicians and practitioners might have for using an integrated qualified CDSM—a free CDSM or a CDSM that is not free but integrated within an existing EHR system. Also, if purchased, whether this would be purchased at the group practice level to be made available to all clinicians in the practice for the same cost that would be incurred by a single practitioner purchasing the same qualified CDSM, and whether the cost of purchasing a CDSM would be incurred in a single year or over multiple years.

For the purposes of estimating the transfer of costs from ordering professionals to qualified CDSM developers, of the estimated 579,687 practitioners that are likely subject to this program, we excluded 181,653 ordering professionals with specialties whose practitioners order on average fewer than 20 advanced diagnostic imaging services per year (physician assistant, nurse practitioner, and diagnostic radiology). The assumption is that lower volume ordering professionals would select a qualified CDSM that is free of charge. This updates the estimate to consider 398,034 ordering professionals who may purchase an integrated qualified CDSM. To this end, if we assume 346,290 (398,034 ordering professionals × 87 percent) ordering professionals already have an EHR system and 30 percent of these ordering professionals (346,290 × 30 percent, or 103,887) make this purchase for $15,000 and spend $1,000 annually to maintain their system for 5 years (initial acquisition cost in year 1 and maintenance costs in years 2–5), then the total annual cost is estimated to be $394,770,600 ((103,887 × $19,000)/5 years)).

It is also reasonable to assume that some ordering professionals may not need additional training in using a qualified CDSM because the EHR Incentive Program required CDS as a core measure. In addition, the EHR Incentive Program incentivized use of computerized provider order entry (CPOE)—an electronic submission of pharmacy, laboratory, or radiology orders. To determine readiness among Medicare practitioners for these and other measures, the 2011 Meaningful Use Census [48] (RTI International, 2012) observed that those participating in the EHR Incentive Program in 2011 on average met and exceeded the established 30 percent threshold for meaningful use of CPOE in Stage 1. Analysis of the distribution of performance on these measures shows that 86 percent of eligible participants were well over the established thresholds. It is important to note that the CPOE measure had a higher threshold in Stage 2, and 60 percent of eligible participants in 2011 attested to meaningful use are already meeting this higher threshold. This report suggests that some ordering professionals may be well prepared to adopt a qualified clinical decision support mechanism, as this experience offset may yield lower costs and burden to learn to incorporate decision support into the ordering workflow through shorter training times.

Additionally, some ordering professionals may voluntarily choose to purchase a certified EHR system to use a qualified CDSM already integrated within the EHR. The first estimate of capital costs for certified EHR system was identified in the first year of the EHR incentive program as an estimated cost of approximately $54,000 (75 FR 44518), which adjusted for inflation using the Consumer Price Index for All Urban Consumers (CPI–U) U.S. city average series for all items, not seasonally adjusted, represents $62,050.40 in 2018. If we assume that 346,290 ordering professionals subject to this program have adopted EHR, then we will also assume that 51,744 ordering professionals (398,034 ordering professionals × 13 percent) have not adopted an EHR system.

Most physicians who have not yet invested in the hardware, software, testing, and training to implement EHRs may continue to work outside the EHR for a number of reasons—lack of standards, lack of interoperability, limited physician acceptance among their peers, maintenance costs, and lack of capital. Adoption of EHR technology necessitates major changes in business processes and practices throughout a provider's office or facility. Business process reengineering on such a scale is not undertaken lightly. Therefore, while we cannot estimate the business decisions of all ordering professionals, we assume for the purposes of this analysis that as a result of this program some ordering professionals will purchase an EHR system in order to access a qualified CDSM that is integrated into that EHR system for the purposes of acquiring long-term process efficiencies in consulting specified applicable AUC.

We do not have data on the characteristics of physicians who have not purchased an EHR system. However, for the purpose of estimating the transfer of costs from ordering professionals to EHR systems, we will assume based on research from business advisors [49] that 30 percent, or 15,523 ordering professionals (51,744 ordering professionals × 30 percent) will seek to purchase an EHR system at an estimated cost of $62,050.40 for a total one-time cost of $963,208,359.20 in EHR system and integrated qualified CDSM infrastructure. As we believe not every ordering professional in this example would purchase such infrastructure immediately, for the purposes of this estimate, we annualized this cost over 5 years to $192,641,671.84/year. We recognize that qualified CDSMs may be modules within or available through certified EHR technology (as defined in section 1848(o)(4) of the Act) or private sector mechanisms independent from certified EHR technology or established by the Secretary.

We recognize that due to the limited data available to make these assumptions our estimates are likely high and we sought comment and information about these assumptions. These estimates might be viewed as an upper bound of the impact of this program beyond consultation with a free tool and note that at the time of publication there were three free tools available as indicated on the CMS website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html*.

[48] Vincent, A. EHR Incentive Program: 2011 Meaningful Use Census. RTI Internatoinal. November 2012.

[49] McCormack M, ''EHR Software Buyer Report—2014'' available at *https://www.softwareadvice.com/resources/ehr-buyer-report-2014/*.

(2) Impact to Medicare Beneficiaries

Additionally, we believe that the additional 2-minute consultation will impact the Medicare beneficiary when their advanced diagnostic imaging service is ordered by the ordering professional by introducing additional time to their office visit. To estimate this annual cost, we multiplied the annual burden of 1,425,000 hours by the BLS occupation code that represents all occupations in the BLS (00–0000) as mean hourly wage plus 100 percent fringe ($47.72/hr) for a total estimate of $68,001,000 per year. Over time, there may be process efficiencies implemented in one or more practices similar to the benefits of deploying CDS [50] (Berner, 2009; Karsh, 2009) that decrease this estimate. For example, we will assume that every time an advanced diagnostic imaging service is ordered, it is the result of a visit by a Medicare beneficiary for evaluation and management. Then, let us assume that 50 percent of practices implemented an improvement process that streamlined the AUC consultation such that Medicare beneficiaries who visited those practices spent the same amount of time in the physician's office regardless of whether an advanced diagnostic imaging service was ordered. As a result of this improvement process in practice we could estimate such efficiency would offset the estimated burden by $34,000,500 annually. Although we could not at the time of the proposed rule identify a concrete solution, we sought comment on this detailed analysis to inform future rulemaking.

The following is a summary of the comments we received on the proposed estimated impact of consultations beyond ordering professionals.

Comment: Commenters responded to our solicitation for comment and information on the preference that physicians and practitioners might have for purchasing an integrated qualified CDSM. One commenter suggested that CMS did not reasonably estimate the percentage of practices that would purchase an integrated CDSM relative to using a free qualified CDSM. This commenter noted that most health systems prefer to go with a commercial product for accountability, attempted standardization, and support when a system goes down or requires updating. To this end, the commenter also asked that CMS estimate the cost of maintenance to a CDSM. In contrast, another commenter asked that CMS provide additional information in the final rule as to how it arrived at the maintenance estimate of $1,000 per year for an integrated CDSM.

Response: We appreciate these comments acknowledging the challenges with determining the percentage of practices that would purchase an integrated CDSM relative to using a free and non-integrated CDSM. While we did not receive any more precise information to change the estimated percent of practitioners that would purchase an integrated CDSM, we will continue to evaluate these estimates as information and published evidence becomes available once the AUC consultation and reporting requirements are implemented beginning January 1, 2020. To clarify our estimate of maintenance, we performed market research by gathering information from IT experts suggesting annualized costs between 5 percent and 10 percent of initial purchase cost.

Comment: A few commenters questioned the lack of ancillary costs attributed to the estimation of using a free qualified CDSM. One commenter cited the need for internet access to use the free tool. Another commenter cited AUC conferences, town hall meetings, as well as other forms of professional education to learn about CDSM consultation.

Response: We continue to believe that a free tool is a qualified CDSM available free of charge. Any ordering professional without internet access would continue to remain eligible for a significant hardship exception from performing an AUC consultation and would instead communicate to the furnishing professional their hardship. We have included updates to our estimate in this final rule to account for education and training of all ordering professionals that we estimated would be subject to this program irrespective of what qualified CDSM is used to perform the AUC consultation.

After reviewing all comments, for purposes of this RIA we are finalizing our proposed estimate representing the acquisition cost, and maintenance of a qualified CDSM. However, we note that these estimates are based on multiple assumptions, which could change the estimate in significant ways, and as such may be an overestimate of burden as a free qualified CDSM is required by law.

d. Considering the Impact of Claims-Based Reporting

In the CY 2018 PFS proposed rule (82 FR 34094), we discussed using a combination of G-codes and modifiers to report the AUC consultation information on the Medicare claim. We received numerous public comments objecting to this potential solution. In the 2018 PFS final rule, we agreed with many of the commenters that additional approaches to reporting AUC consultation information on Medicare claims should be considered, and in the opinion of some commenters, reporting unique consultation identifiers (UCIs) would be a less burdensome and preferred approach. We had the opportunity to engage some stakeholders and we understand that some commenters from the previous rule continue to be in favor of a UCI. Practically examining the workflow of an order for an advanced diagnostic imaging service before and after implementation of the Medicare AUC program, we see that in general the process remains largely unchanged. Before and after the implementation of this program, an ordering professional could employ support staff to transmit an order for an advanced diagnostic imaging service from his or her office to an imaging facility, physician office, or hospital that furnishes advanced diagnostic imaging services. After implementation of this program, the ordering professionals, furnishing professionals and facilities must adapt this existing workflow to accommodate new information not previously required on orders for advanced diagnostic imaging services.

We considered leaving the policy unchanged, and we also considered writing new regulations requiring larger modifications to the form and manner by which AUC consultation information is communicated from the ordering professional to the furnishing professional or facility. However, we believe this final rule minimizes burden and maximizes efficiency by reporting through established coding methods, to include G-codes and modifiers, to report the required AUC information on Medicare claims.

(1) Impact on Transmitting Order for Advanced Diagnostic Imaging Services

We estimate that including AUC consultation information on the order to the furnishing professional or facility is estimated as the additional 5 minutes spent by a medical secretary (BLS #43–6013) at a mean hourly rate of $17.25 plus 100 percent fringe to transmit the order for the advanced diagnostic

[50] Berner ES. Clinical decision support systems: State of the Art. AHRQ Publication No. 09–0069–EF. Rockville, Maryland: Agency for Healthcare Research and Quality. June 2009. Karsh B–T. Clinical practice improvement and redesign: How change in workflow can be supported by clinical decision support. AHRQ Publication No. 09–0054–EF. Rockville, Maryland: Agency for Healthcare Research and Quality. June 2009.

imaging service. Taking into account transmissions through an EHR that could occur on the order of seconds, a facsimile transmission that could occur on the order of few minutes, or a telephone call that occur on the order of several minutes, we believe the estimate of 5 minutes is an estimate that accounts for different transmittal methods, such as through an integrated EHR system, by facsimile, or via telephone call directly to the office of the furnishing professional or facility. In aggregate, if we assume that 40,000,000 advanced diagnostic imaging services are ordered annually, then the total annual burden to communicate additional information in the order is estimated as $114,540,000 ($17.25/hr × 2 × 0.083 hr × 40,000,000 orders).

(2) Impact on CDSM Developers

While we did not finalize use of a UCI to report AUC consultation information, the following section remains important to understanding the impact of standardizing the UCI should we move forward with such additional modifications in the future.

We believe that in considering a distinct UCI we also considered updating the requirements of a qualified CDSM in § 414.94(g)(1)(vi)(B). This would incur additional costs for the developers of these mechanisms to accommodate formatting changes if instructed by CMS. We continue to believe that participation by CDSM developers in this program is voluntary, that any considerations of proposed changes to this policy maximize benefits and minimize burden to ordering professionals and furnishing professionals and facilities. Internally, CMS has explored the possibility of using a UCI to determine feasibility, and provide a detailed estimate of costs to develop, test, and implement an update in the form and manner of the UCI generated by the CDSM.

To estimate the costs to develop, test, and implement this update, we will provide a relevant case study. In 1998, the Year 2000 Information and Readiness Disclosure Act (Pub. L. 105–271, enacted October 19, 1998) was passed to ensure continuity of operations in the year 2000. At the time of passage, millions of information technology computer systems, software programs, and semiconductors were not capable of recognizing certain dates after December 31, 1999, and without modification would read dates in the year 2000 and thereafter as if those dates represented the year 1900 or thereafter, or would have failed to process those dates entirely. The federal government had budgeted $8,300,000,000 to continue processing dates in 2000 and beyond (Department of Commerce, 1999). Additional estimates to repair the date in a form and manner accommodating the year 2000 varied, but one estimate [51] from analysis of the 1998–99 budget bill of the state of California estimated $241,000,000 to repair 3,000 systems, or $80,333.33 per system, which adjusted for inflation using the CPI–U, U.S. city average series for all items, not seasonally adjusted, represents $123,775.95 per system in 2018. If all 16 qualified CDSMs performed an update to the formatting of the UCI to appear on certification or documentation of every AUC consultation, then the one-time total cost incurred by all CDSM developers would be $1,980,415.20. Although this does not represent a direct transfer of costs from CDSM developers to savings and efficiencies for ordering professionals, furnishing professionals and facilities, we do believe that as a result of such a policy modification that the ordering professional could directly communicate a single AUC UCI, and furnishing professionals and facilities can report UCI in place of identifying each individual CDSM qualified for the purposes of this program.

The following is a summary of the comments we received on the proposed estimated impact of claims-based reporting.

Comment: One commenter noted that there is no standardized form and manner for submitting the AUC consultation information with the order for an advanced diagnostic imaging service. This commenter observed that each imaging facility has its own way of accepting an imaging order, therefore, the commenter stated it will be burdensome for the imaging facility to coordinate accurate information for one, let alone multiple imaging services with the many ordering clinicians from whom they receive imaging orders. The commenter also stated that facilities would need to invest considerable resources to develop an appropriate workflow to comply with this policy, such as additional staff time to translate AUC consultation information into appropriate codes and modifiers for billing.

Response: We appreciate this experience of order transmission as we included in the proposed rule burden estimates for the communication between staff of the ordering professional to those furnishing the applicable imaging service ordered in section VII.F.4.d.(1) of this RIA. We also included in section VII.F.4.e. of the proposed rule a burden estimate to account for the potential of updates to billing software to accommodate possible changes in workflow that would accommodate this policy. As we did not require in this final rule a specific form and manner standardized to transmit AUC consultation information, we did not update this area of our burden estimate in this final rule.

Comment: A few commenters expected additional time estimated for communication between ordering and furnishing professionals. For example, one commenter provided the scenario of a furnishing professional or facility receiving an order for an applicable imaging service but the order does not contain AUC consultation information. In another example, a patient obtains an advanced diagnostic imaging service as part of a clinical trial protocol that does not adhere to the AUC consulted. To this end, a few commenters requested that CMS allow the work associated with the additional consultation and communication time between the ordering and furnishing physicians and their teams be separately billable for the purposes of the AUC requirement.

Response: We disagree that additional time for communication between ordering professionals and those furnishing advanced diagnostic imaging services should be included for instances where AUC consultation information was not initially communicated. We remind the commenters that the estimated burden included communicating AUC consultation information for all advanced diagnostic imaging services. In other words, whether the information was initially communicated or whether there was an initial failure and the information was then subsequently communicated, that communication has been accounted in our 5 minute estimate per service. We did not propose to authorize a separately billable service by ordering or furnishing professionals or their teams to communicate and therefore cannot estimate the cost of billing Medicare for time to transmit AUC consultation information.

After reviewing the comments, we are finalizing the proposed estimate of impact of claims based reporting. We note that before and after the implementation of this program, an ordering professional could employ support staff to transmit an order for an advanced diagnostic imaging service

[51] LAO Analysis of the 1998–99 Budget Bill Information Technology Issues. Information Technology Issues Analysis of the 1998–99 Budget Bill. The Year 2000 (''Y2K'') Computer Problem. Published February 18, 1998. Accessed March 25, 2018 at *http://www.lao.ca.gov/analysis_1998/info_tech_anl98.html.*

from his or her office to an imaging facility, physician office, or hospital that furnishes advanced diagnostic imaging services. As a result of the flexibility afforded to the means of order communication and transmission, there are many market-based solutions available to adapt this existing workflow to accommodate new information not previously required on orders for advanced diagnostic imaging services.

e. Impact on Furnishing Professionals and Facilities

We expect that an AUC consultation must take place for every applicable imaging service furnished in an applicable setting and paid for under an applicable payment system. In the CY 2017 PFS final rule (81 FR 80170), we codified the definition of applicable setting in § 414.94(b) to include a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary. In this final rule, we finalize as proposed adding IDTFs to the definition of applicable settings under this program. This was based on the following factors from 2016 CMS Statistics: (1) An IDTF is independent both of an attending or consulting physician's office and of a hospital; (2) diagnostic procedures when performed by an IDTF are paid under the PFS; (3) independent facilities have increased 5,120 percent from 4,828 in 1990 to 252,044 in 2015; (4) Of those facilities, 1,125 received total payments in excess of $100,000 in 2015; (5) there were 37,038 radiology non-institutional providers utilized by fee-for-service Medicare beneficiaries for all Part B non-institutional provider services in 2015, of which 14,341 received total payments in excess of $100,000 in 2015. Taken together, we believe this will result in a more even application of the Medicare AUC program.

To estimate this impact, we assume based on data derived from the CCW's 2014 Part B non-institutional claim line file, which includes services covered by the Part B benefit that were furnished during CY 2014, that approximately 40,000,000 advanced diagnostic imaging services are furnished annually, but questioned whether for the purposes of this estimate we should attribute equal weight for these services furnished by each of the following places: (1) A physician's office; (2) a hospital outpatient department; (3) an ambulatory surgical center; and (4) an IDTF. Therefore, we sought to determine the frequency of advanced diagnostic imaging services furnished by each setting.

For this estimation, we analyzed 2014 Medicare Part B claims data to weight the various applicable settings subject to this program. For this estimate, we analyzed a count of total services furnished for the following 7 Current Procedural Terminology (CPT) codes for advanced diagnostic imaging studies: 70450—computed tomography, head or brain, without contrast material; 74177—computed tomography, abdomen and pelvis, without contrast material; 70553—magnetic resonance (*e.g.,* proton) imaging, brain (including brain stem), without contrast material, followed by contrast material(s) and further sequences; 72148—magnetic resonance (*e.g.,* proton) imaging, spinal canal and contents, lumbar, without contrast material; 78452—Myocardial perfusion imaging, tomographic single-photon emission computed tomography (SPECT) including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed, multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection; 78492—myocardial imaging, positron emission tomography (PET), perfusion, multiple studies at rest and/or stress; 78803—radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s), tomographic SPECT; which represented 10,000,000 total services or approximately a 25 percent sample of the 40,000,000 total advanced diagnostic imaging services furnished under Part B in 2014.

In this sample, we found the following total services and percent of total services for each of the following settings: (1) Physician's office, 2,997,460 total services, 28.5 percent; (2) hospital outpatient department, 7,465,279 total services, 70.9 percent; (3) ambulatory surgical center, 1,062 total services, 0.01 percent; (4) IDTF, 58,900 total services, 0.6 percent. We also examined whether the total services furnished in 2015 for each setting increased more than 10 percent from 2014. We found the following total services and percent change from 2014 for each of the following settings: (1) Physician's office, 2,944,144 total services, 2 percent decrease; (2) hospital outpatient department, 7,854,997 total services, 5 percent increase; (3) ambulatory surgical center, 2,900 total services, 173 percent increase; (4) IDTF, 65,479 total services, 11 percent increase. Taken together, we believe these estimates that attribute 70 percent of all advanced diagnostic imaging services to outpatient, 28 percent to physician's office, and 1 percent each to ambulatory surgical centers and independent diagnostic testing facilities, respectively is generalizable to the total number of visits by Medicare beneficiaries to each of those applicable settings, respectively.

We do not expect that for the purposes of this program furnishing professionals and facilities will need to create new billing practices; however, we assume that the majority of furnishing professionals and facilities will work to alter billing practices through automation processes that accommodate AUC consultation information when furnishing advanced diagnostic imaging services to Medicare beneficiaries. Therefore, we believe a transfer of costs and benefits will be made from furnishing professionals and facilities to medical billing companies to create, test, and implement changes in billing practice for all affected furnishing professionals and facilities.

As mentioned earlier, the 2016 CMS Statistics identified 37,038 radiology non-institutional providers (Table II.8), and 5,470 ambulatory surgical centers (Table II.5) as of December 31, 2015. Because the classification of independent facilities includes both diagnostic radiology and diagnostic laboratory tests, we will assume that 50 percent of the 252,044 facilities existing in 2015 according to 2016 CMS Statistics (126,022 facilities) furnish advanced diagnostic imaging services. The American Hospital Association (AHA) Hospital Statistics published in 2018 by Health Forum, an affiliate of the AHA, identifies the total number of all U.S. registered hospitals to be 5,534. Taken together, we have identified an estimated 174,064 furnishing professionals (37,038 radiologists + 5,470 ASCs + 126,022 independent diagnostic testing facilities + 5,534 hospitals). We will assume for the purposes of this calculation that every identified furnishing professional and facility will choose to update their processes for the purposes of this program in the same way by purchasing an automated solution to reporting AUC consultation information.

The effective date of January 1, 2020 provides some but not extensive time to prepare to update billing processes to accept and report AUC consultation information. Requirements at § 414.94(k) include the following additional information that must be reported: (1) The qualified CDSM consulted by the ordering professional; (2) information indicating whether the service ordered would or would not

adhere to specified applicable AUC, or whether the specified applicable AUC consulted was not applicable to the service ordered; (3) the NPI of the ordering professional who consulted specified applicable AUC as required in paragraph (j) of this section, if different from the furnishing professional. Although we are not familiar with any automated billing solution currently available that accommodates this new information, we based our estimate on medical billing and coding for experienced professionals (*http://www.mb-guide.org/*), which provides estimates ranging from $1,000 to $50,000 for medical billing software. For example,[52] the basic Medisoft software program costs around $1300 while a premium can cost $11,900 for an unlimited amount of users. In another example,[7] a simple claims processing interface through McKesson's Relay Health Clearinghouse costs $200 for preliminary set up, and added monthly service fees that were not described explicitly. Therefore, for the purposes of this calculation such a solution will be estimated to cost each furnishing professional or facility an estimated $10,000. This estimate is based on the assumption that the number of available furnishing professionals and facilities does not equal the number of professionals and facilities furnishing advanced diagnostic imaging services in the Medicare program and although we recognize that more than one furnishing professional or facility may use the same billing service, the combined effectiveness for an automated solution may decrease overall cost. Although we note that this estimate is based on certain assumptions, we estimate that the one-time update will cost $1,740,640,000 (174,064 × $10,000).

The Congressional Budget Office estimates that section 218 of the PAMA would save approximately $200,000,000 in benefit dollars over 10 years from FY 2014 through 2024, which could be the result of identification of outlier ordering professionals and also includes section 218(a) of the PAMA—a payment deduction for computed tomography equipment that is not up to a current technology standard. Because we have not yet proposed a mechanism or calculation for outlier ordering professional identification and prior authorization, we are unable to quantify the impact of prior authorization at this time.

The following is a summary of the comments we received on the proposed estimated impact on furnishing professionals and facilities.

Comment: A few commenters noted that the Medicare claim form would change as a result of the Medicare AUC program. These commenters observed that the electronic claim standard for the institutional provider (837i) does not capture or have a placeholder for reporting the ordering physician's NPI. These commenters stated that hospitals and health systems would need to make sweeping and costly system changes to interface with a modified 837i as a result.

Response: We appreciate the opportunity to clarify our sentence and recognize the overlap between reporting AUC consultation information and standardized communications on Medicare claims forms. The X12N insurance subcommittee develops and maintains standards for healthcare administrative transactions on professional (837p), institutional (837i), and dental (837d) transactions when submitting healthcare claims for a service or encounter. The current mandated version of 837 transactions is 5010™. While we have not finalized a process for implementing the reporting requirements at § 414.94(k), we clarify that implementation of changes to the claim form transactions would not take place outside of the existing process we described.

After reviewing all comments, we are finalizing our proposed estimate without modification. However, we note that these estimates are based on multiple assumptions and as such may be an overestimate of burden.

f. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

We believe that the first 5 years of this program will be dedicated to implementation activities, from installation of the technology to training to operational and behavioral changes. Information on the benefits of adopting qualified CDSMs or automating billing practices specifically meeting the requirements in this final rule does not yet exist—and information on benefits overall is limited. Nonetheless, we believe there are benefits that can be obtained by ordering professionals, furnishing professionals and facilities, beneficiaries and technology infrastructure developers including qualified CDSM developers, EHR systems developers, and medical billing practices. We describe these estimated benefits in more detail in the following sections.

(1) Estimates of Savings

It has been suggested that one-third of imaging procedures are inappropriate, costing the United States between $3 billion and $10 billion annually [53] (Stein, 2003). Data derived from the CCW 2014 Part B non-institutional claim line file, which includes services covered by the Part B benefit that were furnished during CY 2014, identified approximately $3,300,000,000 in total payments for advanced diagnostic imaging services. For illustrative purposes, if implementation of this program were to lead to a 30 percent decrease in total payments, then we could potentially expect $990,000,000 in fewer payments annually. To address this suggestion, the insertion of a pause in the ordering workflow to introduce AUC is a potentially beneficial and cost-effective solution. Some believe that savings could be achieved through the reduction of inappropriate orders, and expenses associated with radiology benefit managers.[54] Indeed, the Institute for Clinical Systems Improvement in Bloomington, Minnesota, performed a clinical decision support pilot project [55] to (1) improve the utility of diagnostic radiology tests ordered, (2) reduce radiation exposure, (3) increase efficiency, (4) aid in shared decision making, and (5) save Minnesota $84,000,000 in 3 years. While not directly tested in Miliard et al., we believe this estimate may be generalizable on a national level and applicable to the Medicare AUC program, as both activities seek to achieve improvements in quality and decrease costs. Therefore, if savings estimated in Minnesota were a general representation of the nation, and on average a single state achieved 50-percent of that representative savings, annualized over 3 years this estimate could be extrapolated to account for $700,000,000 savings per year (($84,000,000/3 years) × 50-percent × 50 states). It is hypothesized [56] that these benefits are the result of educating ordering professionals on the appropriate test for a set of clinical symptoms, rather than just adding time and electronic obstacles between

[52] *http://www.mb-guide.org/medical-billing-software-prices.html.*

[53] Stein C. Code red: partners program aims to rein in skyrocketing costs of diagnostic imaging. Boston Globe, 2003.

[54] Hardy, K. Decision Support for Rad Reports. Radiology Today. Vol. 11, No. 1, p. 16., 2010.

[55] Miliard, M. Nuance, ICSI aim to prevent unnecessary imaging tests. Healthcare IT News. November 10, 2010.

[56] Sistrom CL, Dang PA, Weilburg JB, et al., Effect of Computerized Order Entry with Integrated Decision Support on the Growth of Outpatient Procedure Volumes: Seven-year Time Series Analysis. Radiology. 251(1), 2009.

ordering physicians and advanced diagnostic imaging services as such transfer of knowledge can alter clinical practice. The Center for Health Care Solutions at Virginia Mason Medical Center in Seattle, Washington examined approaches to control imaging utilization, including external authorization methods and clinical decision support systems. A retrospective cohort study [57] was performed by Blackmore and colleagues in 2011 of the staged implementation of evidence-based clinical decision support for the following advanced diagnostic imaging services: Lumbar MRI; brain MRI; and sinus CT. Brain CT was included as a control. The number of patients imaged as a proportion of patients with selected clinical conditions before and after the decision support interventions were determined from billing data from a regional health plan and from institutional radiology information systems. The imaging utilization rates after the implementation of clinical decision support resulted in decreases for lumbar MRI (p-value = 0.001), head MRI (p-value = 0.05), and sinus CT (p-value = 0.003), while a decrease in control service head CT was not statistically significant (p-value = 0.88). Although there are limitations to this retrospective claims data analysis, the authors concluded that clinical decision support is associated with large decreases in the inappropriate utilization of advanced diagnostic imaging services.

It seems reasonable from this and other studies [58] of local implementation of clinical decision support to assume that there may be some savings when regulations become effective January 1, 2020; however, there are also a few hesitations to extrapolating these and other findings broadly to the Medicare population. First, ordering professionals in this program are aware that CMS will pay for advanced diagnostic imaging services that do not adhere to the specified applicable AUC consulted. This awareness may impact the level of interest or extent of behavior modification from exposing ordering professionals to a qualified CDSM. Second, the statute distinguishes between the ordering professional, furnishing professional and facility, recognizing that the professional who orders an applicable imaging service is usually not the same professional or facility reporting to Medicare for that service when furnished. As a result, some ordering professionals may believe that since they are not required to submit AUC consultation information directly to CMS, there are no direct consequences of adhering to specified applicable AUC. Third, many advanced diagnostic imaging services may not have relevant or applicable AUC. Indeed a recent study [59] implementing CDS was only able to prospectively generate a score for 26 percent and 30 percent of requests for advanced diagnostic imaging services before and after implementation of decision support, respectively. Without AUC available, there can be no decision support intervention into the workflow of the ordering professional. Fourth, even when an ordering professional identifies an advanced diagnostic imaging service recognized as adhering to specified applicable AUC from one qualified PLE, discordance between AUC from different specialty societies has been reported,[60] suggesting that full benefits and savings cannot be realized without standard levels of appropriateness. Taken together, these concerns will form the basis for our continued examination of the impact of this and future rulemaking to maximize the benefits of this program.

(2) Benefits to Medicare Beneficiaries

Although qualified CDSMs are not required to demonstrate that their tools provide measurable benefits, we believe that as a result of installation and use, some ordering professionals may find benefits to the patients they serve. For example, if a qualified CDSM creates a flag or alert to obsolete tests, then the patient will benefit from avoiding unnecessary testing. The same outcome would be likely if a qualified CDSM implemented algorithms that recognize advanced diagnostic imaging services that may produce inaccurate results because of medications being taken by the patient. In addition, if the CDSM provides standardized processes for advanced diagnostic imaging orders or clarification for confusing test names, then the patient benefits from a potential decrease in medical errors and less exposure. Finally, we believe it is reasonable to assume that some improvements in shared decision making could result from use of a qualified CDSM, because some CDSMs could provide cost information associated with advanced diagnostic imaging services and/or identify situations of repeated testing.

The following is a summary of the comments we received on the proposed estimated benefits that can be obtained by ordering professionals, furnishing professionals and facilities, beneficiaries and technology infrastructure developers including qualified CDSM developers, EHR systems developers, and medical billing practices.

Comment: A few commenters disagreed that there are any benefits to the Medicare AUC program. As an example, one commenter submitted their experience with a CDSM and found that a change in utilization was not significant. Additionally, a few commenters indicated that every dollar spent on this program is a dollar that cannot be used elsewhere, more specifically, for patient care. One commenter disagreed with these comments, citing a published study [61] that exposing ordering professionals to evidence based medicine improves quality and reduces inappropriate utilization. Another commenter cited several evidence-based studies [15 62 63] that demonstrate the improvement in the quality of clinical outcomes and reduction of cost resulting from engagement using AUC.

Response: We thank the commenters for sharing their experience, and experiences cited in peer-reviewed published literature. This RIA is presented in conjunction with statutory AUC program requirements. We provide these estimates in addition to policies that are consistent with statute and finalized in this rule. However, we note that these estimates are based on multiple assumptions and as such may be an overestimate of burden as a free qualified CDSM is available and required by law.

[57] Blackmore, CC; Mecklenburg, RS; Kaplan GS. Effectiveness of Clinical Decision Support in Controlling Inappropriate Imaging. Journal of the American College of Radiology. 8(1) 2011.

[58] Curry, L. and Reed, M.H. Electronic decision support for diagnostic imaging in a primary care setting. J Am Med Inform Assoc. 2011; 18: 267–270; Ip, I.K., Schneider, L.I., Hanson, R. et al. Adoption and meaningful use of computerized physician order entry with an integrated clinical decision support system for radiology: ten-year analysis in an urban teaching hospital. J Am Coll Radiol. 2012; 9: 129–136.

[59] Moriarity, AK, Klochko C, O'Brien M, Halabi S. The Effect of Clinical Decision Support for Advanced Inpatient Imaging. Journal of American College of Radiology. 12(4) 2015.

[60] Winchester DE et al., Discordance Between Appropriate Use Criteria for Nuclear Myocardial Perfusion Imaging from Different Specialty Societies: a potential concern for health policy. JAMA Cardiol. 1(2) 2016:207–210.

[61] Huber TC, Krishmaraj A, Patrie J, et al. Impact of a commercially available clinical decision support program on provider ordering habits. J Am Coll Radiol. 2018:15:951–7.

[62] Bunt CW, Burke HB, Towbin AJ, et al. Point-of-care estimated radiation exposure and imaging guidelines can reduce pediatric radiation burden. J Am Board Fam Med. 2015:28:343–50.

[63] Tajmir S, Raja AS, Ip IK, et al. Impact of clinical decision support on radiography for acute ankle injuries: a randomized trial. West J Emerg Med. 2017:18(3):487–95.

5. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs) Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

In the Medicaid Promoting Interoperability Program, to keep electronic clinical quality measure (eCQM) specifications current and minimize complexity, we proposed to align the eCQMs available for Medicaid EPs in 2019 with those available for MIPS eligible clinicians for the CY 2019 performance period. We explained that we anticipated that this proposal would reduce burden for Medicaid EPs by aligning the requirements for multiple reporting programs, and that the system changes required for EPs to implement this change would not be significant, as many EPs are expected to report eCQMs to meet the quality performance category of MIPS and therefore should be prepared to report on those eCQMs for 2019. We explained that we expected that this proposal would have only a minimal impact on states, by requiring minor adjustments to state systems for 2019 to maintain current eCQM lists and specifications. State expenditures to make any systems changes required as a result of this proposal would be eligible for ninety percent enhanced Federal financial participation. After careful consideration of the comments received on this proposal, we are finalizing it without change. See discussion of comments in section III.E. of this final rule.

For 2019, we proposed that Medicaid EPs would report on any six eCQMs that are relevant to the EP's scope of practice, including at least one outcome measure, or if no applicable outcome measure is available or relevant, at least one high priority measure, regardless of whether they report via attestation or electronically. This policy would generally align with the MIPS data submission requirement for eligible clinicians using the eCQM collection type for the quality performance category, which is established in § 414.1335(a)(1). After careful consideration of the comments received on this proposal, we are finalizing it without change, and also explain that if no outcome or high priority measure is relevant to a Medicaid EP's scope of practice, he or she may report on any six eCQMs that are relevant. We also proposed that the eCQM reporting period for EPs in the Medicaid Promoting Interoperability Program would be a full CY in 2019 for EPs who have demonstrated meaningful use in a prior year, in order to align with the corresponding performance period for the quality performance category in MIPS. This proposal is also finalized without change, after careful consideration of comments received. (See discussion of comments in section III.E. of this final rule.) We continue to align Medicaid Promoting Interoperability Program requirements with requirements for other CMS quality programs, such as MIPS, to the extent practicable, to reduce the burden of reporting different data for separate programs.

In order to help states to make incentive payments to Medicaid EPs by December 31, 2021, consistent with section 1903(t)(4)(A)(iii) of the Act, we proposed to amend § 495.4 to provide that the EHR reporting period in 2021 for all EPs in the Medicaid Promoting Interoperability Program would be a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that the state can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021. Similarly, we proposed to change the eCQM reporting period in 2021 for EPs in the Medicaid Promoting Interoperability Program to a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that the state can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021.

We proposed to allow states the flexibility to set alternative, earlier final deadlines for EHR or eCQM reporting periods for Medicaid EPs in CY 2021, with prior approval from CMS, through their State Medicaid HIT Plans (SMHP). Providing states with the flexibility to set an alternative, earlier last possible date for the EHR or eCQM reporting period for Medicaid EPs in 2021 would make it easier for states to ensure that all payments are made by the December 31, 2021 deadline, especially for states whose prepayment process may take longer than the 61 days provided for by an October 31, 2021 deadline. We explained that we expect that this proposal would have only a minimal impact on states, by requiring minor adjustments to state systems to meet specifications for the proposed reporting periods, especially because we are also proposed to permit states to set a different end date for all EHR and eCQM reporting periods for Medicaid EPs in 2021. As previously noted, state expenditures for any systems changes required as a result of this proposal would be eligible for 90 percent enhanced Federal financial participation. After careful consideration of the comments received on this proposal, as discussed above in section III.E. of this final rule, we are finalizing it without change. However, in light of comments received from EPs, we are also considering whether to propose in future rulemaking that no state may set a reporting period deadline for CY 2021 that is earlier than June 30, 2021, or an attestation deadline for CY 2021 that is earlier than July 1, 2021.

Finally, we proposed changes to the EP Meaningful Use Objective 6, (Coordination of care through patient engagement) Measure 1 (View, Download, or Transmit) and Measure 2 (Secure Electronic Messaging), and to EP Meaningful Use Objective 8, Measure 2 (Syndromic surveillance reporting). We proposed to amend these measures in response to feedback about the burdens they create for EPs seeking to demonstrate meaningful use, and about how they may not be fully aligned with how states and public health agencies collect syndromic surveillance data. These proposed amendments were expected to reduce EP burden. Again, we expected that any changes these proposals might require to state systems would be minimal and that state expenditures to make any such changes would also be eligible for 90 percent enhanced federal financial participation. After careful consideration of the comments received on these proposals, as discussed in section III.E. of this final rule, we are finalizing them without change.

6. Medicare Shared Savings Program

In section III.F.1.b. of this final rule, we summarize the proposed certain modifications to the quality measure set used to assess the quality of performance of ACOs participating in the Shared Savings Program. Specifically we proposed: (1) The addition of two Patient Experience of Care Survey measures, and (2) the removal of four claims-based outcome measures. After consideration of the comments received, we are finalizing these proposed modifications to the quality measure set for the Shared Savings Program in sections III.F. of this final rule.

The modifications to the Shared Savings Program quality measure set reduce the number of measures in the Shared Savings Program quality measure set from 31 to 23 measures, making the quality measure set more outcome oriented. This reduction in the number of measure is expected to reduce ACO reporting burden and

improve quality outcomes for beneficiaries.

7. Physician Self-Referral Law

The physician self-referral law provisions are discussed in section III.G. of this final rule. We are finalizing regulatory updates to implement the provisions of section 50404 of the Bipartisan Budget Act of 2018 pertaining to the writing and signature requirements in certain compensation arrangement exceptions to the statute's referral and billing prohibitions. The regulatory language for the writing requirement reflects current policy, so we do not anticipate that it will have an impact. We expect that the update regarding temporary non-compliance with signature arrangements will reduce burden by giving parties additional time to obtain all required signatures.

8. Changes Due to Updates to the Quality Payment Program

In section III.I. of this final rule, we included our finalized policies for the Quality Payment Program. In this section of the final rule, we present the overall and incremental impacts to the number of expected QPs and associated APM incentive payments. In MIPS, we analyze the total impact and incremental impact of statutory changes to eligibility from the Bipartisan Budget Act of 2018, as well as final policies to expand MIPS eligibility by expanding the MIPS eligible clinician definition and adding a third criterion for the low-volume threshold and an opt-in policy option for any clinician that exceeds at least one, but not all, of the low-volume threshold criteria. Finally, we estimate the payment impacts by practice size based on various final policies to modify the MIPS final score, such as the new Promoting Interoperability performance category policies, for the performance threshold and additional performance threshold, and as required by the Bipartisan Budget Act of 2018, the impact of applying the MIPS payment adjustments to covered professional services (services for which payment is made under, or is based on, the PFS and that are furnished by an eligible clinician) rather than items and services covered under Part B.

The submission period for the first MIPS performance period ended in early 2018; however, the final data sets were not available in time to incorporate into the CY 2019 PFS proposed rule analysis (83 FR 36057). We stated in the proposed rule that if technically feasible, we intended to use data from the CY 2017 MIPS performance period for the final rule. In this analysis, we have updated our analyses from the proposed rule to consider data submitted for the 2017 MIPS performance period (which we refer to in this section as Quality Payment Program Year 1 data). In section VII.F.8.b. of this final rule, we summarize the high level findings of updating our model with Quality Payment Program Year 1 data.

a. Estimated Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

From 2019 through 2024, through the Medicare Option, eligible clinicians receiving a sufficient portion of Medicare Part B payments for covered professional services or seeing a sufficient number of Medicare patients through Advanced APMs as required to become QPs, for the applicable performance period, will receive a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate payment amounts for Medicare covered professional services in the preceding year. In addition, beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the All-Payer Combination Option. The All-Payer Combination Option will allow eligible clinicians to become QPs by meeting the QP thresholds through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished through Advanced APMs and services furnished through Other Payer Advanced APMs.

The APM Incentive Payment is separate from and in addition to the payment for covered professional services furnished by an eligible clinician during that year. Eligible clinicians who become QPs for a year would not need to report to MIPS and would not receive a MIPS payment adjustment to their Part B PFS payments. Eligible clinicians who do not become QPs, but meet a slightly lower threshold to become Partial QPs for the year, may elect to report to MIPS and, if they elect to report, would then be scored under MIPS and receive a MIPS payment adjustment, but will not receive the APM Incentive Payment. For the 2019 Medicare QP Performance Period, we define Partial QPs to be eligible clinicians in Advanced APMs who collectively have at least 40 percent, but less than 50 percent, of their payments for Part B covered professional services through an APM Entity, or collectively furnish Part B covered professional services to at least 20 percent, but less than 35 percent, of their Medicare beneficiaries through an APM Entity. If the Partial QP elects to be scored under MIPS, they would be subject to all MIPS requirements and would receive a MIPS payment adjustment. This adjustment may be positive, negative or neutral. If an eligible clinician does not meet either the QP or Partial QP standards, and does not meet any another exemption category, the eligible clinician would be subject to MIPS, would report to MIPS, and would receive the corresponding MIPS payment adjustment.

Beginning in payment year 2026, payment rates for services furnished by clinicians who achieve QP status for a year would be increased each year by 0.75 percent for the year, while payment rates for services furnished by clinicians who do not achieve QP status for the year would be increased by 0.25 percent. In addition, MIPS eligible clinicians would receive positive, neutral, or negative MIPS payment adjustments to payment for their Part B PFS services in a payment year based on performance during a prior performance period. Although MACRA amendments established overall payment rate and procedure parameters until 2026 and beyond, this impact analysis covers only the third payment year (2021 MIPS payment year) of the Quality Payment Program in detail.

In section III.I.4.g.(4)(b) of this final rule, we summarized our finalized policy to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights under the TIN participate in a single APM Entity. This option will therefore be available to all TINs participating in Full TIN APMs, such as the Medicare Shared Savings Program. It will also be available to any other TIN for whom all clinicians who have reassigned billing rights to the TIN are participating in a single APM Entity. We also finalized that this third alternative will only be available to eligible clinicians who meet the Medicare threshold at the APM Entity level; it will not be available for eligible clinicians who meet the Medicare threshold individually.

In section III.I.4.g.(4)(c)(ii) of this final rule, we also discussed our finalized policy to extend the same weighting methodology to TIN level Medicare Threshold Scores in situations where a TIN is assessed under the Medicare Option as part of an APM Entity group, and receives a Medicare Threshold Score at the APM Entity group level. In this scenario, we believe that the Medicare portion of the TIN's All-Payer Combination Option Threshold Score should not be lower than the Medicare Threshold Score that they received by

participating in an APM Entity group (82 FR 53881 through 53882). We note this extension of the weighting methodology will only apply to a TIN when that TIN represents a subset of the eligible clinicians in the APM Entity, because when the TIN and the APM Entity are the same there is no need for this weighted methodology. We finalized our proposal to calculate the TIN's QP Threshold Scores both on its own and with this weighted methodology, and then use the most advantageous score when making a QP determination. We believe that, as it does for QP determinations made at the APM Entity level, this approach promotes consistency between the Medicare Option and the All-Payer Combination Option to the extent possible. Additionally, the application of this weighting approach in the case of a TIN level QP determination is consistent with our established policy.

These finalized policies affect the estimated number of QPs for the 2021 payment year. We estimate that approximately 8,100 eligible clinicians in 8 APM Entities representing approximately 225 TINs will become QPs due to these finalized policies representing TIN level QP determinations under the All-Payer Combination Option. Therefore, they will be excluded from MIPS, and qualify for the lump sum incentive payment based on 5 percent of their Part B allowable charges for covered professional services, which are estimated to be approximately $545 million in the 2019 performance year. We also estimated the corresponding increase of the APM incentive payment of 5 percent of Part B allowed charges for these QPs will be approximately $27 million for the 2021 payment year. However, we note that the majority, if not all, of the 8,100 eligible clinicians that would become QPs if these policies are finalized, had already attained QP status in the 2018 QP performance period. Therefore, the associated APM incentive payments for these 8,100 would not be additional impacts in comparison to previous performance years, only additional impacts in the absence of finalizing these proposed policies.

Overall, we estimated that between 165,000 and 220,000 eligible clinicians will become QPs, therefore be excluded from MIPS, and qualify for the lump sum incentive payment based on 5 percent of their Part B allowable charges for covered professional services in the preceding year, which are estimated to be between approximately $12,000 million and $16,000 million in total for the 2019 performance year. We estimated that the aggregate total of the APM incentive payment of 5 percent of Part B allowed charges for QPs will be between approximately $600 and $800 million for the 2021 payment year. The estimated number of QPs in this final rule is slightly higher than the estimates of 160,000 and 215,000 clinicians included in the proposed rule due to more updated information being available for the final rule. The proposed rule used the APM Participation Lists on the most recent MDM provider extract for the Predictive QP determination file for 2018, whereas this final rule uses the APM Participation Lists on the most recent MDM provider extract for the Second QP determination file for the 2018 performance period. This more updated information did not significantly change the estimated amount of total Part B allowed charges and the amount of total APM incentive payments.

We projected the number of eligible clinicians that will be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that will be operating during the 2019 QP performance period, as well as Advanced APMs anticipated to be operational during the 2019 QP performance period. The projections also reflect an estimated number of eligible clinicians that would attain QP status through the All-Payer Combination Option. The following APMs are expected to be Advanced APMs in performance year 2019: Next Generation ACO Model, Comprehensive Primary Care Plus (CPC+) Model, Comprehensive ESRD Care (CEC) Model (Two-Sided Risk Arrangement), Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative),[64] Comprehensive Care for Joint Replacement Payment Model (CEHRT Track), Oncology Care Model (Two-Sided Risk Arrangements), Medicare ACO Track 1+ Model, Bundled Payments for Care Improvement Advanced, Maryland Total Cost of Care Model (Maryland Care Redesign Program; Maryland Primary Care Program), and the Shared Savings Program Tracks 2 and 3. We used the APM Participant Lists (see 81 FR 77444 through 77445 for information on the APM participant lists and QP determination) on the most recent MDM provider extract for the Second QP determination file for 2018 QP performance period to estimate QPs, total Part B allowed charges for covered professional services, and the aggregate total of APM incentive payments for the 2019 QP performance period. We examine the extent to which Advanced APM participants would meet the QP thresholds of having at least 50 percent of their Part B covered professional services or at least 35 percent of their Medicare beneficiaries furnished Part B covered professional services through the APM Entity.

[64] Vermont ACOs are participating in an Advanced APM during 2018 through a version of the Next Generation ACO Model. The Vermont Medicare ACO Initiative is expected to be an Advanced APM beginning in CY 2019.

b. Updates to MIPS Estimates Using Quality Payment Program Year 1 Data

In the CY 2019 PFS proposed rule (83 FR 36058 through 36068), the RIA modeled MIPS eligibility and performance using data from the Physician Quality Reporting System (PQRS), the Value Modifier, and the Medicare/Medicaid EHR Incentive programs to account for the absence of MIPS performance data. We indicated, that if feasible, we would integrate performance data from the CY 2017 MIPS performance period (which we refer to in this section of the final rule as Quality Payment Program Year 1 data). The model in the 2019 PFS proposed rule had several assumptions to proxy MIPS performance and we noted the limitations of the model (83 FR 36067).

In this final rule, we integrated Quality Payment Program Year 1 data into our model estimates and we chose to summarize in this section important differences or findings that are needed for context when interpreting the RIA in this final rule. It should be noted that although we are using Quality Payment Program Year 1 data, the estimates described in this RIA reflect the impact of the finalized policies in this final rule and do not reflect actual CY 2017 MIPS performance period/2019 MIPS payment year results.

First, the Quality Payment Program Year 1 data had more complete group and individual participation and performance data. In the CY 2019 PFS proposed rule (83 FR 36053 through 36061), we estimated group reporting solely based on the submission of quality data as a group to 2016 PQRS. For this final rule, we were able to identify group reporting through submissions to quality, improvement activities or Promoting Interoperability performance categories. As a result, we observed higher group reporting than was previously estimated using PQRS performance data. This finding led to a 42 percent increase (from approximately 390,000 in the CY 2019 PFS proposed

rule to 553,000 in this final rule) in group reporters who otherwise would not have been MIPS eligible clinicians. (See section VII.F.8.c. for more details on eligibility.) The second benefit of group and individual level data through the Quality Payment Program Year 1 data led to our improved ability to better estimate group and individual scores and to appropriately apply scoring policies at the group and individual level. (See section VII.F.8.d.(2) for more details on methodologies for estimating the performance category scores.)

Second, we observed an increase in participation among small practices than previously estimated in the CY 2019 PFS proposed rule. The number of clinicians in small practices (who we believe are estimated to be in MIPS year 3) estimated to submit data increased from 79.7 percent to 89.9 percent. We believe this is related to our policies for the 2017 MIPS performance period which was designed to encourage participation, engage clinicians and help them transition smoothly into MIPS. (See section VII.F.8.d.(3) for more details.)

Third, the Quality Payment Program Year 1 data allowed for the direct observation of performance for the MIPS performance categories. With the availability of actual advancing care information and improvement activities performance category data from the Quality Payment Program Year 1, we improved our estimates for the Promoting Interoperability and improvement activities performance category scores at the individual and group level for the 2019 MIPS performance period/2021 MIPS payment year. This led to more variation in performance at the individual and group level for these performance categories compared to the model in the 2019 PFS proposed rule and to the ability to accurately assess which clinicians are measured on Promoting Interoperability or are reweighted (see section III.I.3.h.(5) of this final rule for more details).

Finally, the Quality Payment Program Year 1 data improved our ability to estimate who is excluded from MIPS, such as newly enrolled clinicians. We found that the previous proxy for the CY 2019 PFS proposed rule overestimated the number of newly enrolled clinicians than the observed with the Quality Payment Program Year 1 data. As a result, fewer clinicians were excluded from MIPS compared to the CY 2019 PFS proposed rule. (See section VII.F.8.c.(2) of this final rule for more details.)

In summary, the estimates presented in the RIA of this final rule differ from the CY 2019 PFS proposed rule due to our ability to improve our estimates of eligibility and performance in MIPS. As a result of data source and methodology changes for the final policies of this final rule, we observe a slight decrease in final scores. For example, the mean and median final scores in the CY 2019 PFS proposed rule analysis were 73.41 and 82.41 respectively,[65] and the mean and median in this final rule are 69.53 and 78.72, respectively. As a result, a higher percentage of clinicians submitting data have scores below the final performance threshold of 30 points for this final rule (8.8 percent) compared to the CY 2019 PFS proposed rule (3.9 percent). Given the increase in participation, we are not surprised by these changes. However, it should be noted we are still using historic data to predict future performance. Therefore, behaviors due to policies in MIPS Year 1 may not reflect behaviors in Year 3. For example, MIPS eligible clinicians had to earn 3 out of 100 points to receive at least a neutral payment adjustment in CY 2017 MIPS performance period/CY 2021 MIPS payment year and therefore may have only submitted a limited amount of information. As the performance threshold increases in Year 3, we anticipate clinicians will continue to participate and will likely increase their performance to meet the higher performance threshold. Therefore, the results presented in this final rule may not accurately reflect performance for CY 2019 performance period/CY 2021 payment year, which is an important limitation of our findings. See section VII.F.8.f. for more limitations of this rule.

c. Estimated Number of Clinicians Eligible for MIPS Eligibility

(1) Summary of Final Policies Related to MIPS Eligibility and Application of MIPS Payment Adjustments

In section III.I.3 of this final rule, we finalized three sets of policy changes that would impact the number of MIPS eligible clinicians starting with CY 2019 MIPS performance period and the associated CY 2021 MIPS payment year. Two of the changes were finalized as proposed and affect the low-volume threshold. The third policy affects the definition of a MIPS eligible clinician and was finalized with modifications.

In section III.I.3.c.(2) of this final rule, we finalized as proposed changes to our policy to comply with the Bipartisan Budget Act of 2018. Specifically, we updated the low-volume threshold starting with the 2020 MIPS payment year to be based on covered professional services (services for which payment is made under, or is based on the PFS and that are furnished by an eligible clinician) rather than items and services covered under Part B, as provided in section 1848(q)(1)(B) as amended by section 51003(a)(1)(A)(i) of the Bipartisan Budget Act of 2018. This finalized policy may affect the previously finalized calculation for the low-volume threshold for certain clinicians because payment for items, such as Part B drugs, which were previously considered in the low-volume determination, are now excluded. In addition, section 51003(a)(1)(E) of the Bipartisan Budget Act of 2018 revised section 1848(q)(6)(E) to apply the MIPS payment adjustments to covered professional services rather than to items and services covered under Part B. This change is effective with the 2019 MIPS payment year. Its effect on the amount of payment adjustments under MIPS is included in this analysis.

Second, in section III.I.3.a. of this final rule, beginning with the 2021 MIPS payment year, we finalized with modification the expansion of the definition of MIPS eligible clinicians to include physical therapists, occupational therapists, speech-language pathologists, audiologists, clinical psychologists, and registered dietitians or nutrition professionals. This finalized list differs from the proposed list of physical therapists, occupational therapists, clinical social workers, and clinical psychologists (83 FR 36058). Specifically, we finalized the definition of MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, as any of the following: A physician (as defined in section 1861(r) of the Act); a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act), physical therapist, occupational therapist, speech-language pathologist, audiologist, clinical psychologist, and registered dietitian or nutrition professional; and a group that includes such clinicians.

Third, as discussed in sections III.I.3.c.(4) and III.I.3.c.(5) of this final rule, in addition to the amendments to comply with Bipartisan Budget Act of 2018, we finalized as proposed our definition of the low-volume threshold by adding a third criterion (for ''covered

[65] The mean and median was not published in the CY 2019 PFS proposed rule RIA, but the methodology is summarized in the CY 2019 PFS proposed rule (83 FR 36058 through 36066).

professional services''). The low-volume threshold now includes a third criterion: Set at 200 covered professional services to Part B-enrolled individuals. Taken together, the low-volume threshold is as follows: (1) Those with $90,000 or less in allowed charges for covered professional services; or (2) 200 or fewer Part B-enrolled individuals who are furnished Medicare PFS services; or (3) 200 or fewer covered professional services. The low volume threshold assessment is applied at the TIN/NPI level for individual reporting, the TIN level for group reporting, or the APM Entity Level for reporting under the APM scoring standard. We also finalized as proposed for any clinician who exceeds the low-volume threshold on at least one, but not all three, low-volume threshold criteria may elect to opt-in to MIPS to be measured on performance, thereby qualifying to receive a positive, neutral, or negative MIPS payment adjustment based on performance. The absence of the opt-in election within this cohort means they are not MIPS eligible clinicians. If a MIPS eligible clinician does not meet at least one of these low-volume criteria, they are excluded from MIPS. For purposes of this impact analysis we refer to these revisions to the low-volume threshold and its application collectively as the ''opt-in policy''.

We discuss how the three finalized policy changes impact MIPS eligibility and payments, later in this section.

(2) Methodology To Assess MIPS Eligibility

(a) Clinicians Included in the Model Prior to Applying the Low-Volume Threshold Exclusion

To estimate the number of MIPS eligible clinicians for the CY 2019 performance period in this final rule, our scoring model used the first determination period from CY 2020 MIPS payment year eligibility file as described in the CY 2018 Quality Payment Program Final Rule (82 FR 53587 through 53592). The first determination period from the CY 2020 MIPS payment year eligibility file was selected to maximize the overlap with the performance period data used in the model. In addition, the low-volume threshold for with the 2020 MIPS payment year was originally finalized in the CY 2018 Quality Payment Program final rule (82 FR 53587 through 53592) as using Part B items and services, but was later finalized in section III.I.3.c of this final rule to be based on covered professional services (services for which payment is made under, or is based on the PFS and that are furnished by an eligible clinician). Therefore, this data file provided the information to calculate a baseline as well as understand the incremental impact of basing the low-volume threshold on covered professional services rather than all items and services under Part B. We included 1.5 million clinicians (see Table 97) who had PFS claims from September 1, 2016 to August 31, 2017 and included a 30-day claim run-out.We excluded individual clinicians who were affected by the automatic extreme and uncontrollable policy finalized for the 2017 MIPS performance period/2019 MIPS payment year in section III.I.3.i.(2)(b)(ii)(B) of this final rule as we are unable to predict how these clinicians would perform in a year where there was no extreme and uncontrollable event.

Clinicians are ineligible for MIPS (and are excluded from MIPS payment adjustment) if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold. Therefore, we excluded these clinicians when calculating those clinicians eligible for MIPS.

For our baseline population, we restricted to clinicians who are a physician (as defined in section 1861(r) of the Act); a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act). For the estimated MIPS eligible population for the CY 2021 MIPS payment year, we added in clinicians who are physical therapists, occupational therapists, speech-language pathologist, audiologist, clinical psychologist, and registered dietitian or nutrition professional.

As noted previously, we excluded QPs from our scoring model, since these clinicians are not eligible for MIPS. To determine which QPs should be excluded, we used the QP List for the first snapshot date of the 2018 QP performance period because these data were available by TIN and NPI and could be merged into our model. This data also included participants in APMs, such as the Medicare ACO Track 1+ Model, which were not available models in the 2017 QP performance period. From this data, we calculated the QP determinations as described in the Qualifying APM Participant definition at § 414.1305 for the 2019 QP performance period. We assumed that all partial QPs would participate in MIPS and included them in our scoring model and eligibility counts. The estimated number of QPs excluded from our model is lower than the projected number of QPs (165,000 to 220,000) for the 2019 QP performance period due to the expected growth in APM participation. Due to data limitations, we could not identify specific clinicians who may become QPs in the 2019 Medicare QP Performance Period; hence, our model may overestimate the fraction of clinicians and allowed charges for covered professional services that will remain subject to MIPS after the exclusions.

We also excluded newly enrolled Medicare clinicians from our model. To identify newly enrolled Medicare clinicians, we used the indicator that was used for the 2017 MIPS performance period/2019 MIPS payment year. The number of newly enrolled clinicians identified using this approach and data source was approximately one third the estimated number of newly enrolled clinicians estimated in the proposed rule which indicates we overestimated the number of newly enrolled clinicians in the CY 2019 PFS proposed rule impact analysis and that more clinicians are eligible for MIPS.

In section III.I.3.j.(4)(c) of this final rule, we finalized that beginning with the 2019 MIPS payment year the MIPS payment adjustment factors would not apply to certain model-specific payments for the duration of a section 1115A model's testing. Due to the aggregated data in our analysis, we were not able to incorporate this policy into our estimate.

In section III.I.3.j.(4)(d) of the final rule, we finalized the proposal to waive the payment consequences (positive, negative or neutral adjustments) of MIPS and to waive the associated MIPS reporting requirements adopted to implement the payment consequences for certain participating clinicians in the MAQI Demonstration subject to conditions outlined in the Demonstration, starting with the 2020 MIPS payment period. Removing eligible clinicians from MIPS may affect the payment adjustments for other MIPS eligible clinicians in each year the waiver is offered. At this time we are unable to identify specific clinicians that would be affected by this proposal (that is, removed from the MIPS payment adjustments), but estimate the first year number of clinicians to be less than 0.1 percent of all MIPS eligible clinicians. We plan to monitor the impact of the MAQI Demonstration on payments received by MIPS eligible

clinicians to whom the waivers do not apply; however, we note that it may be challenging to draw significant conclusions from such monitoring as there are many variables that may impact and influence a clinician's final MIPS adjustment. Due to the lack of information currently available we are unable to account for this proposal in the eligibility or payment adjustment tables.

(b) Assumptions Related to Applying the Low-Volume Threshold Exclusion

The low-volume threshold policy may be applied at the individual (that is, TIN/NPI) or group (that is, TIN or APM entity) levels based on how data are submitted. If no data are submitted, then the low-volume threshold is applied at the TIN/NPI level. A clinician or group that exceeds at least one but not all three low-volume threshold criteria may become MIPS eligible by electing to opt-in and subsequently submitting data to MIPS, thereby getting measured on performance and receiving a MIPS payment adjustment.

Table 97 compares the MIPS eligibility status and the associated PFS allowed charges from the CY 2019 PFS proposed rule (83 FR 36060) with the estimates of MIPS eligibility and the associated PFS allowed charges after using Quality Payment Program Year 1 data and applying the finalized policies for the CY 2019 MIPS performance period.

For the purposes of modeling, we made assumptions on group reporting to apply the low-volume threshold. One extreme and unlikely assumption is that no practices elect group reporting and the low-volume threshold would always be applied at the individual level. Although we believe a scenario in which only these clinicians would participate as individuals is unlikely, this assumption is important because it quantifies the minimum number of MIPS eligible clinicians. For final rule model, we estimate there are approximately 217,000 clinicians [66] who would be MIPS eligible because they exceed the low volume threshold as individuals and are not otherwise excluded. In Table 97,[67] we identify clinicians under this assumption as having ''required eligibility.'' Using this assumption, the number of clinicians with required eligibility in this final rule and their associated PFS allowed charges are very similar to the estimate in the CY 2019 PFS proposed rule (approximately 218,000 clinicians).

Based on CY 2017 Quality Payment Program Year 1 data, we anticipate that group and APM Entities that submitted to MIPS as a group and APM Entity will continue to do so for the CY 2019 MIPS performance period. Therefore, if we revise our model's group reporting assumption such that all clinicians that were participating in ACOs in 2017 (including ACOs participating under the Shared Savings Program or Next Generation ACO Model) or who reported to the Quality Payment Program Year 1 as a group would continue to do so in MIPS, then the MIPS eligible clinician population would be approximately 770,000 clinicians if we only include the 218,000 required clinicians and the 553,000 clinicians who are only eligible because of group reporting. In Table 97, we identify these clinicians who do not meet the low-volume threshold individually but are anticipated to submit to MIPS as a group based on Quality Payment Program Year 1 data as having ''group eligibility.'' Updating the data source for identifying group reporting led to a 42 percent increase (from approximately 390,000 in the proposed rule to 553,000 in this final rule) in clinicians in the ''group eligibility'' category. We also observed a 33 percent increase in the PFS allowed charges in MIPS from $10,262 million in the proposed rule to $13,662 million in this final rule for the clinicians in the ''group eligibility'' category. The previous estimate presented in the proposed rule likely underestimated the number of clinicians using group reporting since previously group reporting could only be identified through the submission of quality data to PQRS. With the availability of CY 2017 Quality Payment Program Year 1 data, we can identify group reporting through the submission of improvement activities, Promoting Interoperability, or quality performance category data.To model the proposed opt-in policy, we assumed that 33 percent of the clinicians who exceed at least one low-volume threshold and submitted data to CY 2017 MIPS performance period would elect to opt-in to MIPS. We selected a random sample of 33 percent of clinicians without accounting for performance. We believe this assumption of 33 percent is reasonable because some clinicians may choose not to submit data due to performance, practice size, or resources or alternatively, some may submit data, but elect to be a voluntary reporter and not be subject to a MIPS payment adjustment based on their performance. Similar to the proposed rule (83 FR 36060), we applied a 33 percent opt-in assumption to estimate opt-in eligibility in this final rule. We sought comment on these assumptions in the proposed rule, including whether modeling eligibility only among clinicians or groups who submitted at least 6 quality measures to PQRS would be more appropriate. As we describe in more detail below, we also explored an alternate opt-in assumption where only high-performers would opt-in to MIPS. In the alternate model, we saw a difference in the maximum payment adjustment of approximately one-tenth of a percent. Given the minimal differences between the two alternatives, we elected to continue the assumption from the CY 2019 PFS proposed rule and present results with the 33 percent random opt-in for this impact analysis. This 33 percent participation assumption is identified in Table 97 as ''Opt-In eligibility''. In the final rule analysis, we estimate an additional 28,000 clinicians would be eligible through this policy for a total MIPS eligible population of approximately 798,000. The leads to an associated $66.6 billion allowed PFS charges estimated to be included in the 2019 MIPS performance period.

We observed a decrease of approximately 14,000 clinicians compared to the proposed rule in the ''opt-in eligibility'' category after updating the data source and applying the finalized policies. This observed decrease in the number of clinicians that would elect to opt-in to MIPS is because there were fewer clinicians from which to randomly select for opt-in eligibility due to the increase in group reporting.

[66] The count of 216,612 MIPS eligible clinicians for required eligibility includes those who participated in MIPS (196,236 MIPS eligible clinicians) as well as those who did not participate (17,376 MIPS eligible clinicians).

[67] Estimates for the proposed rule available at 83 FR 36060.

TABLE 97—DESCRIPTION OF MIPS ELIGIBILITY STATUS FOR CY 2021 MIPS PAYMENT YEAR USING THE PROPOSED AND FINALIZED ASSUMPTIONS ***

Eligibility status	Predicted participation status in MIPS among clinicians *	Proposed rule estimates		Final Rule estimates †	
		Legacy data *		QPP Year 1 data	
		Number of clinicians	PFS allowed charges ($ in mil) ****	Number of clinicians	PFS allowed charges ($ in mil) ****
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria).	Participate in MIPS	186,549	43,546	199,236	47,653
	Do not participate in MIPS.	31,921	7,605	17,376	3,916
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria and submit as a group).	Submit data as a group	389,670	10,262	553,475	13,662
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS and submit data).	Elect to opt-in and submit data.	42,025	2,099	27,903	1,380
Total Number of MIPS Eligible Clinicians	.....	650,165	63,512	** 797,990	66,611
Not MIPS eligible:					
Potentially MIPS eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: 1) meet group eligibility or 2) opt-in eligibility criteria).	Do not opt-in; or ..... Do not submit as a group.	482,574	11,695	390,244	9,290
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria).	Not applicable	88,070	690	77,617	404
Excluded for other reasons (Non-eligible clinician type, newly enrolled, QP).	Not applicable	302,172	13,688	209,403	9,735
Total Number of Clinicians Not MIPS Eligible.	.....	872,816	26,073	677,264	19,429
Total Number of Clinicians (MIPS and Not MIPS Eligible).	.....	1,522,981	89,585	1,475,254	86,040

* Participation in MIPS defined as previously submitting quality or EHR data for PQRS. Group reporting based on 2016 PQRS group reporting.
** Updated Estimated MIPS Eligible Population.
*** Facility-based eligible clinicians are not modeled separately in this table and are captured in the individual eligible category. This table does not consider the impact of the MAQI Demonstration waiver. This table also does not include clinicians impacted by the automatic extreme and uncontrollable policy (approximately 22,000 clinicians and $3.7 billion in PFS allowed charges).
† These estimates reflect the finalized policies, which differ from the proposed rule (that is, change in MIPS eligible clinician types and those identified as QPs).
**** Allowed charges estimated using 2016 and 2017 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

There are approximately 390,000 clinicians who are not MIPS eligible, but could be if their practice decides to participate. We describe this group as ''Potentially MIPS eligible.'' This is the unlikely scenario in which all group practices elect to submit data as a group and all clinicians that could elect to opt-into MIPS do elect to opt-in. This assumption is important because it quantifies the maximum number of MIPS eligible clinicians. When this unlikely scenario is modeled, we estimate that the MIPS eligible clinician population could be as high as 1.2 million clinicians. We observed a decrease of approximately 92,000 clinicians compared to the model in the proposed rule after updating the data source and applying the finalized policies. This observed decrease is due to the increase in group reporting.

Finally, there are some clinicians who would not be MIPS eligible either because they are below the low-volume threshold on all three criteria (approximately 78,000) or because they are excluded for other reasons (approximately 209,000). We observed a decrease of approximately 93,000 clinicians after updating the data source and applying the finalized policies. This observed decrease is due to much lower estimated number of newly enrolled clinicians but slightly higher number of QPs in the 2017 Quality Payment Program Year 1 data.

Since eligibility among some clinicians is contingent on submission to MIPS as a group or election to opt-in, we will not know the exact number of MIPS eligible clinicians until the submission period for the CY 2019 MIPS performance period is closed. For this impact analysis, we are using the estimated population of 797,990 MIPS eligible clinicians described above.

We received the following comments on our methodology:

Comment: One commenter requested CMS explain how the number of clinicians affected by the proposed MIPS opt-in policy for the 2021

payment year was estimated. The commenter supported the proposed MIPS opt-in policy starting in 2019 but would like to know how CMS estimated the number of clinicians that would be impacted by the policy.

Response: For the proposed rule, to estimate the number of clinicians that may elect to opt-in to MIPS, we randomly selected 33 percent of clinicians that met at least one but not all the low-volume criteria and submitted data to 2016 PQRS. This led to an estimated 42,025 number of clinicians that will opt-in to MIPS.

For this final rule, we randomly selected 33 percent of clinicians that met at least one but not all the low-volume criteria and submitted to CY 2017 MIPS performance period. This led to an estimated 27,903 number of clinicians that will opt-in to MIPS. We also estimated the impact if we had assumed only those who expect to perform well would elect to opt-in. In the alternate model assumption where only high performers would opt-in to MIPS, we assumed 100 percent of clinicians with final scores above the additional performance threshold would opt-in and 50 percent of clinicians above the performance threshold but below the additional performance threshold would opt-in. We observed a decrease in the budget neutral pool from $310 million to $296 comparing the model with the 33 percent random opt-in to the model where only high-performers opt-in. We observed a minimal impact to the maximum payment adjustment compared to the model with 33 percent random opt-in (4.7 percent versus 4.6 percent). We refer readers to section III.I.3.c.(5) of this final rule for additional results on that analysis. Because we did not see much difference in results, we present the model with the 33 percent random opt-in this impact analysis.

Comment: One commenter recommended CMS present specialty-specific data for exemption criteria. Specifically, the commenter recommended CMS present specialty specific information on the number of clinicians exempt from MIPS because they are newly enrolled in Medicare and/or Qualified Participants (QPs) or Partial QPs in Advanced APMs, and the number of clinicians assigned to certain special categories (for example, non-patient facing, hospital-based, facility-based, and ASC-based for the purposes of the ACI exemption). The commenter noted the provision of this information will allow for the assessment of how many clinicians are exempt by specialty and for member education activities.

Response: We appreciate that some stakeholders would like specialty specific information; however, given the numerous assumptions for group reporting and opt-in participation, we believe presenting the overall number of MIPS eligible clinicians is the most transparent way to present the information.

After consideration of the public comments, we have updated our methodology to estimate the number of MIPS eligible clinicians for the 2019 MIPS performance period/2021 MIPS payment year to account for the Quality Payment Program Year 1 data and the policies finalized in this final rule.

(3) Impact of MIPS Eligibility Finalized Policies

We illustrate in Table 98[68] how each finalized policy for the CY 2021 payment year affects the estimated number of MIPS eligible clinicians. The baseline is the number of individuals that would have been MIPS eligible clinicians for the 2019 MIPS performance period/2021 MIPS payment year if this regulation did not exist. In the CY 2019 PFS proposed rule (83 FR 36060), we estimated the baseline was 591,010. After updating the model to reflect the updated data sources, the new baseline population is 751,498. All incremental impact estimates are relative to this baseline.

TABLE 98—INCREMENTAL CHANGE TABLE FOR FINALIZED POLICIES FOR 2021 MIPS PAYMENT YEAR

Policy changes *	Estimated number of MIPS eligible clinicians impacted by policy change	Estimated effect of policy changes on number of MIPS eligible clinicians	Estimated % change from baseline	Estimated Part B allowed charges (mil) ***	Estimated PFS allowed charges (mil) ***	Estimated % change in PFS from baseline
Baseline: Applying previously finalized policy for the 2021 payment year if this regulation did not exist	N/A	751,498	N/A	79,375	64,382	N/A
Policy Change 1: Low-volume threshold (LVT) determination based on covered professional services (as required by Bipartisan Budget Act of 2018)	−1,651	749,847	−0.2	79,160	64,266	−0.2%
Policy Change 2: Expansion of eligible clinician types to include physical therapists, occupational therapists, qualified speech-language pathologist, or qualified audiologist, clinical psychologist, and registered dietician or nutrition professional based with policy change 1	20,240	770,087	2.5	N/A	65,231	1.3%
Policy Change 3: Cumulative change of Opt-in Policy with policy changes 1 and 2 **	27,903	797,990	6.2	N/A	66,611	3.5%

* This table does not consider the impact of the MAQI Demonstration waiver and does not include clinicians impacted by the extreme and uncontrollable policy.

** Model assumption is 33 percent clinicians who are eligible will elect to opt-in.

*** Allowed charges estimated using 2016 and 2017 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

[68] Estimates for the proposed rule available at 83 FR 36061.

First, as shown in Table 98, the first row shows the effect of changing the application of the MIPS payment adjustments, as required by section 51003(a)(1)(E) of the Bipartisan Budget Act of 2018 to apply them to covered professional services (services for which payment is made under, or is based on, the Medicare PFS and are furnished by an eligible clinician) rather than to items and services covered under Part B. As shown, the baseline allowed charges for Part B is $79.4 billion, compared with $64.4 billion in covered professional services, which is a difference of almost $15 billion. Beginning in the 2019 MIPS payment year, payment adjustments will only be applied to the total paid amount for covered professional services.

In Table 98, under the first policy change, basing the low-volume threshold on covered professional services (services provided under the PFS rather than items and services covered under Part B) has minimal impact in terms of clinicians (less than half of one percent decrease).

When the second policy change, to expand the definition of MIPS eligible clinician types, was added to the first policy change, the total effect is small. The change in the potential MIPS eligible clinician population increased by less than 3 percent and the allowed charges in the PFS increased by 1.3 percent.

When the third policy change, which implements the opt-in policy, is added to the other two policies, the estimated number of MIPS eligible clinicians increases by 6.2 percent. The estimated increase in the allowed charges in the PFS is 3.5 percent.

d. Estimated Impacts on Payments to MIPS Eligible Clinicians

(1) Summary of Approach

In sections III.I.3.h., III.I.3.i. and III.I.3.j. of this final rule, we finalized several proposals which impact the measures and activities that impact the performance category scores, final score calculation, and the MIPS payment adjustment. We discuss these changes in more detail in section VII.F.8.d.(2) of this RIA as we describe our methodology to estimate MIPS payments for the 2021 MIPS payment year. We note that many of the MIPS policies from the CY 2018 Quality Payment Program final rule were only defined for the 2018 MIPS performance period and 2020 MIPS payment year (including the performance threshold, the additional performance threshold, the policy for redistributing the weights of the performance categories, and many scoring policies for the quality performance category) which precludes us from developing a baseline for the 2019 MIPS performance period and 2021 MIPS payment year if there was no new regulatory action. Therefore, our impact analysis looks at the total effect of the finalized MIPS policy changes on the MIPS final score and payment adjustment for CY 2019 MIPS performance period/CY 2021 MIPS payment year.

The payment impact for a MIPS eligible clinician is based on the clinician's final score, which is a value determined by their performance in the four MIPS performance categories: Quality, cost, improvement activities, and Promoting Interoperability. As described in the CY 2019 PFS proposed rule (83 FR 36061), the performance and participation data submitted for the 2017 MIPS performance period were not available to estimate the final score and the projected payment adjustments for MIPS eligible clinicians. This analysis has been updated with the Quality Payment Program Year 1 data and those results are presented in this final rule. We refer readers to CY 2019 PFS proposed rule (83 FR 36061 through 36066) for additional details on how we estimated the final scores and payment adjustments in the proposed rule.

The estimated payment impacts presented in this final rule reflect averages by practice size based on Medicare utilization. The payment impact for a MIPS eligible clinician could vary from the average and would depend on the combination of services that the MIPS eligible clinician furnishes. The average percentage change in total revenues would be less than the impact displayed here because MIPS eligible clinicians generally furnish services to both Medicare and non-Medicare patients; this program does not impact payment from non-Medicare patients. In addition, MIPS eligible clinicians may receive Medicare revenues for services under other Medicare payment systems, such as the Medicare Federally Qualified Health Center Prospective Payment System or Medicare Advantage that would not be affected by MIPS payment adjustment factors.

(2) Methodology To Assess Impact

To estimate participation in MIPS for the CY 2019 Quality Payment Program for this final rule, we used CY 2017 Quality Payment Program Year 1 performance period data. Our scoring model includes the 797,990 estimated number of MIPS eligible clinicians as described in section VII.F.8.c of this RIA.

To estimate the impact of MIPS on eligible clinicians, we used the Quality Payment Program Year 1 submission data, including data submitted for the quality, improvement activities, and advancing care information performance categories, CAHPS for MIPS and CAHPS for ACOs, the total per capita cost measure, Medicare Spending Per Beneficiary (MSPB) measures and other data sets.[69] We calculated a hypothetical final score for the 2019 MIPS performance period/2021 MIPS payment year for each MIPS eligible clinician based on quality, cost, Promoting Interoperability, and improvement activities performance categories.

Starting in CY 2018 MIPS performance period, solo practitioner or a group of 10 or fewer eligible clinicians may elect to participate in MIPS as a virtual group (82 FR 53604). We had two virtual groups register for the 2018 performance period, of which one had all its participants participating in a MIPS APM for the 2018 performance period. While we anticipate an increase in the number of virtual groups for the 2019 MIPS performance period, we did not attempt to model virtual groups in this model as the participants in one virtual group who are in a MIPS APM would receive the MIPS APM score which left just one virtual group to measure.

(a) Methodology To Estimate the Quality Performance Category Score

We estimated the quality performance category score using measures submitted to MIPS for the 2017 performance period. For the quality measures, we started with the assigned measure achievement points assigned for the 2017 MIPS performance period. As finalized as proposed in III.I.3.i.(1)(b)(iii)(A) of this final rule, we applied a 3-point floor for measures that cannot be reliably scored against a baseline benchmark in the 2019 MIPS performance period. As described in section III.I.3.h.(2)(b)(iii) of this final rule, we finalized the proposal to remove many measures that were previously able to be reported in PQRS and in previous MIPS performance periods. For our estimates, we assumed that clinicians who reported Medicare Part B claims, eCQM, MIPS CQM and QCDR measures that are removed would find alternate measures; therefore, we assigned points to these measures and included them in our scoring model. For CY 2019, we maintained the policies for

[69] 2016 PQRS and Value Modifier data was used for the improvement score for the quality performance category.

scoring measures that do not meet the quality category requirements (case minimum, benchmark, and data completeness) as described in the CY 2018 Quality Payment Program final rule (82 FR 53727 through 53730). As finalized in the CY 2018 Quality Payment Program final rule, we also applied a 7-point cap for measures that are topped out for two or more years (82 FR 53721 through 53727).

As stated in section III.I.3.h.(2)(a)(iii)(A)(bb) of this final rule, we finalized the proposal to remove several Web Interface measures. For that collection type, which has a standard set of measures, we estimated performance on the measures that we propose to continue.

As finalized in sections III.I.3.i.(1)(b)(ix) and (x) of this final rule, we maintained the cap on bonus points for high-priority measures and end-to-end electronic bonus points at 10 percent of the denominator and, beginning with the 2019 MIPS performance period, discontinue high priority bonus points for CMS Web Interface Reporters. Because we are able to use MIPS performance data in our models, we assigned 1 point for each measure that was submitted with end-to-end electronic reporting with a cap of 10 percent of the total possible measure achievement points. To be consistent with our small practice bonus finalized policy in section III.I.3.i.(1)(b)(viii) of this final rule, we added 6 measure achievement points to the quality performance category score for small practices that had a quality performance category score greater than 0 points.

As finalized in the CY 2018 Quality Payment Program final rule (82 FR 53625 through 52626) and further discussed in III.I.3.h.(2)(a)(iii) of this final rule, we are allowing MIPS eligible clinicians and groups to submit data collected via multiple collection types within a performance category beginning with the 2019 performance period. The requirements for the performance categories remain the same regardless of the number of collection types used. We do not apply the validation process that is discussed in section III.I.3.i.(1)(b)(vii) of this final rule.

To estimate the impact of improvement for the quality performance category, we estimated a quality performance category percent score using 2019 MIPS data, 2015 and 2018 CAHPS for ACOs and MIPS data, and 2016 PQRS VM data. For MIPS eligible clinicians with an estimated quality performance category score less than or equal to a 30 percent score in the previous year, we compared 2019 performance to an assumed 2018 quality score of 30 percent for their improvement score as described in III.I.3.i.(1)(b)(xiii) of this final rule.

Due to data limitations, we are unable to model all the finalized policies in this rule. We are not able to incorporate the policy to reduce the denominator for the quality performance category score by 10 points for groups that registered for CAHPS for MIPS but were unable to report due to insufficient sample size as discussed in section III.I.3.i.(1)(b)(iii)(B) of this final rule. We also did not apply the finalized scoring policy for measures that are significantly impacted by clinical guideline or other changes discussed in section III.I.3.i.(1)(b)(vi) of this final rule.

Our model applied the MIPS APM scoring standards finalized in section III.I.3.h.(6) of this final rule to quality data from MIPS eligible clinicians that participated in the Shared Savings Program, and the Next Generation ACO Model in 2017.

(b) Methodology To Estimate the Cost Performance Category Score

In section III.I.3.h.(3)(b)(ii) of this final rule, we finalized the proposal to add 8 episode-based measures to the cost performance category beginning with the 2019 performance period. For the episode-based measures, we used the episode specifications proposed in the CY 2019 PFS proposed rule (83 FR 35902 through 35903) and claims data from June 2016 through May 2017. As discussed in section III.I.3.h.(3)(b)(ii) of this final rule, we made updates to the specifications for three episode measures. Due to timing constraints we were not able to incorporate the updated specifications into this impact analysis; however, we anticipate that the updates will only have a marginal effect on the cost measure scores.

We estimated the cost performance category score using the total per capita cost measure and Medicare Spending Per Beneficiary (MSPB) measures from the CY 2017 Quality Payment Period Year 1 data that was presented in the MIPS feedback reports. Cost measure scores were used only when the associated case size met or exceeded the previously finalized or newly finalized case minimum: 20 for the total per capita cost measure, 35 for MSPB, 10 for procedural episodes, and 20 for acute medical inpatient medical condition episodes. The cost measures are computed for both the TIN/NPI and the TIN. For clinicians participating as individuals, the TIN/NPI level score was used if available and if the minimum case size was met. For clinicians participating as groups, the TIN level score was used, if available, and if the minimum case size was met. For clinicians with no measures meeting the minimum case requirement, we did not estimate a score for the cost performance category, and the weight for the cost performance category was reassigned to the quality performance category. The raw cost measure scores were mapped to scores on the scale of 1–10, using benchmarks based on all measures that met the case minimum during the relevant performance period. For the episode-based cost measures, separate benchmarks were developed for TIN/NPI level scores and TIN level scores. For each clinician, a cost performance category score was computed as the average of the measure scores available for the clinician.

(c) Methodology To Estimate the Facility-Based Measurement Scoring

As discussed in section III.I.3.i.(1)(d) of this final rule, we are implementing facility-based measurement for the 2019 MIPS performance period. In facility-based measurement, we determine the eligible clinician's MIPS score based on Hospital VBP Total Performance Score for eligible clinicians or groups who meet the eligibility criteria, which we designed to identify those who primarily furnish services within a hospital. Given that we are not requiring eligible clinicians to opt-in to facility-based measurement, it is possible that a MIPS eligible clinician or a group is automatically eligible for facility-based measurement but they participate in MIPS as an individual or a group. In these cases, we use the higher combined quality and cost performance category score from facility-based scoring compared to the combined quality and cost performance category score from MIPS submission based scoring.

Data was not available to attribute specific Hospital VBP Total Performance Score to MIPS eligible clinicians, hence we made the following assumptions. For MIPS eligible clinicians and groups who are eligible for facility-based measurement and who submitted quality data to the Quality Payment Program for the 2017 MIPS performance period, we did not estimate a facility-based score. We instead calculated a MIPS quality and cost score based on the available quality measures and cost data. Some clinicians who submitted Quality Payment Program quality data may receive a higher combined quality and cost score through facility-based measurement, but we are unable to identify those clinicians due to data limitations and therefore believe the score based on

their submitted data is more likely to reflect their performance.

For MIPS eligible clinicians that did not submit data to the Quality Payment Program for the 2017 MIPS performance period and were eligible for facility-based measurement, we estimated a facility-based score by taking the median MIPS quality and cost performance score. We believe it is important to develop an estimate for this cohort because we would have otherwise assigned this group a quality performance category percent score of zero percent which we believe would underestimate their MIPS final score. Given the data limitations in assigning a specific hospital score to a clinician, we selected the median MIPS quality and cost performance scores as that represents the quality and cost performance category scores that a clinician working in a hospital with median performance would receive.

(d) Methodology To Estimate the Promoting Interoperability Performance Category Score

As discussed in section III.I.3.h.(5)(d)(ii) of this final rule, we finalized the proposal to modify the measures and scoring for the Promoting Interoperability performance category score. We simplified scoring by eliminating the concept of base and performance scores and focusing on a smaller set of measures which are scored on performance. We estimated Promoting Interoperability performance category scores using the advancing care information performance category data from the CY 2017 Quality Payment Period Year 1 data. The Promoting Interoperability performance category scores were based on the individual level for individual submissions and on the group level for clinicians that were part of a group submission or part of an APM entity.

For the e-Prescribing objective, we only estimated the e-Prescribing measure and did not assume any bonus points for the Query of Prescription Drug Monitoring Program (PDMP) or the Verify Opioid Treatment Agreement measures. To estimate the e-Prescribing measure, we used the reported numerator and denominator values for the e-Prescribing measure for the advancing care information performance category, unless a measure exclusion applied.

For the Health Information Exchange objective, we used the required measures in the Health Information Exchange objective from the advancing care information performance category to proxy performance for the two finalized measures in the Promoting Interoperability objective. We used the Send Summary of Care measure and the Health Information Exchange transition measure for the Support Electronic Referral Loops by Sending Health Information measure. For MIPS eligible clinicians that reported data using 2015 CEHRT, we used the Request/Accept Summary of Care measure for the Support Electronic Referral Loops by Receiving and Incorporating Health Information. If this information was not available, then we used just the Send Summary of Care measure. If there was an exclusion for the Send Summary of Care measure or the Health Information Exchange transition measure, then for purpose of this model, we reweighted the measure to the Patient Electronic Access objective.

For the Provider to Patient Exchange objective, we used the Provide Patient Access measure to estimate performance for the finalized Provide Patients Electronic Access to Their Health Information measure.

For the Public Health and Clinical Data Exchange objective, we estimated the score by using the reported responses for the following advancing care information measures: Immunization Registry Reporting, Syndromic Surveillance Reporting, Electronic Case Reporting, Public Health Registry Reporting, Clinical Data Registry Reporting and Specialized Registry Reporting.

To calculate the Promoting Interoperability performance category, we summed the performance category measure scores and divided the total sum by the total number of possible points (100), as described in section III.I.3.i.(1)(d) of this final rule. As discussed in section III.I.3.i.(1)(d) of this final rule, a TIN/NPI must report on all required measures in the Promoting Interoperability performance category and complete all actions included in the Security Risk Analysis measure during the year to receive a non-zero performance category score. For APM Entities, we aggregated the scores of the participants consistent with the requirements for the 2017 MIPS performance period.

For eligible clinicians who did not submit a required Promoting Interoperability measure and did not complete all actions included in the Security Risk Analysis measure, we evaluated whether the MIPS eligible clinician could have their Promoting Interoperability performance category reweighted and applied the reweighting policies described in section III.I.3.h.(5)(d) of this final rule. For the Registry Reporting measures, which did not have an exclusion defined for the 2017 MIPS performance period, we assumed that failure to submit data or submissions with all ''No'' answers implied a request for exclusion. A group was only reweighted for the Promoting Interoperability performance category if all the TIN/NPIs were eligible for reweighting, thereby reweighting only applying to 24 percent of MIPS eligible clinicians as opposed to 62 percent of MIPS eligible clinicians scores in the CY 2019 PFS proposed rule (83 FR 36063) in which Promoting Interoperability was always assessed at the individual level.

As finalized in the CY 2017 (81 FR 77069 through 77070) and CY 2018 (82 FR 53625 through 52626) Quality Payment Program final rules, the Promoting Interoperability performance category weight is set equal to 0 percent, and the weight is redistributed to the quality or improvement activities performance category for non-patient facing MIPS eligible clinicians, hospital-based MIPS eligible clinicians, ASC-based MIPS eligible clinicians, or those who request and are approved for a significant hardship or other type of exception, including a significant hardship exception for small practices, or clinicians who are granted an exception based on decertified EHR technology (82 FR 53780 through 53786). We also finalized in section III.I.3.h.(5)(h) of this final rule to continue automatic reweighting for NPs, PAs, CNSs and CRNAs and to add an automatic reweighting policy for physical therapists, occupational therapist, speech-language pathologists, audiologists, clinical psychologists, and registered dietitians or nutrition professionals, which we have incorporated into our model. We used the non-patient facing and hospital-based indicators and specialty and small practice indicators as calculated in the initial MIPS eligibility run for the 2017 MIPS performance period (81 FR 77069 through 77070). For significant hardship exceptions, we used the approved significant hardship file for the 2017 MIPS performance period.

If a TIN/NPI did not report on all required measures and did not qualify for reweighting for a required measure, then their Promoting Interoperability performance category score was set to zero percent.

(e) Methodology To Estimate the Improvement Activities Performance Category Score

We modeled the improvement activities performance category score based on CY 2017 Quality Payment Period Year 1 data and APMs participation in the 2017 MIPS performance period. We did not make

any policy changes that impact scoring for the improvement activities performance category. Our model identified participants in APMs during the 2017 performance period, including but not limited to those in the Shared Savings Program, Next Generation ACO Model, and assigned them an improvement activity score of 100 percent, consistent with our policy to assign an improvement activities score of 100 percent to ACO participants who were not excluded due to being QPs.

Clinicians and groups not participating in a MIPS APM were assigned their CY 2017 Quality Payment Period Year 1 improvement activities performance category score.

(f) Methodology To Estimate the Complex Patient Bonus

In sections III.I.3.i.(2)(a)(ii) of this final rule, we finalized the proposed policy to continue the complex patient bonus. Consistent with the policy to define complex patients as those with high medical risk or with dual eligibility, our scoring model calculated the bonus by using the average Hierarchical Condition Category (HCC) risk score, as well as the MIPS eligible clinician's patients dual eligible proportion calculated for each NPI in the 2016 Physician and Other Supplier Public Use File. The dual eligible proportion for each MIPS eligible clinician was multiplied by 5. We also generated a group average HCC risk score by weighing the scores for individual clinicians in each group by the number of beneficiaries they have seen. We generated group dual eligible proportions using the weighted average dual eligible patient ratio for all MIPS eligible clinicians in the groups, which was then multiplied by 5. The complex patient bonus was calculated by adding together the average HCC risk score and the percent of dual eligible patients multiplied by 5, with a 5-point cap.

(g) Methodology To Estimate the Final Score

As finalized in sections III.I.3.h.(2)(a)(ii), III.I.3.h.(3)(a), III.I.3.h.(4)(a), III.I.3.h.(5)(d)(i) and summarized in section III.I.3.i.(2)(b) of this final rule, our model assigns a final score for each TIN/NPI by multiplying each performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, and adding the complex patient bonus. After adding any applicable bonus for complex patients, we reset any final scores that exceeded 100 points equal to 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for the Promoting Interoperability due to a significant hardship or other type of exception, the weight for the Promoting Interoperability performance category was redistributed to the quality performance category. For MIPS eligible clinicians who did not have a cost performance category score, the weight for the cost performance category was redistributed to the quality performance category. In our scoring model, we did not address scenarios where a zero percent weight would be assigned to the quality performance category or the improvement activities performance category.

(h) Methodology To Estimate the MIPS Payment Adjustment

As described in the CY 2018 Quality Payment Program final rule (82 FR 53785 through 53787), we applied a hierarchy to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available (for example if a clinician qualifies for a score for an APM entity and a group score, we select the APM entity score).

We then calculated the parameters of an exchange function in accordance with the statutory requirements related to the linear sliding scale, budget neutrality, minimum and maximum adjustment percentages and additional payment adjustment for exceptional performance (as finalized under § 414.1405), using a performance threshold of 30 points and the additional performance threshold of 75 points (as finalized in sections III.I.3.j.(2) and III.I.3.j.(3) of this final rule). We used these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the PFS paid amount. We considered other performance thresholds which are discussed in section VII.G. of this RIA.

(3) Impact of Payments by Practice Size

Using the assumptions provided above, our model estimates that $310 million would be redistributed through budget neutrality and that the maximum positive payment adjustments are 4.7 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. The observed decrease in the funds available for redistribution and the maximum positive payment adjustment from the proposed rule to the final rule is due to the change in the data sources used to estimate final scores for MIPS eligible clinicians and the decrease in the additional performance threshold.

The use of 2017 Quality Payment Program Year 1 data to estimate the impact of the 2019 Quality Payment Program Year 3 finalized policies led to lower average final scores compared to the proposed rule. The main contributors to the lower estimated final scores were the changes in the estimated quality and Promoting Interoperability performance categories scores. The average quality scores were lower because some of the group reporters did not have quality data. As described in section VII.F.8.c.(2) of this final rule, we previously identified group reporters based on the submission of quality data submitted to PQRS; therefore, all group reporters submitted quality data and had a quality score. As a result of the 2017 Quality Payment Program Year 1 data, we can identify group reporters through submissions for the improvement activities or the Promoting Interoperability performance category who may not have submitted quality data. Therefore, these new groups in the estimated MIPS population received a zero (or close to zero) quality performance category score for not submitting quality data.

Table 99 shows the impact of the payments by practice size and whether clinicians are expected to submit data to MIPS.[70] We estimate that a smaller proportion of clinicians in small practices (1–15 clinicians) who participate in MIPS will receive a positive or neutral payment adjustment compared to larger size practices. Overall, clinicians in small practices participating in MIPS would receive a 1.2 percent increase in their paid amount, which is similar to the payment amount received by MIPS eligible clinicians in practices with 16 to 24 and 25 to 99 clinicians. After considering the positive adjustments and subtracting the negative adjustments, eligible clinicians in small practices would have an increase in funds which is consistent with all MIPS eligible clinicians. Table 99 also shows that 91.2 percent of MIPS eligible clinicians that participate in MIPS are expected to receive positive or neutral payment adjustments. The combined impact of negative and positive adjustments and exceptional performance payment as percent of paid

[70] The proposed rule estimated MIPS participation and performance using historical PQRS and EHR data because MIPS CY 2017 performance period data were not available in time for analysis in the proposed rule (83 36058 through 36066). This final rule presents the results from analysis of MIPS CY 2019 performance period data. Previous estimates are available in the proposed (83 FR 36066).

amount among those that do not submit data to MIPS was not the maximum negative payment adjustment possible because not all MIPS eligible clinicians that do not submit to MIPS receive a final score of zero. Indeed, some MIPS eligible clinicians that do not submit data to MIPS may receive final scores above zero through the cost performance category, which does not require submission to MIPS. Among those who we estimate would not submit data to MIPS, 90 percent are in small practices (15,680 out of 17,376 clinicians). To address participation concerns, we have policies targeted towards small practices including technical assistance and special scoring policies to minimize burden and facilitate small practice participation in MIPS or APMs.

TABLE 99—MIPS ESTIMATED PAYMENT YEAR 2021 IMPACT ON TOTAL ESTIMATED PAID AMOUNT BY PARTICIPATION STATUS AND PRACTICE SIZE * [a]

Practice size *	Number of MIPS eligible clinicians	Percent MIPS eligible clinicians with positive or neutral payment adjustment (percent)	Percent MIPS eligible clinicians with a positive adjustment with exceptional payment adjustment (percent)	Percent MIPS eligible clinicians with negative payment adjustment (percent)	Combined Impact of negative and positive adjustments and exceptional performance payment as percent of paid amount ** (percent)
Among those submitting data * **					
(1) 1–15	140,251	80.1	47.2	19.9	1.2
(2) 16–24	41,226	86.1	41.4	13.9	1.1
(3) 25–99	185,140	89.8	48.6	10.2	1.3
(4) 100+	413,997	96.1	69.0	3.9	2.0
Overall	780,614	91.2	58.8	8.8	1.5
Among those not submitting data					
(1) 1–15	15,680	0.0	0.0	100.0	−6.3
(2) 16–24	629	0.0	0.0	100.0	−6.6
(3) 25–99	860	0.0	0.0	100.0	−6.6
(4) 100+	207	0.0	0.0	100.0	−6.9
Overall	17,376	0.0	0.0	100.0	−6.4

* Practice size is the total number of TIN/NPIs in a TIN.
** 2016 and 2017 data used to estimate 2019 performance period payment adjustments. Payments estimated using 2016 and 2017 dollars.
*** Includes facility-based clinicians whose quality data is submitted through hospital programs.
[a] This table does not account for clinicians that are in the MAQI Demonstration waiver.

The following is a summary of the public comments received regarding the estimated impact on payments for MIPS eligible clinicians:

Comment: A few commenters encouraged CMS to use Year 1 MIPS participation data to inform changes to the program, citing that actual QPP data is needed for assessing the best ways to improve the program and how these changes will impact clinicians financially.

Response: We thank the commenter for this suggestion. As described in this RIA for this final rule, the 2017 Quality Payment Program Year 1 data were available in time to assess impact of the finalize policies and are now presented in this final rule.

Comment: A few commenters recommended CMS present specialty specific tables. Specifically, they requested the estimated payment impact table by specialty as presented in previous years and additional performance data by specialty on each performance category (Data on reporting and performance rates for quality measures (similar to what was released via the PQRS Experience Reports); Statistics on clinical improvement activities reported; Statistics on clinician attribution to cost measures and performance on cost measures.). This would allow for better understanding of MIPS for their stakeholders.

Response: We chose to only present the payment impact by practice size in this final rule; however, we may provide additional analyses via the Quality Payment Program website or other forums.

After consideration of public comments, we have updated our analyses to incorporate the Quality Payment Program Year 1 data and the final policies.

e. Potential Costs of Compliance With the Promoting Interoperability and Improvement Activities Performance Categories for Eligible Clinicians

(1) Potential Costs of Compliance With Promoting Interoperability Performance Category

In section III.I.3.h.(5)(c) of this final rule, we discussed the requirement to use EHR technology certified to the 2015 Edition beginning with the 2019 MIPS performance period for the Promoting Interoperability performance category. As discussed in section V.B.3 of this final rule, we assumed a slight decrease in overall information collection burden costs for the Promoting Interoperability performance category related to having fewer measures to submit.

With respect to any costs unrelated to data submission, although this final rule would require some investment in systems updates, our policy prior to this regulation as reflected in § 414.1305, is that 2015 Edition CEHRT will be required beginning with the 2019 MIPS

performance period/2021 MIPS payment year (82 FR 53671). Therefore, we do not anticipate any additional costs due to this regulation.

The following is a summary of the public comments received regarding these assumptions:

Comment: A few commenters stated that complying with Promoting Interoperability performance category is a financial burden for many clinicians due to their practice size and their administrative capability, and the costs required by the EMR and EHR vendors. One commenter suggested that state and federal legislation ought to take these challenges into account, while another commenter suggested CMS work with stakeholders to establish mechanisms for providers to be compensated for creating interoperable data.

Response: We reiterate that this policy was finalized in the CY 2018 Quality Payment Program final rule (82 FR 53671) and thus this is not a new obligation for this final rule. We do have policies that recognize challenges, such as significant hardship exceptions for small practices.

After consideration of public comments, we are not making any modifications on our potential cost for compliance with Promoting Interoperability performance category.

(2) Potential Costs of Compliance With Improvement Activities Performance Category

Under the policies established in the CY 2017 Quality Payment Program final rule, the costs for complying with the improvement activities performance category requirements could have potentially led to higher expenses for MIPS eligible clinicians. Costs per full-time equivalent primary care clinician for improvement activities will vary across practices, including for some activities or certified patient-centered medical home practices, in incremental costs per encounter, and in estimated costs per (patient) member per month.

Costs for compliance with previously finalized policies may vary based on panel size (number of patients assigned to each care team) and location of practice among other variables. For example, Magill (2015) conducted a study of certified patient-centered medical home practices in two states.[71] That study found that costs associated with a full-time equivalent primary care clinician, who was associated with certified patient-centered medical home practices, varied across practices. Specifically, the study found an average cost of $7,691 per month in Utah practices, and an average of $9,658 in Colorado practices. Consequently, incremental costs per encounter were $32.71 for certified patient-centered medical home practices in Utah and $36.68 in Colorado (Magill, 2015). The study also found that the average estimated cost per patient member, per month, for an assumed panel of 2,000 patients was $3.85 in Utah and $4.83 in Colorado. However, given the lack of comprehensive historical data for improvement activities, we are unable to quantify those costs in detail at this time. The findings presented in these papers have not changed. We have improvement activities information from the 2017 performance period, but additional analysis would be required before using that data to report the costs and benefits of implementing the improvement activities; and we are not able to do this in time for publication of this final rule. We have considered factors that also contribute to the difficulty of identifying compliance costs for the improvement activities performance category in the CY 2018 Quality Payment Program final rule (82 FR 53845).

We believe that because we finalized an opt-in policy (as described in section II.C.2.c of this final rule), we would add approximately 28,000 additional clinicians to the MIPS eligible clinicians. In section V.B.4 of this final rule, we assumed that those who have elected to opt-in have already been voluntary reporters in MIPS and would not have additional compliance costs as a result of this regulation. Thus, we believe the overall potential cost of compliance would not increase because of this final rule.

Further, we anticipate that the vast majority of clinicians submitting improvement activities data to comply with existing MIPS policies could continue to submit the same activities under the policies established in this final rule. Previously finalized improvement activities continue to apply for the current and future years unless otherwise modified per rule-making (82 FR 54175). We refer readers to Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199) and Tables F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229) for our previously finalized 112 improvement activities established in the Improvement Activities Inventory. In section III.I.3.h.(4)(d)(ii) of this final rule, we finalized 6 new improvement activities, 5 modifications, and 1 removal of an existing activity.

Similarly, we believe that third parties who submit data on behalf of clinicians who prepared to submit data in the transition year will not incur additional costs as a result of this final rule. We requested comments that provide additional information that would enable us to quantify the costs, costs savings, and benefits associated with implementation of improvement activities in the inventory, but did not receive comments with information that would enable us to quantify the costs, costs savings, and benefits associated with the implementation and compliance with the requirements of the improvement activities performance category: In section III.I.3.h.(4)(e) of this final rule, we discuss how eligible clinicians can participate in the CMS study on burdens associated with reporting quality measures for each MIPS performance period. Eligible clinicians who are interested in participating can sign up and an adequate sample size is then selected by CMS from these potential participants. In the CY 2018 Quality Payment Program final rule, the sample size for the CY 2018 performance period was set at a minimum of 102 MIPS eligible clinicians (81 FR 77196). Each study participant is required to complete a survey prior to submitting MIPS data and another survey after submitting MIPS data. In section III.I.3.h.(4)(e) of this final rule, for the CY 2019 performance period, we finalized the increase to the sample size to a minimum of 200 MIPS eligible clinicians.

However, we made the focus group a requirement only for a selected subset of the study participants, using purposive sampling and random sampling methods, beginning with the CY 2019 performance period and future years. Completing each survey is estimated to require approximately 15 minutes; therefore, the annual hourly burden per participant is approximately 30 minutes. The annual hourly burden associated with the increase in sample size by 98 clinicians (from 102 clinicians to 200) is estimated to be 49 hours (98 clinicians $\times$ 0.5 hours). Using the hourly rate for physicians in section V.A of this final rule, the total estimated annual cost burden is estimated to be $10,116 ($206.44/hour $\times$ 49 hours). While the sample size of the study is increasing, we did not make a change to the sample size of MIPS eligible clinicians participating in the focus group, so no burden is estimated for participating in that activity. We did

[71] Magill et al. ''The Cost of Sustaining a Patient-Centered Medical Home: Experience from 2 States.'' Annals of Family Medicine, 2015; 13:429–435.

receive a comment on the burden associated with the study.

f. Assumptions & Limitations

We note several limitations to our estimates of MIPS eligible clinicians' eligibility and participation, negative MIPS payment adjustments, and positive payment adjustments for the 2021 MIPS payment year. We based our analyses on the data prepared to support the 2018 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on *qpp.cms.gov*),[72] participant lists using the APM Participation List for the first snapshot date of the 2018 QP performance period, CY 2017 Quality Payment Program Year 1 data and CAHPS for ACOs. The scoring model results presented in this final rule assume that CY 2017 Quality Payment Program Year 1 data submissions and performance are representative of CY 2017 Quality Payment Program Year 3 data submissions and performance. The scoring model does not reflect the growth in Advanced APM participation between 2018 and 2019 (Quality Payment Program Years 2 and 3) because that data is not available at the detailed level needed for our scoring analysis. The estimated performance for CY 2019 MIPS performance period using Quality Payment Program Year 1 data may be underestimated because the performance threshold to avoid a negative payment adjustment for the 2017 MIPS performance period/2019 MIPS payment year was significantly lower (3 out of 100 points) than the performance threshold for the 2019 MIPS performance period/2021 MIPS payment year (30 out of 100). We anticipate clinicians may submit more performance categories to meet the higher performance threshold to avoid a negative payment adjustment.

In our MIPS eligible clinician assumptions, we assumed that 33 percent of the opt-in eligible clinicians that participated in the CY 2017 Quality Payment Program Year 1 would elect to opt-in to the MIPS program. It is difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the finalized policy.

There are additional limitations to our estimates: (1) We only estimated the potential impact of facility-based scoring for MIPS eligible clinicians that are eligible for facility-based measurement and would have a quality performance category score of zero from failure to submit quality data; (2) because we used historic data, we assumed participation in the three performance categories in MIPS Year 1 would be similar to MIPS Year 3 performance; and (3) to the extent that there are year-to-year changes in the data submission, volume and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table 99. Due to the limitations described, there is considerable uncertainty around our estimates that is difficult to quantify in detail.

9. Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success

This final rule includes certain provisions originally proposed for the Medicare Shared Savings Program (Shared Savings Program) in a proposed rule titled ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success'' (hereinafter referred to as the ''August 2018 proposed rule'') that appeared in the **Federal Register** on August 17, 2018 (83 FR 41786). As described in section V. of this final rule, certain provisions of the August 2018 proposed rule are being finalized in this final rule in order to ensure that certain payment and policy changes for the Medicare Shared Savings Program are in place prior to the start of performance years under the program that begin on January 1, 2019. In a forthcoming final rule, we anticipate summarizing and responding to public comments on the remaining proposals in the August 2018 proposed rule that are not addressed in this final rule.

The most consequential of the changes to the Medicare Shared Savings Program being finalized in this final rule is the option for existing ACOs whose agreement periods expire on December 31, 2018, to elect an extension to their current agreement period for a fourth performance year, defined as the period from January 1, 2019, through June 30, 2019. Absent the voluntary 6-month extension as finalized in this rule, approximately 203 ACOs would be required to leave the program at least temporarily until the availability of an opportunity to enter a new agreement period for program participation. We estimate that up to 200 ACOs would elect the extension for the first 6 months of 2019, and therefore, would continue to improve care coordination and efficiency, and have the opportunity to receive shared savings for such period estimated to total approximately $170 million. As noted in the August 2018 proposed rule (83 FR 41922), we assumed that ACOs dropping out of the program may continue to produce residual savings in certain years following their exit from the program because of efficient practices put in place that may continue even after participation in the program ends. Therefore, while we estimate that ACOs electing the extension would produce additional savings on claims exceeding the cost of the anticipated $170 million in shared savings payments for the extension period, we note that lesser residual claims savings would also be expected for the baseline where such ACOs are not allowed to extend their participation in the program in the first 6 months of 2019 and therefore would not earn shared savings payments for that period. However, when considering the residual difference in savings on claims attributable to the 6-month extension period over the 12 months following the end of the extension we estimate that the $170 million in shared savings payments for the extension period would be fully offset by the effect of the extension on preserving a higher savings trajectory than the up to 200 ACOs that are expected to elect the extension would have exhibited absent the extension.

Lastly, we note that the modifications to the Shared Savings Program finalized in this rule that rely on the authority of section 1899(i)(3) of the Act, including most notably the methodology for determining the financial performance for the 6-month performance year from January 1, 2019, through June 30, 2019, for ACOs that voluntarily elect the extension, based on the entire 12-month CY 2019 and pro-rating the amount of any shared savings or shared losses to reflect the ACO's participation during a 6-month period, comply with requirements of section 1899(i)(3)(B). The considerations we described in the August 2018 proposed rule (83 FR 41851) (as well as those considerations discussed in section V.B.1. of this final rule) were relevant in making this determination. Specifically, we do not believe that the methodology for determining the financial performance of ACOs in a 6-month performance year from January 1, 2019, through June 30, 2019, would result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology prescribed in section 1899(d) of the Act.

Finalizing the voluntary 6-month extension for ACOs whose agreement periods expire on December 31, 2018, supports continued participation by these ACOs, and therefore also allows

[72] The time period for this eligibility file (September 1, 2016 to August 31, 2017) maximizes the overlap with the performance data in our model.

for lower growth in Medicare FFS expenditures based on projected participation trends. The extension is estimated to produce net savings over the baseline non-extension scenario when considering the residual benefit to savings on claims for Parts A and B services over a period of one or more years after the end of the 6-month extension period. Further, we believe the approach we are finalizing for determining the performance of ACOs for the 6-month performance year from January 1, 2019, through June 30, 2019, would continue to lead to improvement in the quality of care furnished to Medicare FFS beneficiaries. As described in section V.B.1.c.4. of this final rule, the approach to measuring ACO quality performance for the 6-month performance year from January 1, 2019, through June 30, 2019, based on quality data reported for CY 2019, would maintain accountability for the quality of care ACOs provide to their assigned beneficiaries. Participating ACOs would have an incentive to perform well on the quality measures in order to maximize any shared savings they may receive and minimize any shared losses they must pay in tracks where the loss sharing rate is determined based on the ACO's quality performance.

The anticipated forthcoming final rule will provide a detailed estimate of the impact of all other changes that may be finalized from the August 2018 proposed rule.

G. Alternatives Considered

This final rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our proposed policies and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this final rule, we presented the estimated impact on total allowed charges by specialty. The alternatives we considered, as discussed in the preceding preamble sections, would result in different payment rates, and therefore, result in different estimates than those shown in Table 94 (CY 2019 PFS Estimated Impact on Total Allowed Charges by Specialty).

1. E/M Coding and Payment Alternatives Considered

For the CY 2019 PFS proposed rule, we considered a number of other options for simplifying coding and payment for E/M services to align with the proposed reduction in documentation requirements and better account for the resources associated with inherent complexity, visit complexity, and visits furnished on the same day as a 0-day global procedure. For example, as we noted in the proposed rule, we considered establishing single payment rates for new and established patients for combined E/M visit levels 2 through 4, as opposed to combined E/M visit levels 2 through 5, as we proposed. We considered the potential impacts of making this change in isolation.

TABLE 100—UNADJUSTED ESTIMATED SPECIALTY IMPACTS OF SINGLE PFS RATE FOR OFFICE/OUTPATIENT E/M LEVELS 2 THROUGH 4

[As displayed in the CY 2019 PFS proposed rule]

Specialty	Allowed charges (millions)	Impact (percent)
Podiatry	$2,022	10
Dermatology	3,525	6
Hand Surgery	202	5
Oral/Maxillofacial Surgery	57	4
Otolaryngology	1,220	4
Cardiology	6,723	−3
Hematology/Oncology	1,813	−3
Neurology	1,565	−3
Rheumatology	559	−6
Endocrinology	482	−8

Note: All other specialty level impacts were within +/−3%.

Table 100 shows the specialties that would experience the greatest increase or decrease by establishing single payment rates for E/M visit levels 2 through 4, while maintaining the value of the level 1 and the level 5 E/M visits. We note that this alternative is similar to the policy we are finalizing for CY 2021. However, we are also finalizing the inherent visit complexity add-on codes that will likely result in mitigating some of the more significant estimated specialty-level impacts of establishing a single rate for the level 2–4 visits.

While considering whether to finalize a single payment rate for new and established office/outpatient E/M visit levels 2–5, we explored a number of alternative scenarios based on commenters' varied responses to aspects of our proposal. For example, we considered the potential impacts on finalizing all elements of the proposal except for the MPPR and the single PE/hr value across the office/outpatient E/M code set.

TABLE 101—SPECIALTY LEVEL IMPACTS OF FINALIZING AS PROPOSED WITH THE EXCEPTION OF THE MPPR AND PE/hr ADJUSTMENTS

Specialty	Allowed charges (mil)	Impact of work RVU changes (%)	Impact of PE RVU changes (%)	Impact of MP RVU changes (%)	Combined impact (%)
(A)	(B)	(C)	(D)	(E)	(F)
Allergy/Immunology	$239	1	1	0	2
Anesthesiology	1,981	0	0	0	−1
Audiologist	68	0	1	0	1
Cardiac Surgery	294	−1	−1	0	−2
Cardiology	6,618	0	−1	0	−1
Chiropractor	754	0	0	0	−1
Clinical Psychologist	776	0	2	0	1
Clinical Social Worker	728	−1	2	0	2
Colon And Rectal Surgery	166	0	1	0	2
Critical Care	342	−1	−1	0	−2
Dermatology	3,486	3	4	0	7
Diagnostic Testing Facility	733	0	−4	0	−5
Emergency Medicine	3,121	−1	0	0	−1
Endocrinology	482	0	−1	0	−1
Family Practice	6,208	0	0	0	0
Gastroenterology	1,757	−1	0	0	−1
General Practice	429	0	0	0	0
General Surgery	2,093	0	0	0	1
Geriatrics	197	−2	−1	0	−4
Hand Surgery	214	3	2	0	5
Hematology/Oncology	1,741	−1	−1	0	−2
Independent Laboratory	646	0	4	0	3
Infectious Disease	649	−1	−1	0	−2
Internal Medicine	10,767	−1	0	0	−1
Interventional Pain Mgmt	868	2	3	0	5
Interventional Radiology	386	0	−1	0	−1
Multispecialty Clinic/Other Phys	149	−1	−1	0	−2
Nephrology	2,190	−2	−1	0	−3
Neurology	1,529	−1	−1	0	−2
Neurosurgery	804	0	0	0	0
Nuclear Medicine	50	−1	−1	0	−2
Nurse Anes/Anes Asst	1,242	−1	0	0	−1
Nurse Practitioner	4,065	1	1	0	1
Obstetrics/Gynecology	638	3	3	0	6
Ophthalmology	5,448	0	−1	0	−1
Optometry	1,309	1	0	0	1
Oral/Maxillofacial Surgery	68	1	1	0	2
Orthopedic Surgery	3,743	1	2	0	3
Other	31	−1	3	0	3
Otolarngology	1,210	4	4	0	8
Pathology	1,165	0	−1	0	−1
Pediatrics	61	−1	0	0	−1
Physical Medicine	1,107	−1	0	0	−1
Physical/Occupational Therapy	3,950	0	−2	0	−2
Physician Assistant	2,457	1	2	0	3
Plastic Surgery	377	1	1	0	3
Podiatry	1,974	0	−3	0	−4
Portable X-Ray Supplier	99	0	0	0	0
Psychiatry	1,187	0	1	0	1
Pulmonary Disease	1,715	−2	−2	0	−4
Radiation Oncology And Radiation Therapy Centers	1,766	−1	−1	0	−2
Radiology	4,911	0	−1	0	−1
Rheumatology	541	0	0	0	0
Thoracic Surgery	358	−1	−1	0	−2
Urology	1,738	3	3	0	6
Vascular Surgery	1,148	0	−2	0	−1
Total	92,771	0	0	0	0

We also explored an alternative of finalizing all elements of the proposal except for separate coding for podiatric E/M visits and the application of a single PE/hr across the office/outpatient E/M codes.

TABLE 102—SPECIALTY LEVEL IMPACTS OF FINALIZING AS PROPOSED WITH THE EXCEPTION OF THE SEPARATE PODIATRIC G CODES AND PE/hr ADJUSTMENTS

Specialty	Allowed charges (mil)	Impact of work RVU changes (%)	Impact of PE RVU changes (%)	Impact of MP RVU changes (%)	Combined impact (%)
(A)	(B)	(C)	(D)	(E)	(F)
Allergy/Immunology	$239	1	1	0	2
Anesthesiology	1,981	0	0	0	0
Audiologist	68	0	2	0	1
Cardiac Surgery	294	−1	−1	0	−2
Cardiology	6,618	0	−1	0	−1
Chiropractor	754	0	1	0	0
Clinical Psychologist	776	0	2	0	1
Clinical Social Worker	728	0	2	0	2
Colon And Rectal Surgery	166	0	0	0	0
Critical Care	342	−1	−1	0	−2
Dermatology	3,486	1	1	0	2
Diagnostic Testing Facility	733	0	−4	0	−4
Emergency Medicine	3,121	0	0	0	−1
Endocrinology	482	0	−1	0	−1
Family Practice	6,208	0	0	0	0
Gastroenterology	1,757	−1	0	0	−1
General Practice	429	0	0	0	0
General Surgery	2,093	0	0	0	0
Geriatrics	197	−2	−1	0	−3
Hand Surgery	214	1	1	0	2
Hematology/Oncology	1,741	−1	−1	0	−2
Independent Laboratory	646	0	4	0	4
Infectious Disease	649	−1	−1	0	−2
Internal Medicine	10,767	−1	0	0	−1
Interventional Pain Mgmt	868	2	2	0	4
Interventional Radiology	386	1	−1	0	0
Multispecialty Clinic/Other Phys	149	−1	−1	0	−2
Nephrology	2,190	−1	−1	0	−2
Neurology	1,529	−1	−1	0	−2
Neurosurgery	804	0	0	0	0
Nuclear Medicine	50	−1	−1	0	−2
Nurse Anes/Anes Asst	1,242	0	0	0	0
Nurse Practitioner	4,065	0	1	0	1
Obstetrics/Gynecology	638	3	2	0	5
Ophthalmology	5,448	0	−1	0	−1
Optometry	1,309	1	0	0	1
Oral/Maxillofacial Surgery	68	1	1	0	2
Orthopedic Surgery	3,743	1	1	0	1
Other	31	−1	4	0	3
Otolarngology	1,210	2	2	0	4
Pathology	1,165	0	−1	0	−1
Pediatrics	61	−1	0	0	−1
Physical Medicine	1,107	−1	0	0	−1
Physical/Occupational Therapy	3,950	0	−1	0	−1
Physician Assistant	2,457	0	1	0	1
Plastic Surgery	377	1	1	0	2
Podiatry	1,974	5	5	0	10
Portable X-Ray Supplier	99	0	0	0	1
Psychiatry	1,187	0	1	0	1
Pulmonary Disease	1,715	−2	−1	0	−4
Radiation Oncology And Radiation Therapy Centers	1,766	0	0	0	−1
Radiology	4,911	0	−1	0	0
Rheumatology	541	−1	−1	0	−2
Thoracic Surgery	358	−1	−1	0	−2
Urology	1,738	2	3	0	5
Vascular Surgery	1,148	0	−1	0	−1
Total	92,771	0	0	0	0

We considered alternatives that included finalizing all elements of the proposal, except for the PE/hr change and separate coding for podiatric E/M visits and establishing a single payment rate for office/outpatient new and established E/M visit levels 2 through 4, rather than a single payment rate for office/outpatient E/M levels 2 through 5 as proposed. Table 103 illustrates the specialty level impacts of this alternative.

TABLE 103—SPECIALTY LEVEL IMPACT OF FINALIZING SINGLE PFS RATES FOR OFFICE/OUTPATIENT E/M LEVELS 2 THROUGH 4 AND OTHER PROPOSED ELEMENTS WITH THE EXCEPTION OF PE/hr ADJUSTMENT AND THE G-CODES FOR PODIATRIC VISITS

Specialty	Allowed charges (mil)	Impact of work RVU changes (%)	Impact of PE RVU changes (%)	Impact of MP RVU changes (%)	Combined impact (%)
(A)	(B)	(C)	(D)	(E)	(F)
Allergy/Immunology	$239	1	1	0	1
Anesthesiology	1,981	−1	0	0	−1
Audiologist	68	−1	1	0	1
Cardiac Surgery	294	−1	−1	0	−1
Cardiology	6,618	0	−1	0	−1
Chiropractor	754	−1	0	0	−1
Clinical Psychologist	776	−1	1	0	1
Clinical Social Worker	728	−1	2	0	1
Colon And Rectal Surgery	166	−1	0	0	−1
Critical Care	342	−1	−1	0	−2
Dermatology	3,486	0	0	0	0
Diagnostic Testing Facility	733	0	−4	0	−4
Emergency Medicine	3,121	−1	0	0	−1
Endocrinology	482	0	−1	0	−1
Family Practice	6,208	1	1	0	2
Gastroenterology	1,757	−1	0	0	−2
General Practice	429	−1	0	0	−1
General Surgery	2,093	0	0	0	0
Geriatrics	197	0	0	0	−1
Hand Surgery	214	0	0	0	0
Hematology/Oncology	1,741	1	0	0	1
Independent Laboratory	646	0	4	0	4
Infectious Disease	649	−1	−1	0	−2
Internal Medicine	10,767	0	0	0	1
Interventional Pain Mgmt	868	1	2	0	3
Interventional Radiology	386	0	−1	0	−1
Multispecialty Clinic/Other Phys	149	−1	−1	0	−2
Nephrology	2,190	−2	−1	0	−2
Neurology	1,529	0	0	0	0
Neurosurgery	804	−1	0	0	−1
Nuclear Medicine	50	−1	−1	0	−2
Nurse Anes/Anes Asst	1,242	−1	0	0	−1
Nurse Practitioner	4,065	2	1	0	3
Obstetrics/Gynecology	638	2	2	0	4
Ophthalmology	5,448	−1	−1	0	−2
Optometry	1,309	0	−1	0	0
Oral/Maxillofacial Surgery	68	0	1	0	1
Orthopedic Surgery	3,743	0	0	0	0
Other	31	−1	4	0	3
Otolarngology	1,210	1	1	0	2
Pathology	1,165	−1	−1	0	−2
Pediatrics	61	1	0	0	1
Physical Medicine	1,107	−1	0	0	−2
Physical/Occupational Therapy	3,950	−1	−1	0	−2
Physician Assistant	2,457	1	1	0	2
Plastic Surgery	377	0	0	0	1
Podiatry	1,974	3	4	0	8
Portable X-Ray Supplier	99	0	1	0	1
Psychiatry	1,187	0	1	0	1
Pulmonary Disease	1,715	−2	−1	0	−3
Radiation Oncology And Radiation Therapy Centers	1,766	0	0	0	−1
Radiology	4,911	0	−1	0	−1
Rheumatology	541	−1	−1	0	−2
Thoracic Surgery	358	−1	0	0	−1
Urology	1,738	1	2	0	4
Vascular Surgery	1,148	0	−1	0	−1
Total	92,771	0	0	0	0

In this scenario, specialties that furnish a large volume of standalone office/outpatient E/M visits in conjunction with minor procedures see decreases in overall impacts, while specialties who tend to only bill E/M office/outpatient visits see minor increases and in many instances, the application of the MPPR adjustment is

not enough to overcome the negative impacts of the single payment rate on specialties that bill a higher volume of level 4 visits relative to their overall allowed services.

We also modeled the specialty level impacts associated with finalizing all elements of the proposal with the exception of the PE/hr adjustment and the MPPR, but establishing a single payment rate for office/outpatient new and established E/M visit levels 2–4, rather than a single payment rate for office/outpatient E/M levels 2–5 as proposed. Table 104 illustrates the specialty level impacts for this alternative.

TABLE 104—SPECIALTY LEVEL IMPACT OF FINALIZING SINGLE PFS RATES FOR OFFICE/OUTPATIENT E/M LEVELS 2 THROUGH 4 AND OTHER ELEMENTS AS PROPOSED

Specialty	Allowed charges (mil)	Impact of work RVU changes (%)	Impact of PE RVU changes (%)	Impact of MP RVU changes (%)	Combined impact (%)
(A)	(B)	(C)	(D)	(E)	(F)
Allergy/Immunology	$239	0	0	0	1
Anesthesiology	1,981	−1	0	0	−2
Audiologist	68	−1	1	0	0
Cardiac Surgery	294	−1	−1	0	−2
Cardiology	6,618	−1	−1	0	−2
Chiropractor	754	−1	−1	0	−2
Clinical Psychologist	776	−1	1	0	0
Clinical Social Worker	728	−1	2	0	1
Colon And Rectal Surgery	166	0	1	0	1
Critical Care	342	−2	−1	0	−3
Dermatology	3,486	2	3	0	5
Diagnostic Testing Facility	733	0	−5	0	−5
Emergency Medicine	3,121	−1	0	0	−2
Endocrinology	482	−1	−1	0	−1
Family Practice	6,208	1	1	0	3
Gastroenterology	1,757	−2	0	0	−2
General Practice	429	2	1	0	4
General Surgery	2,093	0	0	0	0
Geriatrics	197	−1	0	0	−1
Hand Surgery	214	1	2	0	3
Hematology/Oncology	1,741	0	0	0	0
Independent Laboratory	646	−1	3	0	3
Infectious Disease	649	−1	0	0	−1
Internal Medicine	10,767	0	0	0	0
Interventional Pain Mgmt	868	1	2	0	3
Interventional Radiology	386	0	−1	0	−1
Multispecialty Clinic/Other Phys	149	−1	−1	0	−2
Nephrology	2,190	−1	0	0	−1
Neurology	1,529	0	0	0	−1
Neurosurgery	804	−1	0	0	−1
Nuclear Medicine	50	−1	−1	0	−2
Nurse Anes/Anes Asst	1,242	−1	0	0	−2
Nurse Practitioner	4,065	2	1	0	3
Obstetrics/Gynecology	638	2	2	0	5
Ophthalmology	5,448	−1	−1	0	−2
Optometry	1,309	0	−1	0	−1
Oral/Maxillofacial Surgery	68	1	1	0	1
Orthopedic Surgery	3,743	0	1	0	1
Other	31	−1	3	0	2
Otolarngology	1,210	3	3	0	6
Pathology	1,165	−1	−1	0	−2
Pediatrics	61	1	0	0	1
Physical Medicine	1,107	−1	0	0	−2
Physical/Occupational Therapy	3,950	−1	−2	0	−3
Physician Assistant	2,457	2	2	0	4
Plastic Surgery	377	0	1	0	1
Podiatry	1,974	−1	−4	0	−5
Portable X-Ray Supplier	99	0	0	0	0
Psychiatry	1,187	3	2	0	5
Pulmonary Disease	1,715	−1	−1	0	−1
Radiation Oncology And Radiation Therapy Centers	1,766	0	−1	0	−1
Radiology	4,911	−1	−1	0	−2
Rheumatology	541	0	0	0	0
Thoracic Surgery	358	−1	−1	0	−2
Urology	1,738	2	3	0	5
Vascular Surgery	1,148	0	−2	0	−2
Total	92,771	0	0	0	0

2. E/M Documentation Alternatives Considered

We considered several alternatives to our final policies on documentation of E/M office/outpatient visits. Under all of these alternatives, we would finalize the documentation proposals that are not associated with coding and payment changes (the documentation proposals for home visits and avoiding redundant data recording that we are finalizing for January 1, 2019 as proposed).

Regarding the rest of the documentation policies, one alternative we considered was to maintain all five current E/M office/outpatient visit levels and eliminate additional documentation requirements. Under this option, there would be no minimum documentation standard because payment rates for multiple code levels would not be combined, but we could still have allowed choice in documentation methodology (current framework, MDM or time). Overall payments would likely change due to increased ability to use different key components to reach different code levels relative to the status quo. There would be no new add-on codes for primary care, other non-procedural specialty care or prolonged services, since the current code set would continue to differentiate levels of complexity. We estimate that this alternative would have reduced the documentation burden for office/outpatient visits by approximately 5 percent or 0.32 minutes per impacted visit. However, this alternative could result in significant and unpredictable redistributive effects as there would be a financial incentive to code to the highest possible visit level. Given that possibility, we chose not to finalize this alternative.

Another alternative was our proposed policies, which in the proposed rule we estimated would have reduced administrative burden by approximately 1.6 minutes per impacted visit. A large part of this time savings was attributed to the associated application of the minimum level 2 visit documentation standard to most visits (levels 2 through 5). We did not finalize this proposal because we were persuaded by public comments (detailed elsewhere in this final rule), indicating that Medicare should continue to recognize distinctions in visit complexity among the current level 2 through 5 visits.

3. Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services Alternatives Considered

We considered not finalizing our proposal in the CY 2019 PFS proposed rule to recognize a discrete set of services that are defined by and inherently involve the use of communication technology. If we had not finalized making separate coding and payment for HCPCS codes G2010 ((Remote evaluation of recorded video and/or images submitted by an established patient (*e.g.,* store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment) and G2012 ((Brief communication technology-based service, *e.g.* virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion) for CY 2019, we estimate that there would have been a 0.2 percent increase to the CF, based on our estimate that usage of these services will result in fewer than 1 million visits in the first year but will eventually result in more than 19 million visits per year, ultimately increasing payments under the PFS by about 0.2 percent.

4. Alternatives Considered for the AUC Program

For the purposes of estimating potential alternatives to the proposals in the CY 2019 PFS proposed rule for the AUC program, we considered the alternative scenarios below.

a. Consultation With More Than One Qualified CDSM

We considered an alternative scenario that would result in ordering professionals or auxiliary staff consulting more than one qualified CDSM prior to ordering advanced diagnostic imaging. In this scenario, we assumed a goal of decreasing the frequency that a ''not applicable'' consultation result would be reported on Medicare claims. One outcome of reducing ''not applicable'' responses is the potential to improve the quality and quantity of claims-based data available for calculating outlier ordering professionals. In future rulemaking the agency will establish the methodology to identifying outlier ordering professionals. Reducing ''not applicable'' responses will increase responses for adherence or non-adherence thereby increasing the total number of responses that can be used to calculate outlier ordering professionals. Additionally, according to the Medicare Imaging Demonstration Evaluation Report,[1] clinicians were conceptually interested in learning about how to improve ordering patterns. Ordering professionals receiving ''not applicable'' responses for some of their orders may not be able to achieve desired learning directly through the CDSM and may have to seek information elsewhere. Therefore reducing the number of ''not applicable'' responses may allow ordering professionals to achieve more of their learning within the CDSM.

In this assumption, the ordering professional or auxiliary personnel would consult their primary, qualified CDSM to find that such AUC were not available. For example, a consultation using CDSM 1 for a patient with unspecified abdominal pain results in no specified applicable AUC being available, and therefore, provides a ''not applicable'' result. In this clinical scenario, we know that specified applicable AUC are available (*https://acsearch.acr.org/docs/69467/Narrative/*) in qualified CDSM 2 and that CDSM 2 is available free of charge. Second, we assumed that additional requirements to reduce ''not applicable'' consultation outcomes, through tighter stipulations on AUC consultation, would change behavior in that a second consultation would occur (qualified CDSM 2). For example, we know that all CDSMs are required, consistent with § 414.94(g)(1)(iii) of our regulations to make available, at a minimum, specified applicable AUC that reasonably address common and important clinical scenarios within all priority clinical areas. Therefore, there may be clinical scenarios (for example, unspecified abdominal pain) outside of priority clinical areas that are not addressed within all qualified CDSMs. However, tighter requirements on AUC consultation—to consult a second CDSM when a ''not applicable'' response is the result of the first consultation in specific clinical scenarios—would reduce ''not applicable'' reporting on Medicare claims and would motivate ordering professionals to access a secondary CDSM that is qualified and available free of charge. CMS did not propose to require any ordering professional to

perform any additional AUC consultation if the initial consultation yields a result of ''not applicable.'' Rather, the ordering professional would have completely satisfied their AUC consultation requirement under § 414.94(j) with the first AUC consultation, regardless of the determination of the qualified CDSM.

Based on these assumptions, we identified examples of the advanced diagnostic imaging services that are outside the priority clinical areas yet have AUC available for a specific clinical scenario in a qualified, free CDSM. We focused our analysis on abdominal pain (any locations and flank pain). In addition, we identified the top five advanced diagnostic imaging services from data derived from the CCW's 2014 Part B non-institutional claim line file, which includes services covered by the Part B benefit that were furnished during calendar year 2014. These data are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/data.html*.

We estimated the burden of consulting a second, free CDSM to reduce the frequency of ''not applicable'' responses, which we did not propose. We did this by calculating the number of advanced diagnostic imaging services for unspecified abdominal pain based on 2014 claims data (Computed tomography of abdomen & pelvis with contrast—CPT 74177—299,644 services; Computed tomography of abdomen & pelvis with and without contrast—CPT 74176—233,088 services; Computed tomography of abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions—CPT 74178—36,992 services; Diagnostic nuclear medicine procedures on the gastrointestinal system with pharmacologic intervention—CPT 78227—20,997 services; Diagnostic nuclear medicine procedures on the gastrointestinal system—CPT 78226–10,713 services). According to the Medicare Imaging Demonstration Evaluation Report,[1] clinicians were conceptually interested in learning about how to improve ordering patterns, and in the context of clinical practice, most clinician focus group participants noted that they expected that a clinical decision support tool would provide more detailed feedback that would help clinicians reduce the number of inappropriately rated orders. Unfortunately, data compiled [73] as of 2002 suggested that appropriateness criteria could not be applied to 41-percent of MRI imaging requests. These gaps in appropriateness criteria often prompt local providers to augment the criteria produced by professional societies with their own decisions on appropriateness. One study [74] has shown that clinicians use appropriateness criteria far less often than other resources, such as specialist consults and UpToDate (Wolters Kluwer Health), to guide the management of their patients. In order to meet the expressed needs of ordering professionals, and direct ordering behaviors towards qualified CDSMs with specific applicable AUC, we considered pursuing tighter requirements in the context of the following impact estimate.

If we assume that 50 percent of these 601,434 total services required a second consultation because the specified applicable AUC were available in CDSM 1 then this estimate would be the time and effort for a 2-minute repeat consultation with another qualified CDSM available free of charge for 300,717 services annually (601,434 services × 50 percent). If 90 percent of those consultations (300,717 services × 90 percent × 0.033 hr/service) for 8,931.285 total hours were performed by a medical assistant (occupation code 31–9092) at a rate of $32.30/hour for a total of $288,480.50 and 10 percent of consultations (300,717 services × 10 percent × 0.033 hr/service) for 992.376 total hours were performed by the ordering professional at a rate of $200.54/hour for a total of $199,011.08 then annually the burden estimate would be 9,923.661 total hours (8,931.285 hours + 992.376 hours) and $487,491.58 ($288,480.50 + $199,011.08) to perform the second consultations. This analysis was limited to abdominal pain because that is one example of a clinical scenario that falls outside of the priority clinical areas. In the proposed rule we did not propose tighter requirements on the frequency to which ordering professionals or applicable staff would be required to consult at this time this was due to the agency's efforts to minimize burden whereas a second consultation would result in added time and cost to the ordering professional.

b. Significant Hardship Application Process

To illustrate the consideration that a self-attestation of a significant hardship exception is a less burdensome approach, we compared this to the alternative consideration of requiring a significant hardship exception application process to review and approve applicants in near real-time. We recognize that there are some benefits to a significant hardship exception application that could not be directly quantified. For instance, some ordering professionals may gain confidence knowing that they have documentation confirming that a significant hardship exception application was submitted and/or received by CMS. Those same ordering professionals and others may appreciate a process that includes receipt of a determination from CMS as to the acceptance of their application for significant hardship exception. Finally some furnishing professionals and facilities that provide advanced diagnostic imaging services as a result of orders placed by ordering professionals could have reassurance knowing that such ordering professionals have a significant hardship exception granted by CMS and confirmed for 1 year.

As a basis for comparison of the significant hardship exception application to self-attestation, we estimate that such an application would be similar to the existing application (CMS–10621, OCN 0938–1314) to request a reweighting to zero for the advancing care information performance category (renamed the promoting interoperability performance category) due to significant hardship. This is a short online form that requires identifying which type of hardship applies, and a description of how the circumstances impair the ability to submit advancing care information data, as well as some proof of circumstances. The estimate for the $44.59 mean hourly wage and 100-percent fringe benefits of a computer system analyst (BLS #15–1121) to submit this application is 0.5 hours. Given that we would expect 6,699 AUC hardship applications per year, the annual total burden hours are estimated to be 3349.50 hours (6,699 respondents × 0.5 burden hours per respondent). The estimated total annual burden is $298,708.41 (3349.50 hours × $89.18 per hour). Based in part on the cost and burden estimates, we did not propose the use of a significant hardship exception application.

[73] Levy, G et al. 2006. Nonradiologist utilization of American College of Radiology appropriateness criteria in apreauthorization center for MRI requests: Applicability and effects. AJR Am J Roentgenol, 187(4), 855–858. doi: 10.2214/AJR.05.1055.

[74] Bautista, AB et al. 2009. Do clinicians use the American College of Radiology appropriateness criteria in the management of their patients? AJR Am J Roentgenol, 192(6), 1581–1585. doi: 10.2214/AJR.08.1622.

5. Alternatives Considered for the Quality Payment Program

For purposes of the payment impact on the Quality Payment Program, we view the performance threshold and the additional performance threshold, as the critical factors affecting the distribution of payment adjustments. We ran two separate models with performance thresholds of 25 and 35 respectively (as an alternative to the finalized performance threshold of 30) to estimate the impact of a moderate and aggressive increase in the performance threshold. A lower performance threshold would be a more gradual transition and could potentially allow more clinicians to meet or exceed the performance threshold. The lower performance threshold would lower the amount of budget neutral dollars to redistribute and increase the number of clinicians with a positive payment adjustment but the scaling factor would be lower. In contrast, a more aggressive increase would likely lead to higher positive payment adjustments for clinicians that exceed the performance threshold because the budget neutral pool would be redistributed among fewer clinicians. We ran each of these models using the finalized additional performance threshold of 75. In the model with a performance threshold of 25, we estimate that $271 million would be redistributed through budget neutrality. There would be a maximum payment adjustment of 4.5 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 7.2 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data. In the model with a performance threshold of 35, we estimate that $349 million would be redistributed through budget neutrality, and that there would be a maximum payment adjustment of 4.9 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 10.5 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data. We finalized a performance threshold of 30 because we believe increasing the performance threshold to 30 points was not unreasonable or too steep, but rather a moderate step that encourages clinicians to gain experience with all MIPS performance categories. We refer readers to section III.I.3.j.(2) of this final rule for additional rationale on the selection of performance threshold.

To evaluate the impact of modifying the additional performance threshold, we ran two models with additional performance thresholds of 70 and 80 as an alternative to the finalized 75 points. We ran each of these models using a performance threshold of 30. The benefit of the model with the additional performance threshold of 70 would maintain the additional performance threshold that was in years 2 and 3. In the model with the additional performance threshold of 70, we estimate that $310 million would be redistributed through budget neutrality, and there would be a maximum payment adjustment of 3.9 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 8.8 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data. In the model with an additional performance threshold of 80, for which the benefit was to assess the impact of the proposed additional performance threshold in the 2019 PFS proposed rule, we estimate that $310 million would be redistributed through budget neutrality, and that there would be a maximum payment adjustment of 6.1 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance among those that submit data. Also, that 8.8 percent of MIPS eligible clinicians will receive a negative payment adjustment. We finalized the additional performance threshold at 75 points, which is halfway between our proposal of 80 and the CY 2018 MIPS performance period additional performance threshold at 70 because we believe raising the additional performance threshold, but for less than the original amount proposed, would incentivize continued improved performance while accounting for policy changes in the third year of the program. We refer readers to section III.I.3.j.(3) of this final rule for additional rationale on the selection of additional performance threshold.

To examine the impact of changes to the low-volume threshold on the number of MIPS eligible clinicians, we ran estimates for three different low-volume threshold criteria. As we discuss in section III.I.3.c of this final rule, we analyzed the impact of alternate low-volume thresholds because the low-volume threshold can affect the number of MIPS eligible clinicians and some public commenters were concerned about the associated impacts of the exclusions on the MIPS payment adjustments. When we set the third low volume threshold at 100 as an alternative to 200 covered professional services, we estimate that 32,828 clinicians would elect to opt-in for a total population of 802,915. When we apply the opt-in policy without adding the third finalized low-volume criterion at 200 covered professional services, we estimate that 12,242 clinicians would elect to opt-in for a total population of 782,329. When we lower the low-volume threshold criteria to $30,000 or fewer allowed charges for covered professional services; 100 or fewer Part B-enrolled individuals; and 100 or fewer furnished covered professional services to Medicare Part B-enrolled beneficiaries, we estimate a total of 871,238 MIPS eligible clinicians. To assess the impact of the number of MIPS eligible clinicians on payment adjustments, we ran a model with the lowest low-volume threshold and, therefore, highest number of MIPS eligible clinicians (871,238). We estimate that $440 million would be redistributed through budget neutrality. There would be a maximum payment adjustment of 5.0 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 9.7 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data. These alternative low-volume thresholds were not selected because we did not observe a meaningful difference on the maximum payment adjustment from the finalized low-volume threshold in this final rule. As we stated in section III.I.3.c.(4) of this final rule, we will continue to strike a balance between ensuring sufficient participation in MIPS while also addressing the needs of small practices that may find it difficult to meet the program requirements. We refer readers to section III.I.3.c.(4) of this final rule for additional rationale on the selection of the low-volume threshold.

H. Impact on Beneficiaries

There are a number of changes in this final rule that will have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through regular updates to the inputs used to calculate payments under the PFS, will have a positive impact and improve the quality and value of care provided to Medicare providers and beneficiaries.

I. Burden Reduction Estimates

1. Evaluation and Management Documentation

All health care practitioners, as part of their routine record keeping activities, create and maintain documentation in the patient medical record for clinical and payment purposes. It is standard industry practice that when healthcare practitioners bill insurers, payers and health plans, such as Medicare, state plans under Title XIX, and commercial or other third party payers, for office and outpatient E/M services, that health care practitioners report the services using the common coding framework and definitions developed and maintained by the AMA CPT Editorial Panel. The 1995/1997 E/M services documentation guidelines provide guidance to medical practitioners regarding medical record documentation of E/M services based on the AMA CPT coding framework and definitions. In response to comments received from RFIs released to the public under our Patients Over Paperwork Initiative, we proposed to address medical documentation by simplifying the payment framework for E/M services and allowing greater flexibility on the components practitioners could choose to document when billing Medicare for E/M visits.

We estimate that the E/M visit documentation changes finalized in section II.I. of this final rule may significantly reduce the amount of time practitioners spend documenting office/outpatient E/M visits. Although little research is available on exactly how much time physicians and non-physician practitioners (NPPs) spend specifically documenting E/M visits, according to one recent estimate, primary care physicians spend on average, 84 minutes or 1.4 hours per day (24 percent of the time that they spend working within an EHR) documenting progress notes.[75] Another study found that primary care physicians spend an average of 2.1 hours per day writing progress notes (both in-clinic and remote access).[76] Assuming an average of 20 patient visits per day, one E/M visit per patient, and using the higher figure of 2.1 hours per day spent documenting these visits, in our proposed rule we estimated that documentation of an average outpatient/office E/M visit takes 6.3 minutes.[77]

We stated our belief that our proposals to reduce redundancy in visit documentation, to allow auxiliary staff and the beneficiary to enter certain information in the medical record that would be verified but not required to be re-documented by the billing practitioner, to allow the choice of visit level and documentation based on MDM or time as alternatives to the current framework, and to require only minimum documentation (the amount required for a level 2 visit) for all visits except level 1 visits may reduce the documentation time by one quarter of the current time for the average office/outpatient visit. Under this assumption, we estimated these proposals would save clinicians approximately 1.6 minutes of time per office/outpatient E/M visit billed to Medicare. For a full-time practitioner whose panel of patients is 40 percent Medicare (60 percent other payers), this would translate to approximately 51 hours saved per year.[78]

We noted that stakeholders had emphasized to us in public comments that whatever reductions may be made to the E/M documentation guidelines for purposes of Medicare payment, physicians and non-physician practitioners will still need to document substantial information in their progress notes for clinical, legal, operational, quality reporting and other purposes, as well as potentially for other payers. Furthermore, we recognized that there may be a ramp-up period for physicians and non-physician practitioners to implement the proposed documentation changes in their clinical workflow and EHR such that the effects of mitigating documentation burden may not be immediately realized. Accordingly, we believed the total amount of time practitioners spend on E/M visit documentation may remain high, despite the time savings that we estimated in our proposed rule could result from our E/M documentation proposals. These and all other improvements to payment accuracy that we proposed for CY 2019 were described in greater detail in section II.I. of the proposed rule. We welcomed public comments on our assumptions for the estimated reduction in documentation burden related to our E/M visit proposals.

Comment: We received many public comments on our assumptions regarding the potential burden reduction associated with our E/M proposals. The commenters stated that CMS overestimated how much the proposals would reduce burden, and noted they would reduce burden less than CMS estimated or, according to some commenters, might increase burden overall. Some commenters stated that the time and labor saved on documentation would be time currently spent after hours and on weekends, so it would not translate into additional ''work time'' or availability to see more patients. They stated that documentation time, in general, would remain high, due to the need to continue documenting for clinical, legal and many other purposes such as risk adjustment, quality reporting and other payers. Many of the commenters stated concerns that other payers including Medicaid and secondary payers might not adopt the same policies as Medicare, and that incongruities in documentation rules between payers would necessitate extra effort by practices to assess the best or required documentation method, among so many choices, for different patients. They noted that which payer(s) a given patient has is not always known at the outset of the visit.

Many commenters stated there would be significant burden and cost to update EHRs and educate and train coders, staff and auditors. Also, they noted that without appropriate medical documentation for each visit, the proposals might result in insufficient documentation by one member of the care team that another member might have to make up for, and that fractured care from incomplete or insufficient documentation might inadvertently create additional burdens, as well as impact quality of care. While many commenters supported allowing a choice in documentation methodology (current framework, medical decision-making, or time), other commenters noted such a policy would increase burden due to increased variation in how visits would be documented, and the need to restructure EHR templates to accommodate different options and decide which method was best for a given patient or practice. Most of the commenters noted our proposals regarding billing eligibility and supporting documentation for the proposed add-on codes for primary care, other specialty care, prolonged services, and documenting using time were unclear and might create new burdens that would equal or exceed the current

[75] Arndt BG, Beasley JW, Watkinson MD, et al. Tethered to the EHR: Primary care physician workload assessment using EHR event log data and time-motion observations. Ann Fam Med. 2017;15:427–33.

[76] Tai-Seale M, Olson CW, Li J, et al. Electronic health record logs indicate that physicians split time evenly between seeing patients and desktop medicine. Health Aff (Milwood). 2017;36:655–62.

[77] 20 patient visits per day based on the average number reported in the Physicians Foundation 2016 Survey of America's Physicians, available online at *https://physiciansfoundation.org/wp-content/uploads/2018/01/Biennial_Physician_Survey_2016.pdf.*

[78] Forty percent of 20 total patients per day = 8 Medicare vists per day. (8 visits per day)*(1.6 minutes per visit)*(240 days per year) = 51.2 hours.

burden. Some commenters stated that our proposals layered on complexity that would counteract the goal of reducing administrative burden, and that the negative impacts of the payment proposals would outweigh positive impacts of documentation changes.

Other commenters were concerned about impacts on MA plan payments, plan quality, and provider access. Some commenters were concerned that paying for visits based on a single rate would not allow an understanding of the complexity of care being delivered and might lead to abuse. Another commenter noted that the proposed add-on codes to account for care complexity would increase complexity and result in a need for perpetual fixes from unanticipated consequences. Similar to other commenters, this commenter was concerned that a single payment rate would redistribute payments without reducing the burden associated with determining the right codes, because the coding structure would remain the same. The commenter also expressed concern that practitioners would be less willing to see complex patients, and that the proposal would incentivize gaming by certain specialties to make up for lost revenue. The commenter's preferred approach was to simplify the current guidelines and rather than implement a single payment rate, CMS should wait for the AMA/CPT's E/M workgroup results. Finally, the commenter recommended that if CMS finalized as proposed, CMS should phase implementation and create a monitoring process.

Response: We understand that practitioners would continue to need to document substantial information in the medical record for clinical, legal and many other purposes such as risk adjustment, quality reporting, productivity measures and potentially other payers. In making our proposal, we did not aim to eliminate the need to document any history, exam, and/or MDM, but rather, we ocused on eliminating unnecessary, and outdated requirements that are associated with payment for visit ''levels.'' This would allow the practitioner to document what is clinically relevant and needed to support the service within whatever framework they chose to apply—along with medical necessity—rather than outdated aspects of the current guidelines. We understand that other payers might not adopt the same approach, at least not in the short term. The AMA/CPT has stated an intention to revise the E/M code set by 2020 or 2021, which would help to establish uniformity among payers. However, we agree with the commenters that it would be critical to allow time for education, changing workflows and billing systems. We understand that particularly in the initial year(s) of any changes, there would be a cost to these activities for practitioners and providers, including a cost to update EHRs. We are reducing our estimate of burden reduction to account for these issues.

We note that we believe that time physicians spend fulfilling current documentation requirements on evenings and weekends are burdensome, and that even if that additional time would not necessarily be spent seeing additional patients, that time is a quantifiable resource cost to physicians and other practitioners.

After considering the comments, we adjusted our proposed burden reduction estimate, including our estimates on the documentation of an average outpatient/office E/M. We are still assuming an average of 20 patient visits per day, one E/M visit per patient, but instead are using the more conservative figure of 1.4 hours per day spent documenting E/M visits that we identified in our review of available research. As a result, we estimate that documentation of an average outpatient/office E/M visit takes 4.2 minutes versus our initial estimate of 6.3 minutes. The final rule estimated time savings is monetized into practitioner wages and summarized as follows.

TABLE 105—ESTIMATED BURDEN REDUCTION FOR E/M DOCUMENTATION FINAL POLICIES

[Practitioner wages]

	2019	2020	2021	2022	2023 and annually thereafter
Grand Total	$84,059,794.68	$84,059,794.68	$298,522,913.92	$405,754,473.54	$512,986,033.15

We calculated the time savings associated with documentation changes annually, and converted this time to practitioner wages using 2016 hourly wage data from the Bureau of Labor Statistics (BLS) [79] multiplied by two to adjust for overhead and benefits. We adjusted for the estimated proportion of impacted visits furnished by NPPs earning lower wages than physicians, which we acknowledge is unclear due to the ability to report services as ''incident to'' a physician when they are furnished directly by an NPP. We approximated the portion attributable to NPP wages using the number of visits directly reported by NPPs (reported with a specialty of NP, PA, CNS or CNM).

The estimated savings for 2019 and 2020 are for the initial changes to documentation in these years (those not impacted by coding and payment changes, including provisions to no longer require documentation of the medical necessity of a home visit in lieu of an office visit and to expand current policy reducing the need to re-document prior data in the medical record). These savings would impact levels 2 through 5 visits, and are estimated to save 0.11 minutes [80] per impacted visit, which translates into approximately $84 million in wages across all impacted visits.

Additional savings are estimated annually starting in 2021 for the finalized payment and coding-related changes. These savings would impact levels 3 and 4 visits, and are estimated to save 0.63 minutes [81] per impacted visit, which translates into approximately $513 million annually in wages across all impacted visits. We assume half of these estimated savings in year 1 (2021), 75 percent in year 2 (2022) and 100 percent each subsequent year (2023 and each year thereafter) to account for information provided in the public comments that there is

[79] *https://www.bls.gov/oes/2016/may/oes_nat.htm.*

[80] 2.5% of the 4.2 minutes we estimate that it currently takes to document an office/outpatient E/M visit.

[81] We reduced the final rule time savings estimate of 25% (1.1 minutes) to 15 percent (0.63 minutes). We reduced it by 10 percentage points to account for the burden of documenting level 5 visits, as well as the level 2–4 combined visit. This is to account for the uncertainty of the future code structure/definitions, as well as public comments that introducing variation in documentation choices and methods and providing for a bare bones minimum standard could increase burden).

potentially off-setting burden associated with the continued need to document for MA and potentially other payers, quality reporting, and clinical, legal and other purposes, as well as ramp-up costs to update EHRs and conduct training and education. The estimate assumes very minimal burden associated with use and documentation of the add-on codes for primary care and other specialty care, as well as the extended visit add-on code and otherwise documenting using time, as we are clarifying these policies and establishing minimal documentation rules discussed in section II.I. of this final rule. We intend to allow flexibility in how office/outpatient visits are documented and to allow a choice in using the current framework, medical decision-making or time, though we will take into consideration any changes in the code set that may impact these options in future years.

2. Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services

As noted in section II.D. of this final rule, for CY 2019, we aimed to increase access for Medicare beneficiaries to physicians' services that are routinely furnished via communication technology by clearly recognizing a discrete set of services that are defined by and inherently involve the use of communication technology. Accordingly, we made several proposals for modernizing Medicare physician payment for communication technology-based services.

The use of communication technology-based services will provide new options for physicians to treat patients. These services could help to avoid unnecessary office visits, could consist of services that are already occurring but are not being separately paid, or could constitute new services. Medicare would pay $14 per visit in the first year for these communication technology-based services, compared with $92 per visit for the corresponding established patient visits.

Practitioners have a choice of when to use the communication technology-based services. Because of the low payment rate relative to that for an office visit, we are assuming that usage of these services will be relatively low. In addition, we expect that the number of new or newly billable visits and subsequent treatments will outweigh the number of times that communication technology-based services will be used instead of more costly services. As a result, we expect that the financial impact of paying for the communication technology-based services will be an increase in Medicare costs. We estimate that usage of these services will result in fewer than 1 million visits in the first year but will eventually result in more than 19 million visits per year, ultimately increasing payments under the PFS by about 0.2 percent. In order to maintain budget neutrality in setting proposed rates for CY 2019, we assumed the number of services that would result in a 0.2 percent reduction in the CF.

As with all estimates, and particularly those for new separately billable services, this outcome is highly uncertain. Because recognition of communication technology-based services is a new area for healthcare coverage, the available information on which to base estimates is limited and is usually not directly applicable, particularly to a new Medicare payment. The cost and utilization estimates are based on Medicare claims data together with a study published in *Health Affairs,*[82] which examined the cost and utilization of telehealth in the private sector. While this study was the most applicable for an estimate, we note that the results from this program may be different because Medicare experience may differ from private sector behavior and because the study was limited to acute respiratory infection visits. We also note that the study cites the use of direct-to-consumer telehealth companies, many of which provide access to care 24 hours per day, 7 days per week, 365 days per year, whereas the services described by HCPCS codes G2010 and G2012 are limited to only established patients.

We proposed to make separate payment for these services when furnished by RHCs and FQHCs. A potential estimate of utilization and overall cost of these services by RHCs and FQHCs could be derived by comparing their use of chronic care management and other care management services to the same services furnished by practitioners paid under the PFS, since these care management services are also separately billable and do not take place in-person. Based on this comparison, and without considering potential variables and issues specific to these services, the impact the finalized policy would be less than $1 million in additional Medicare spending in the first year and could eventually result in up to $20 million in spending per year in future years. These estimates are uncertain and could change after further consideration of the potential variables and issues specific to these services.

3. Outpatient Therapy Services

As noted in section II.M. of this final rule, we are finalizing our proposal to end functional reporting for outpatient therapy services as part of our burden reduction efforts in response to the RFI on CMS Flexibilities and Efficiencies that was issued in the CY 2018 PFS proposed rule (82 FR 34172 through 34173). Under our functional reporting system therapy practitioners and providers are required to report, whenever functional reporting is required, non-payable HCPCS G-codes and modifiers—typically in pairs—to convey information about the beneficiary's functional limitation category and functional status throughout the PT, OT, or SLP episode of care. In addition, each time functional reporting is required on the claim, the therapy provider must also document the functional reporting G-codes and their modifiers in the medical record. In this final rule, we are finalizing our proposal to eliminate this requirement that therapy practitioners and providers report HCPCS G-codes and modifiers or document in the medical record to convey functional reporting status for PT, OT or SLP episode of care.

To quantify the amount of burden reduction, we estimated the total amount of time that therapy practitioners spend doing functional reporting. To do this, we first looked at our data for CY 2017 for professional claims by the type of plan of care reported primarily by therapists in private practice (TPPs), including physical therapists, occupational therapists, and speech-language pathologists. We found that the overall utilization of the 42 functional reporting HCPCS G-codes totaled 15,456,421 single units, or 7,728,211 pairs.

We then considered the time, on average, it might take to report on the claim and document in the medical record each pair of HCPCS G-codes. We noted this includes the time it takes to make the initial determination of the HCPCS G-code functional limitation category, as well as the time needed to make each initial and/or subsequent assignments for the applicable severity modifiers in order to define the patient's functional status. We then made the assumption that it would take between 1 minute and 1.5 minutes, on average, to report the HCPCS G-code and modifier pair each time functional reporting is required. Using the total utilization of G-code pairs and the range of 1 minute to 1.5 minutes, we

[82] Ashwood, J.S. (2017 March) Direct-To-Consumer Telehealth May Increase Access To Care But Does Not Decrease Spending. *Health Affairs.*

calculated that TPPs would have saved between 128,804 and 193,206 hours (or 7,728,211 to 11,592,317 minutes) collectively in CY 2017 if the functional reporting requirements had not been in place. We continue to believe this is a reasonable projection for the potential savings to TPPs, physicians and certain nonphysician practitioners in future years with the finalization of our proposal to end functional reporting effective January 1, 2019.

Because therapy services are also furnished by providers of outpatient therapy services such as hospitals, SNFs and rehabilitation agencies that submit institutional claims, typically representing a greater amount of expenditures than practitioners submitting professional claims, we calculated additional savings for these providers using the same time assumptions of 1 to 1.5 minutes to report the HCPCS G-code and modifier pair each time functional reporting is required. Our 2017 data showed a total utilization of the functional reporting HCPCS G-codes is 29,053,921 single units, or 14,526,961 pairs, indicating that therapy providers would collectively save between 242,116 to 363,174 hours (or 14,526,961 to 21,790,442 minutes) for CY 2017 if the functional reporting requirements had not been effective during that year.

As discussed in section II.M. of this final rule, we received many comments on our burden reduction proposal to eliminate our functional reporting requirements, and nearly all comments were supportive. We believe it is reasonable to estimate that in CY 2019 TPPs and other practitioners submitting professional claims and therapists working for providers submitting institutional claims will collectively save, at a minimum, the same number of collective hours we calculated they would save for CY 2017, as specified previously in this RIA, with dates of service on and after January 1, 2019.

4. Physician Supervision of Diagnostic Imaging Procedures

We believe that the changes to the physician supervision requirements for RAs furnishing diagnostic imaging procedures as described in section II.F. of this final rule will significantly reduce burden for physicians. While approximately 215,000 diagnostic imaging services per year are currently performed that require personal supervision, we are not able to determine the number of these services that are performed by an RA due to limitations in the claims data. As a result, we are not able to quantify the amount of time potentially saved by physicians and practitioners under the policy we are finalizing to require direct supervision of diagnostic imaging procedures done by RAs in cases where personal supervision would ordinarily be required. That said, stakeholders representing the practitioner community have indicated that changing the required supervision level for RAs will result in a redistribution of workload from radiologists to RAs, potentially resulting in improved practice efficiency and patient satisfaction. Stakeholders have stated that practitioners that utilize RAs have experienced improvements in practice efficiency, as use of RAs allows radiologists more time for professional services such as interpretation of images, and these practitioners cite greater flexibility that results in reduced wait times. Furthermore, stakeholders contend that the Medicare supervision requirements currently create disincentives to use RAs, as practitioners cannot make full use of them for Medicare patients, and the change to the supervision requirement would allow RAs to be more fully utilized. For these reasons, we believe the change in supervision requirements we are finalizing for RAs will contribute to burden reduction for physicians and practitioners providing diagnostic imaging procedures for Medicare beneficiaries.

5. Beneficiary Liability

Many proposed policy changes could result in a change in beneficiary liability as it relates to coinsurance (which is 20 percent of the fee schedule amount, if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in our public use file Impact on Payment for Selected Procedures available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/,* the CY 2018 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) was $109.80, which means that in CY 2018, a beneficiary would be responsible for 20 percent of this amount, or $21.96. Based on this final rule, using the CY 2019 CF, the CY 2019 national payment amount in the nonfacility setting for CPT code 99203, as shown in the Impact on Payment for Selected Procedures public use file, is $109.92, which means that, in CY 2019, the final beneficiary coinsurance for this service would be $21.98.

J. Impact on Beneficiaries in the Quality Payment Program

There are several changes in this rule that would have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through regular updates to the inputs used to calculate payments under the PFS, would have a positive impact and improve the quality and value of care provided to Medicare beneficiaries. For example, several of the new proposed measures include patient-reported outcomes, which may be used to help patients make more informed decisions about treatment options. Patient-reported outcome measures provide information on a patient's health status from the patient's point of view and may also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which may not otherwise be available through routine clinical data collection. Patient-reported outcomes are factors frequently of interest to patients when making decisions about treatment.[83] Further, the proposed policy changes in the Promoting Interoperability performance category shifts the focus to the interoperable, seamless exchange of electronic information. With the requirement that program participants use 2015 Edition CEHRT, the interoperable exchange of patient health information should be easier because the certification criteria are designed to facilitate information exchange. In combination with the newly proposed Promoting Interoperability measure to receive and incorporate health information, beneficiaries should begin to experience improved care coordination and care transitions because clinicians have improved access to the beneficiaries' health information across the spectrum of care.

Impact on Other Health Care Programs and Providers

We estimate that CY 2019 Quality Payment Program will not have a significant economic effect on eligible clinicians and groups and believe that MIPS policies, along with increasing participation in APMs over time may succeed in improving quality and reducing costs. This may in turn result in beneficial effects on both patients and some clinicians, and we intend to continue focusing on clinician-driven, patient-centered care.

[83] Institute of Medicine. 2013. Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis. Washington, DC: The National Academies Press. *https://doi.org/10.17226/18359.*

K. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's rule will be the number of reviewers of this rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcomed any comments on the approach in estimating the number of entities which will review this rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $107.38 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately 8.0 hours for the staff to review half of this rule. For each facility that reviews the rule, the estimated cost is $859.04 (8.0 hours × $107.38). Therefore, we estimated that the total cost of reviewing this regulation is $5,105,275 ($859.04 × 5,943 reviewers).

L. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Tables 106 and 107 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2018 to CY 2019 based on the FY 2019 President's Budget baseline.

TABLE 106—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2019 Annualized Monetized Transfers	Estimated increase in expenditures of $0.3 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 107—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfer
CY 2019 Annualized Monetized Transfers of beneficiary cost coinsurance.	$0.1 billion.
From Whom to Whom?	Beneficiaries to Federal Government.

M. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides an RIA. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Drugs, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

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

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 is revised to read as follows:

Authority: 42 U.S.C. 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k)) and 42 U.S.C. 263a.

■ 2. Section 405.2401 is amended in paragraph (b) by—

■ a. Revising the introductory text of the definition of ''Federally qualified health center''; and

■ b. Revising the definition of ''Secretary''.

The revisions read as follows:

§ 405.2401 Scope and definitions.

* * * * *

(b) * * *

Federally qualified health center (FQHC) means an entity that has entered into an agreement with CMS to meet Medicare program requirements under § 405.2434 and—

* * * * *

Secretary means the Secretary of Health and Human Services or his or her delegate.

* * * * *

■ 3. Section 405.2462 is amended by revising paragraph (g) introductory text to read as follows:

§ 405.2462 Payment for RHC and FQHC services.

* * * * *

(g) To receive payment, the RHC or FQHC must do all of the following:

* * * * *

■ 4. Section 405.2464 is amended by—

■ a. Revising paragraphs (a)(1), (b) heading, (b)(1), (c), and (d); and

■ b. Adding a new paragraph (e)

The revisions and additions read as follows:

§ 405.2464 Payment rate.

(a) * * *

(1) Except as specified in paragraphs (d) and (e) of this section, an RHC that is authorized to bill under the reasonable cost system is paid an all-inclusive rate that is determined by the MAC at the beginning of the cost reporting period.

* * * * *

(b) *Payment rate for FQHCs that are authorized to bill under the prospective payment system.* (1) Except as specified in paragraphs (d) and (e) of this section, a per diem rate is calculated by CMS by dividing total FQHC costs by total FQHC daily encounters to establish an average per diem cost.

* * * * *

(c) *Payment for care management services.* For chronic care management services furnished between January 1, 2016 and December 31, 2017, payment to RHCs and FQHCs is at the physician fee schedule national non-facility payment rate. For care management services furnished on or after January 1, 2018, payment to RHCs and FQHCs is at the rate set for each of the RHC and FQHC payment codes for care management services.

(d) *Payment for FQHCs that are authorized to bill as grandfathered tribal FQHCs.* Grandfathered tribal FQHCs are paid at the outpatient per visit rate for Medicare as set annually by the Indian Health Service for each beneficiary visit for covered services. There are no adjustments to this rate.

(e) *Payment for communication technology-based and remote evaluation services.* For communication technology-based and remote evaluation services furnished on or after January 1, 2019, payment to RHCs and FQHCs is at the rate set for each of the RHC and FQHC payment codes for communication technology-based and remote evaluation services.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 5. The authority citation for part 410 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 6. Section 410.32 is amended by adding paragraph (b)(4) to read as follows:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

* * * * *

(b) * * *

(4) *Supervision requirement for RRA or RPA.* Diagnostic tests that are performed by a registered radiologist assistant (RRA) who is certified and registered by the American Registry of Radiologic Technologists or a radiology practitioner assistant (RPA) who is certified by the Certification Board for Radiology Practitioner Assistants, and that would otherwise require a personal level of supervision as specified in paragraph (b)(3) of this section, may be furnished under a direct level of physician supervision to the extent permitted by state law and state scope of practice regulations.

* * * * *

§ 410.59 [Amended]

■ 7. Section 410.59 is amended by removing paragraph (a)(4).

§ 410.60 [Amended]

■ 8. Section 410.60 is amended by removing paragraph (a)(4).

■ 9. Section 410.61 is amended by revising paragraph (c) to read as follows:

§ 410.61 Plan of treatment requirements for outpatient rehabilitation services.

* * * * *

(c) *Content of the plan.* The plan prescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual, and indicates the diagnosis and anticipated goals.

* * * * *

§ 410.62 [Amended]

■ 10. Section 410.62 is amended by removing paragraph (a)(4).

■ 11. Section 410.78 is amended by—

■ a. Adding paragraphs (b)(3)(ix), (x), (xi), and (xii);

■ b. Revising paragraph (b)(4) introductory text, and

■ c. Adding paragraph (b)(4)(iv).

The additions and revision read as follows:

§ 410.78 Telehealth services.

* * * * *

(b) * * *

(3) * * *

(ix) A renal dialysis facility (only for purposes of the home dialysis monthly ESRD-related clinical assessment in section 1881(b)(3)(B) of the Act);

(x) The home of an individual (only for purposes of the home dialysis ESRD-related clinical assessment in section 1881(b)(3)(B) of the Act).

(xi) A mobile stroke unit (only for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke provided in accordance with section 1834(m)(6) of the Act).

(xii) The home of an individual (only for purposes of treatment of a substance use disorder or a co-occurring mental health disorder, furnished on or after July 1, 2019, to an individual with a substance use disorder diagnosis.

(4) Except as provided in paragraph (b)(4)(iv) of this section, originating sites must be:

* * * * *

(iv) The geographic requirements specified in paragraph (b)(4) of this section do not apply to the following telehealth services:

(A) Home dialysis monthly ESRD-related clinical assessment services furnished on or after January 1, 2019, at an originating site described in paragraphs (b)(3)(vi), (ix) or (x) of this section, in accordance with section 1881(b)(3)(B) of the Act; and

(B) Services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke.

(C) Services furnished on or after July 1, 2019 to an individual with a substance use disorder diagnosis, for purposes of treatment of a substance use disorder or a co-occurring mental health disorder.

* * * * *

§ 410.105 [Amended]

■ 12. Section 410.105 is amended—

■ a. In paragraph (c)(1)(ii) by removing the phrase ''that are consistent with the patient function reporting on the claims for services''; and

■ b. By removing paragraph (d).

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 13. The authority citation for part 411 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 14. Section 411.353 is amended by—
■ a. Revising paragraph (g)(1); and
■ b. Removing and reserving paragraph (g)(2).

The revision reads as follows:

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

* * * * *

(g) * * *

(1) An entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—

(i) The compensation arrangement between the entity and the referring physician fully complies with an applicable exception in this subpart except with respect to the signature requirement of the exception; and

(ii) The parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant and the compensation arrangement otherwise complies with all criteria of the applicable exception.

(2) [Reserved]

■ 15. Section 411.354 is amended by adding paragraph (e) to read as follows:

§ 411.354 Financial relationship, compensation, and ownership or investment interest.

* * * * *

(e) *Special rule on compensation arrangements*—(1) *Application.* This paragraph (e) applies only to compensation arrangements as defined in section 1877 of the Act and this subpart.

(2) *Writing requirement.* In the case of any requirement in this subpart for a compensation arrangement to be in writing, such requirement may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 16. The authority citation for part 414 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 17. Section 414.65 is amended by—
■ a. Revising paragraph (a) introductory text;
■ b. Removing paragraph (a)(1);
■ c. Redesignating paragraphs (a)(2) and (3), as paragraphs (a)(1) and (2), respectively; and
■ d. Adding paragraph (b)(3).

The revision and addition reads as follows:

§ 414.65 Payment for telehealth services.

(a) *Professional service.* The Medicare payment amount for telehealth services described under § 410.78 of this chapter is equal to the current fee schedule amount applicable for the service of the physician or practitioner, subject to paragraphs (a)(1) and (2) of this section, but must be made in accordance with the following limitations:

* * * * *

(b) * * *

(3) No originating site facility fee payment is made to an originating site described in § 410.78(b)(3)(x), (xi), or (xii); or to an originating site for services furnished under the exception at § 410.78(b)(4)(iv)(A) or (B) of this chapter.

* * * * *

■ 18. Section 414.94 is amended—
■ a. In paragraph (b), by revising the definition of ''Applicable setting''; and
■ b. By revising paragraphs (i)(3), (j), and (k) introductory text.

The revisions read as follows:

§ 414.94 Appropriate use criteria for advanced diagnostic imaging services.

* * * * *

(b) * * *

Applicable setting means a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, an independent diagnostic testing facility, and any other provider-led outpatient setting determined appropriate by the Secretary.

* * * * *

(i) * * *

(3) Significant hardships for ordering professionals who experience any of the following:

(i) Insufficient internet access.

(ii) EHR or CDSM vendor issues.

(iii) Extreme and uncontrollable circumstances.

(j) *Consulting.* (1) Except as specified in paragraphs (i) and (j)(2) of this section, ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system, and ordered on or after January 1, 2020.

(2) Ordering professionals may delegate the consultation with specified applicable AUC required under paragraph (j)(1) of this section to clinical staff acting under the direction of the ordering professional.

(k) *Reporting.* The following information must be reported on Medicare claims for advanced diagnostic imaging services furnished in an applicable setting, paid for under an applicable payment system defined in paragraph (b) of this section, and ordered on or after January 1, 2020:

* * * * *

■ 19. Section 414.502 is amended in the definition of ''Applicable laboratory'' by adding paragraph (2)(i), adding and reserving paragraph (2)(ii), and revising paragraph (3) introductory text to read as follows:

§ 414.502 Definitions.

* * * * *

Applicable laboratory * * *

(2) * * *

(i) For hospital outreach laboratories—bills Medicare Part B on the CMS 1450 under bill type 14x;

(ii) [Reserved]

(3) In a data collection period, receives more than 50 percent of its Medicare revenues, which includes fee-for-service payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period from one or a combination of the following sources:

* * * * *

■ 20. Section 414.610 is amended—
■ a. In paragraphs (c)(1)(ii) introductory text and (c)(5)(ii) by removing the date ''December 31, 2017'' and adding in its place the date ''December 31, 2022''; and
■ b. By revising paragraph (c)(8).

The revision reads as follows:

§ 414.610 Basis of payment.

* * * * *

(c) * * *

(8) *Transport of an individual with end-stage renal disease for renal dialysis services.* For ambulance services furnished during the period October 1, 2013 through September 30, 2018, consisting of non-emergency basic life support (BLS) services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B) of the Act) furnished other than on an emergency basis by a provider of services or a renal dialysis facility, the fee schedule amount otherwise applicable (both base rate and mileage) is reduced by 10 percent. For such services furnished on or after October 1, 2018, the fee schedule amount otherwise applicable (both base rate and mileage) is reduced by 23 percent.

* * * * *

§ 414.904 [Amended]

■ 21. Section 414.904 is amended in paragraph (e)(4) by removing the phrase

''acquisition cost or the applicable Medicare Part B drug payment'' and adding in its place the phrase ''acquisition cost or the Medicare Part B drug payment''.

■ 22. Section 414.1305 is amended by—

■ a. Revising the definition of ''Ambulatory Surgical Center (ASC)-based MIPS eligible clinician'';

■ b. Adding in alphabetical order definitions for ''Collection type'' and ''Health IT vendor'';

■ c. Revising the definitions of ''High priority measure'', ''Hospital-based MIPS eligible clinician'', and ''Low-volume threshold'';

■ d. Adding in alphabetical order a definition for ''MIPS determination period'';

■ e. Revising the definitions of ''MIPS eligible clinician'', ''Non-patient facing MIPS eligible clinician'', ''Qualified Clinical Data Registry (QCDR)'', ''Qualifying APM Participant (QP)'', and ''Small practice''; and

■ f. Adding in alphabetical order a definition for ''Submission type'', ''Submitter type'', and ''Third party intermediary''.

The revisions and additions read as follows:

§ 414.1305 Definitions.

* * * * *

Ambulatory Surgical Center (ASC)-based MIPS eligible clinician means:

(1) For the 2019 and 2020 MIPS payment years, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the Place of Service (POS) codes used in the HIPAA standard transaction as an ambulatory surgical center setting based on claims for a period prior to the performance period as specified by CMS; and

(2) Beginning with the 2021 MIPS payment year, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an ambulatory surgical center setting based on claims for the MIPS determination period.

* * * * *

Collection type means a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: electronic clinical quality measures (eCQMs); MIPS Clinical Quality Measures (MIPS CQMs), QCDR measures, Medicare Part B claims measures, CMS Web Interface measures, the CAHPS for MIPS survey, and administrative claims measures.

* * * * *

Health IT vendor means an entity that supports the health IT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician's CEHRT).

* * * * *

High priority measure means:

(1) For the 2019 and 2020 MIPS payment years, an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, or care coordination quality measure.

(2) Beginning with the 2021 MIPS payment year, an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure.

Hospital-based MIPS eligible clinician means:

(1) For the 2019 and 2020 MIPS payment years, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the Place of Service (POS) codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus-outpatient hospital, or emergency room setting based on claims for a period prior to the performance period as specified by CMS; and

(2) Beginning with the 2021 MIPS payment year, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period.

* * * * *

Low-volume threshold means:

(1) For the 2019 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the low-volume threshold determination period described in paragraph (4) of this definition, has Medicare Part B allowed charges less than or equal to $30,000 or provides care for 100 or fewer Medicare Part B-enrolled individuals.

(2) For the 2020 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the low-volume threshold determination period described in paragraph (4) of this definition, has allowed charges for covered professional services less than or equal to $90,000 or furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals.

(3) Beginning with the 2021 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the MIPS determination period, has allowed charges for covered professional services less than or equal to $90,000, furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare Part B-enrolled individuals.

(4) For the 2019 and 2020 MIPS payment years, the low-volume threshold determination period is a 24-month assessment period consisting of:

(i) An initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding to the performance period; and

(ii) A second 12-month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible clinician, group, or APM Entity group that is identified as not exceeding the low-volume threshold during the initial 12-month segment will continue to be excluded under § 414.1310(b)(1)(iii) for the applicable year regardless of the results of the second 12-month segment analysis. For the 2019 MIPS payment year, each segment of the low-volume threshold determination period includes a 60-day claims run out. For the 2020 MIPS payment year, each segment of the low-volume threshold determination period includes a 30-day claims run out.

* * * * *

MIPS determination period means:

(1) Beginning with the 2021 MIPS payment year, a 24-month assessment period consisting of:

(i) An initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period, and that includes a 30-day claims run out; and

(ii) A second 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs.

(2) Subject to § 414.1310(b)(1)(iii), an individual eligible clinician, group, or APM Entity group that is identified as not exceeding the low-volume threshold

or as having special status during the first segment of the MIPS determination period will be identified as such for the applicable MIPS payment year regardless of the results of the second segment of the MIPS determination period. An individual eligible clinician, group, or APM Entity group for which the unique billing TIN and NPI combination is established during the second segment of the MIPS determination period will be assessed based solely on the results of such segment.

MIPS eligible clinician as identified by a unique billing TIN and NPI combination used to assess performance, means any of the following (except as excluded under § 414.1310(b)):

(1) For the 2019 and 2020 MIPS payment years:

(i) A physician (as defined in section 1861(r) of the Act);

(ii) A physician assistant, a nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act);

(iii) A certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); and

(iv) A group that includes such clinicians.

(2) For the 2021 MIPS payment year and future years:

(i) A clinician described in paragraph (1) of this definition;

(ii) A physical therapist or occupational therapist;

(iii) A qualified speech-language pathologist;

(iv) A qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act);

(v) A clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act);

(vi) A registered dietician or nutrition professional; and

(vii) A group that includes such clinicians.

* * * * *

Non-patient facing MIPS eligible clinician means:

(1) For the 2019 and 2020 MIPS payment year, an individual MIPS eligible clinician who bills 100 or fewer patient facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act), as described in paragraph (3) of this definition, during the non-patient facing determination period described in paragraph (4) of this definition, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a non-patient facing individual MIPS eligible clinician.

(2) Beginning with the 2021 MIPS payment year, an individual MIPS eligible clinician who bills 100 or fewer patient facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act), as described in paragraph (3) of this definition, during the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a non-patient facing individual MIPS eligible clinician.

(3) For purposes of this definition, a patient-facing encounter is an instance in which the individual MIPS eligible clinician or group bills for items and services furnished such as general office visits, outpatient visits, and procedure codes under the PFS, as specified by CMS.

(4) For the 2019 and 2020 MIPS payment year, the non-patient facing determination period is a 24-month assessment period consisting of:

(i) An initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding the performance period; and

(ii) A second 12-month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible MIPS clinician, group, or virtual group that is identified as non-patient facing during the initial 12-month segment will continue to be considered non-patient facing for the applicable year regardless of the results of the second 12-month segment analysis. For the 2019 MIPS payment year, each segment of the non-patient facing determination period includes a 60-day claims run out. For the 2020 MIPS payment year and future years, each segment of the non-patient facing determination period includes a 30-day claims run out.

* * * * *

Qualified clinical data registry (QCDR) means:

(1) For the 2019, 2020 and 2021 MIPS payment year, a CMS-approved entity that has self-nominated and successfully completed a qualification process to determine whether the entity may collect medical or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

(2) Beginning with the 2022 MIPS payment year, an entity that demonstrates clinical expertise in medicine and quality measurement development experience and collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

* * * * *

Qualifying APM participant (QP) means an eligible clinician determined by CMS to have met or exceeded the relevant QP payment amount or QP patient count threshold under § 414.1430(a)(1), (a)(3), (b)(1), or (b)(3) for a year based on participation in an APM Entity that is also participating in an Advanced APM.

* * * * *

Small practice means:

(1) For the 2019 MIPS payment year, a TIN consisting of 15 or fewer eligible clinicians.

(2) For the 2020 MIPS payment year, a TIN consisting of 15 or fewer eligible clinicians during a 12-month assessment period that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding the performance period and includes a 30-day claims run out.

(3) Beginning with the 2021 MIPS payment year, a TIN consisting of 15 or fewer eligible clinicians during the MIPS determination period.

* * * * *

Submission type means the mechanism by which the submitter type submits data to CMS, including, but not limited to: Direct, log in and upload, log in and attest, Medicare Part B claims and the CMS Web Interface.

Submitter type means the MIPS eligible clinician, group, virtual group, or third party intermediary acting on behalf of a MIPS eligible clinician, group, or virtual group, as applicable, that submits data on measures and activities under MIPS.

Third party intermediary means an entity that has been approved under § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the quality, improvement activities, and promoting interoperability performance categories.

* * * * *

■ 23. Section 414.1310 is amended by revising paragraphs (a), (b)(1)(ii), (iii), (d), (e)(1) and (2) to read as follows:

§ 414.1310 Applicability.

(a) *Program implementation.* Except as specified in paragraph (b) of this section, MIPS applies to payments for

covered professional services furnished by MIPS eligible clinicians on or after January 1, 2019.

(b) * * *

(1) * * *

(ii) Is a Partial Qualifying APM Participant and does not elect to participate in MIPS as a MIPS eligible clinician; or

(iii) Does not exceed the low-volume threshold. Beginning with the 2021 MIPS payment year, if an individual eligible clinician, group, or APM Entity group in a MIPS APM exceeds at least one, but not all, of the low-volume threshold criteria and elects to participate in MIPS as a MIPS eligible clinician, the individual eligible clinician, group, or APM Entity group is treated as a MIPS eligible clinician for the applicable MIPS payment year. For such solo practitioners and groups that elect to participate in MIPS as a virtual group (except for APM Entity groups in MIPS APMs), the virtual group election under § 414.1315 constitutes an election under this paragraph and results in the solo practitioners and groups being treated as MIPS eligible clinicians for the applicable MIPS payment year. For such APM Entity groups in MIPS APMs, only the APM Entity group election can result in the APM Entity group being treated as MIPS eligible clinicians for the applicable MIPS payment year.

* * * * *

(d) *Clarification.* In no case will a MIPS payment adjustment factor (or additional MIPS payment adjustment factor) apply to payments for items and services furnished during a year by a eligible clinician, including an eligible clinician described in paragraph (b) or (c) of this section, who is not a MIPS eligible clinician, including an eligible clinician who voluntarily reports on applicable measures and activities under MIPS.

(e) * * *

(1) Except as provided under § 414.1370(f)(2), each MIPS eligible clinician in the group will receive a MIPS payment adjustment factor (or additional MIPS payment adjustment factor) based on the group's combined performance assessment.

(2) For individual MIPS eligible clinicians to participate in MIPS as a group, all of the following requirements must be met:

(i) Groups must meet the definition of a group at all times during the applicable performance period.

(ii) Individual eligible clinicians that elect to participate in MIPS as a group must aggregate their performance data across the group's TIN.

(iii) Individual eligible clinicians that elect to participate in MIPS as a group will have their performance assessed at the group level across all four MIPS performance categories.

(iv) Groups must adhere to an election process established by CMS, as applicable.

* * * * *

■ 24. Section 414.1315 is revised to read as follows:

§ 414.1315 Virtual groups.

(a) *Eligibility.* (1) For a MIPS payment year, a solo practitioner or a group of 10 or fewer eligible clinicians may elect to participate in MIPS as a virtual group with at least one other such solo practitioner or group. The election must be made prior to the start of the applicable performance period and cannot be changed during the performance period. A solo practitioner or group may elect to be in no more than one virtual group for a performance period, and, in the case of a group, the election applies to all MIPS eligible clinicians in the group.

(2) Except as provided under § 414.1370(f)(2), each MIPS eligible clinician in the virtual group receives a MIPS payment adjustment factor and, if applicable, an additional MIPS payment adjustment factor based on the virtual group's combined performance assessment.

(b) *Election deadline.* The election deadline is December 31 of the calendar year preceding the applicable performance period.

(c) *Election process.* For the 2020 MIPS payment year and future years, the virtual group election process is as follows:

(1) *Stage 1: Virtual group eligibility determination.* (i) For the 2020 MIPS payment year, the virtual group eligibility determination period is an assessment period of up to 5 months beginning on July 1 and ending as late as November 30 of the calendar year preceding the applicable performance period, and that includes a 30-day claims run out.

(ii) Beginning with the 2021 MIPS payment year, the virtual group eligibility determination period is the first segment of the MIPS determination period.

(2) *Stage 2: Virtual group formation.* (i) Solo practitioners and groups that elect to participate in MIPS as a virtual group must establish a formal written agreement that satisfies paragraph (c)(3) of this section prior to the election.

(ii) A designated virtual group representative must submit an election, on behalf of the solo practitioners and groups that compose a virtual group, to participate in MIPS as a virtual group for a performance period in a form and manner specified by CMS by the election deadline specified in paragraph (b) of this section. The virtual group election must include each TIN and NPI associated with the virtual group and contact information for the virtual group representative.

(iii) After an election is made, the virtual group representative must contact their designated CMS contact to update any election information that changed during a performance period at least one time prior to the start of data submission.

(3) *Virtual group agreement.* The virtual group arrangement must be set forth in a formal written agreement among the parties, consisting of each solo practitioner and group that composes a virtual group. The agreement must comply with the following requirements:

(i) Identifies each party by name, TIN, and each NPI under the TIN, and includes as parties only the solo practitioners and groups that compose the virtual group.

(ii) Is for a term of at least one performance period.

(iii) Requires each party to notify each NPI under the party's TIN regarding their participation in the MIPS as a virtual group.

(iv) Sets forth each NPI's rights and obligations in, and representation by, the virtual group, including, but not limited to, the reporting requirements and how participation in the MIPS as a virtual group affects the NPI's ability to participate in the MIPS outside of the virtual group.

(v) Describes how the opportunity to receive payment adjustments will encourage each member of the virtual group (and each NPI under each TIN in the virtual group) to adhere to quality assurance and improvement.

(vi) Requires each party to update its Medicare enrollment information, including the addition or removal of NPIs billing under its TIN, on a timely basis in accordance with Medicare program requirements and to notify the other parties of any such changes within 30 days of the change.

(vii) Requires completion of a close-out process upon termination or expiration of the agreement that requires each party to furnish all data necessary for the parties to aggregate their data across the virtual group's TINs.

(viii) Expressly requires each party to participate in the MIPS as a virtual group and comply with the requirements of the MIPS and all other applicable laws (including, but not limited to, Federal criminal law, the Federal False Claims Act, the Federal

anti-kickback statute, the Federal civil monetary penalties law, the Federal physician self-referral law, and the Health Insurance Portability and Accountability Act of 1996).

(ix) Is executed on behalf of each party by an individual who is authorized to bind the party.

(d) *Virtual group reporting requirements.* For solo practitioners and groups of 10 or fewer eligible clinicians to participate in MIPS as a virtual group, all of the following requirements must be met:

(1) Virtual groups must meet the definition of a virtual group at all times during the applicable performance period.

(2) Solo practitioners and groups of 10 or fewer eligible clinicians that elect to participate in MIPS as a virtual group must aggregate their performance data across the virtual group's TINs.

(3) Solo practitioners and groups of 10 or fewer eligible clinicians that elect to participate in MIPS as a virtual group will have their performance assessed at the virtual group level across all four MIPS performance categories.

(4) Virtual groups must adhere to the election process described in paragraph (c) of this section.

■ 25. Section 414.1320 is amended by revising paragraphs (b)(2) and (c)(2) and adding paragraphs (d) and (e) to read as follows:

§ 414.1320 MIPS performance period.

* * * * *

(b) * * *

(2) Promoting Interoperability and improvement activities performance categories is a minimum of a continuous 90-day period within CY 2018, up to and including the full CY 2018 (January 1, 2018 through December 31, 2018).

(c) * * *

(2) Promoting Interoperability and improvement activities performance categories is a minimum of a continuous 90-day period within CY 2019, up to and including the full CY 2019 (January 1, 2019 through December 31, 2019).

(d) Beginning with the 2022 MIPS payment year, the performance period for:

(1) The quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year.

(2) The improvement activities performance categories is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(e) For purposes of the 2022 MIPS payment year, the performance period for:

(1) The Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(2) [Reserved]

■ 26. Section 414.1325 is revised to read as follows:

§ 414.1325 Data submission requirements.

(a) *Applicable performance categories.* (1) Except as provided in paragraph (a)(2) of this section or under § 414.1370, as applicable, individual MIPS eligible clinicians and groups must submit data on measures and activities for the quality, improvement activities, and Promoting Interoperability performance categories in accordance with this section. Except for the Medicare Part B claims submission type, the data may also be submitted on behalf of the individual MIPS eligible clinician or group by a third party intermediary described at § 414.1400.

(2) There are no data submission requirements for:

(i) The cost performance category or administrative claims-based quality measures. Performance in the cost performance category and on such measures is calculated by CMS using administrative claims data, which includes claims submitted with dates of service during the applicable performance period that are processed no later than 60 days following the close of the applicable performance period.

(ii) The quality and cost performance categories, as applicable, for MIPS eligible clinicians and groups that are scored under the facility-based measurement scoring methodology described in § 414.1380(e).

(b) *Data submission types for individual MIPS eligible clinicians.* An individual MIPS eligible clinician may submit their MIPS data using:

(1) For the quality performance category, the direct, login and upload, and Medicare Part B claims (beginning with the 2021 MIPS payment year for small practices only) submission types.

(2) For the improvement activities or Promoting Interoperability performance categories, the direct, login and upload, or login and attest submission types.

(c) *Data submission types for groups.* Groups may submit their MIPS data using:

(1) For the quality performance category, the direct, login and upload, Medicare Part B claims (beginning with the 2021 MIPS payment year, for small practices only), and CMS Web Interface (for groups consisting of 25 or more eligible clinicians or a third party intermediary submitting on behalf of a group) submission types.

(2) For the improvement activities or Promoting Interoperability performance categories, the direct, login and upload, or login and attest submission types.

(d) *Use of multiple data submission types.* Beginning with the 2021 MIPS payment year, MIPS eligible clinicians, groups, and virtual groups may submit their MIPS data using multiple data submission types for any performance category described in paragraph (a)(1) of this section, as applicable; provided, however, that the MIPS eligible clinician, group, or virtual group uses the same identifier for all performance categories and all data submissions.

(e) *Data submission deadlines.* The data submission deadlines are as follows:

(1) For the direct, login and upload, login and attest, and CMS Web Interface submission types, March 31 following the close of the applicable performance period or a later date as specified by CMS.

(2) For the Medicare Part B claims submission type, data must be submitted on claims with dates of service during the applicable performance period that must be processed no later than 60 days following the close of the applicable performance period.

■ 27. Section 414.1330 is revised to read as follows:

§ 414.1330 Quality performance category.

(a) For a MIPS payment year, CMS uses the following quality measures, as applicable, to assess performance in the quality performance category:

(1) Measures included in the MIPS final list of quality measures established by CMS through rulemaking;

(2) QCDR measures approved by CMS under § 414.1400;

(3) Facility-based measures described in § 414.1380; and

(4) MIPS APM measures described in § 414.1370.

(b) Unless a different scoring weight is assigned by CMS, performance in the quality performance category comprises:

(1) 60 percent of a MIPS eligible clinician's final score for MIPS payment year 2019.

(2) 50 percent of a MIPS eligible clinician's final score for MIPS payment year 2020.

(3) 45 percent of a MIPS eligible clinician's final score for MIPS payment year 2021.

■ 28. Section 414.1335 is amended by revising paragraphs (a)(1) through (3) to read as follows:

§ 414.1335 Data submission criteria for the quality performance category.

(a) * * *

(1) *For Medicare Part B claims measures, MIPS CQMs, eCQMs, or QCDR measures.* (i) Except as provided in paragraph (a)(1)(ii) of this section, submit data on at least six measures, including at least one outcome measure. If an applicable outcome measure is not available, report one other high priority measure. If fewer than six measures apply to the MIPS eligible clinician or group, report on each measure that is applicable.

(ii) MIPS eligible clinicians and groups that report on a specialty or subspecialty measure set, as designated in the MIPS final list of quality measures established by CMS through rulemaking, must submit data on at least six measures within that set, including at least one outcome measure. If an applicable outcome measure is not available, report one other high priority measure. If the set contains fewer than six measures or if fewer than six measures within the set apply to the MIPS eligible clinician or group, report on each measure that is applicable.

(2) *For CMS Web Interface measures.* (i) Report on all measures included in the CMS Web Interface. The group is required to report on at least one measure for which there is Medicare patient data.

(ii) [Reserved]

(3) *For the CAHPS for MIPS survey.* (i) For the 12-month performance period, a group that wishes to voluntarily elect to participate in the CAHPS for MIPS survey must use a survey vendor that is approved by CMS for the applicable performance period to transmit survey measures data to CMS.

(ii) [Reserved]

* * * * *

■ 29. Section 414.1340 is amended by revising paragraphs (a) introductory text, (b) introductory text, and (c) to read as follows:

§ 414.1340 Data completeness criteria for the quality performance category.

(a) MIPS eligible clinicians and groups submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs must submit data on:

* * * * *

(b) MIPS eligible clinicians and groups submitting quality measure data on Medicare Part B claims measures must submit data on:

* * * * *

(c) Groups submitting quality measures data on CMS Web Interface measures or the CAHPS for MIPS survey must submit data on the sample of the Medicare Part B patients CMS provides, as applicable.

(1) *For CMS Web Interface measures.* (i) The group must report on the first 248 consecutively ranked beneficiaries in the sample for each measure or module. If the sample of eligible assigned beneficiaries is less than 248, then the group must report on 100 percent of assigned beneficiaries.

(ii) [Reserved]

(2) [Reserved]

■ 30. Section 414.1350 is revised to read as follows:

§ 414.1350 Cost performance category.

(a) *Specification of cost measures.* For purposes of assessing performance of MIPS eligible clinicians on the cost performance category, CMS specifies cost measures for a performance period.

(b) *Attribution.* (1) Cost measures are attributed at the TIN/NPI level.

(2) For the total per capita cost measure, beneficiaries are attributed using a method generally consistent with the method of assignment of beneficiaries under § 425.402 of this chapter.

(3) For the Medicare Spending per Beneficiary (MSPB) measure, an episode is attributed to the MIPS eligible clinician who submitted the plurality of claims (as measured by allowed charges) for Medicare Part B services rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the applicable performance period.

(4) For the acute condition episode-based measures specified for the 2017 performance period, an episode is attributed to each MIPS eligible clinician who bills at least 30 percent of inpatient evaluation and management (E&M) visits during the trigger event for the episode.

(5) For the procedural episode-based measures specified for the 2017 performance period, an episode is attributed to each MIPS eligible clinician who bills a Medicare Part B claim with a trigger code during the trigger event for the episode.

(6) For the acute inpatient medical condition episode-based measures specified beginning with the 2019 performance period, an episode is attributed to each MIPS eligible clinician who bills inpatient E&M claim lines during a trigger inpatient hospitalization under a TIN that renders at least 30 percent of the inpatient E&M claim lines in that hospitalization.

(7) For the procedural episode-based measures specified beginning with the 2019 performance period, an episode is attributed to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes.

(c) *Case minimums.* (1) For the total per capita cost measure, the case minimum is 20.

(2) For the Medicare spending per beneficiary measure, the case minimum is 35.

(3) For the episode-based measures specified for the 2017 performance period, the case minimum is 20.

(4) For the procedural episode-based measures specified beginning with the 2019 performance period, the case minimum is 10.

(5) For the acute inpatient medical condition episode-based measures specified beginning with the 2019 performance period, the case minimum is 20.

(d) *Scoring weight.* Unless a different scoring weight is assigned by CMS under section 1848(q)(5)(F) of the Act, performance in the cost performance category comprises:

(1) Zero percent of a MIPS eligible clinician's final score for MIPS payment year 2019.

(2) 10 percent of a MIPS eligible clinician's final score for MIPS payment year 2020.

(3) 15 percent of a MIPS eligible clinician's final score for MIPS payment year 2021.

■ 31. Section 414.1355 is amended by revising paragraphs (a), (b) introductory text, and (c) to read as follows:

§ 414.1355 Improvement activities performance category.

(a) For a MIPS payment year, CMS uses improvement activities included in the MIPS final inventory of improvement activities established by CMS through rulemaking to assess performance in the improvement activities performance category.

(b) Unless a different scoring weight is assigned by CMS under section 1848(q)(5)(F) of the Act, performance in the improvement activities performance category comprises:

* * * * *

(c) The following are the list of subcategories, of which, with the exception of Participation in an APM, include activities for selection by a MIPS eligible clinician or group:

(1) Expanded practice access, such as same day appointments for urgent needs and after-hours access to clinician advice.

(2) Population management, such as monitoring health conditions of

individuals to provide timely health care interventions or participation in a QCDR.

(3) Care coordination, such as timely communication of test results, timely exchange of clinical information to patients or other clinicians, and use of remote monitoring or telehealth.

(4) Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision making mechanisms.

(5) Patient safety and practice assessment, such as through the use of clinical or surgical checklists and practice assessments related to maintaining certification.

(6) Participation in an APM.

(7) Achieving health equity, such as for MIPS eligible clinicians that achieve high quality for underserved populations, including persons with behavioral health conditions, racial and ethnic minorities, sexual and gender minorities, people with disabilities, people living in rural areas, and people in geographic HPSAs.

(8) Emergency preparedness and response, such as measuring MIPS eligible clinician participation in the Medical Reserve Corps, measuring registration in the Emergency System for Advance Registration of Volunteer Health Professionals, measuring relevant reserve and active duty uniformed services MIPS eligible clinician activities, and measuring MIPS eligible clinician volunteer participation in domestic or international humanitarian medical relief work.

(9) Integrated behavioral and mental health, such as measuring or evaluating such practices as: Co-location of behavioral health and primary care services; shared/integrated behavioral health and primary care records; cross training of MIPS eligible clinicians, and integrating behavioral health with primary care to address substance use disorders or other behavioral health conditions, as well as integrating mental health with primary care.

■ 32. Section 414.1360 is amended by revising paragraph (a)(1) to read as follows:

§ 414.1360 Data submission criteria for the improvement activities performance category.

(a) * * *

(1) *Via direct, login and upload, and login and attest.* For the applicable performance period, submit a yes response for each improvement activity that is performed for at least a continuous 90-day period during the applicable performance period.

* * * * *

§ 414.1365 [Removed]

■ 33. Section 414.1365 is removed.

■ 34. Section 414.1370 is amended by revising paragraphs (b)(3), (f)(2), (g)(4), (h)(4) introductory heading, (h)(5)(i)(A) and (B), and (h)(5)(ii) introductory text.

The revisions read as follows:

§ 414.1370 APM scoring standard under MIPS.

* * * * *

(b) * * *

(3) The APM bases payment on quality measures and cost/utilization; and

* * * * *

(f) * * *

(2) MIPS eligible clinicians who participate in a group or have elected to participate in a virtual group and who are also on a MIPS APM Participation List will be included in the assessment under MIPS for purposes of producing a group or virtual group score and under the APM scoring standard for purposes of producing an APM Entity score. The MIPS payment adjustment for these eligible clinicians is based solely on their APM Entity score; if the APM Entity group is exempt from MIPS all eligible clinicians within that APM Entity group are also exempt from MIPS.

(g) * * *

(4) *Promoting Interoperability.* (i) For the 2019 and 2020 MIPS payment years, each Shared Savings Program ACO participant TIN must report data on the Promoting Interoperability performance category separately from the ACO, as specified in § 414.1375(b)(2). The ACO participant TIN scores are weighted according to the number of MIPS eligible clinicians in each TIN as a proportion of the total number of MIPS eligible clinicians in the APM Entity group, and then aggregated to determine an APM Entity score for the ACI performance category.

(ii) For the 2019 and 2020 MIPS payment years, for APM Entities in MIPS APMs other than the Shared Savings Program, CMS uses one score for each MIPS eligible clinician in the APM Entity group to derive a single average APM Entity score for the Promoting Interoperability performance category. Beginning with the 2021 MIPS payment year, for APM Entities in MIPS APMs including the Shared Savings Program, CMS uses one score for each MIPS eligible clinician in the APM Entity group to derive a single average APM Entity score for the Promoting Interoperability performance category. The score for each MIPS eligible clinician is the higher of either:

(A) A group score based on the measure data for the Promoting Interoperability performance category reported by a TIN for the MIPS eligible clinician according to MIPS submission and reporting requirements for groups; or

(B) An individual score based on the measure data for the Promoting Interoperability performance category reported by the MIPS eligible clinician according to MIPS submission and reporting requirements for individuals.

(iii) In the event that a MIPS eligible clinician participating in a MIPS APM receives an exception from the Promoting Interoperability performance category reporting requirements, such eligible clinician will be assigned a null score when CMS calculates the APM Entity's Promoting Interoperability performance category score under the APM scoring standard.

(A) If all MIPS eligible clinicians in an APM Entity have been excepted from reporting the Promoting Interoperability performance category, the performance category weight will be reweighted to zero for the APM Entity for that MIPS performance period.

(B) [Reserved]

(h) * * *

(4) *Promoting Interoperability.* * * *

(5) * * *

(i) * * *

(A) In 2017, the improvement activities performance category is reweighted to 25 percent and the Promoting Interoperability performance category is reweighted to 75 percent; and

(B) Beginning in 2018, the Promoting Interoperability performance category is reweighted to 75 percent and the improvement activities performance category is reweighted to 25 percent.

(ii) If CMS reweights the Promoting Interoperability performance category to zero percent:

* * * * *

■ 35. Section 414.1375 is amended by revising the section heading, paragraphs (a), (b) introductory text, and (b)(2) to read as follows:

§ 414.1375 Promoting Interoperability (PI) performance category.

(a) *Final score.* Unless a different scoring weight is assigned by CMS under sections 1848(o)(2)(D), 1848(q)(5)(E)(ii), or 1848(q)(5)(F) of the Act, performance in the Promoting Interoperability performance category comprises 25 percent of a MIPS eligible clinician's final score for each MIPS payment year.

(b) *Reporting for the Promoting Interoperability performance category.* To earn a performance category score for the Promoting Interoperability performance category for inclusion in the final score, a MIPS eligible clinician must:

* * * * *

(2) *Report MIPS—Promoting Interoperability objectives and measures.* Report on the objectives and associated measures as specified by CMS for the Promoting Interoperability performance category for the performance period as follows:

(i) For the 2019 and 2020 MIPS payment years: For each base score measure, as applicable, report the numerator (of at least one) and denominator, or yes/no statement, or claim an exclusion for each measure that includes an option for an exclusion; and

(ii) For the 2021 and 2022 MIPS payment years:

(A) Report that the MIPS eligible clinician completed the actions included in the Security Risk Analysis measure during the year in which the performance period occurs; and

(B) For each required measure, as applicable, report the numerator (of at least one) and denominator, or yes/no statement, or an exclusion for each measure that includes an option for an exclusion.

* * * * *

■ 36. Section 414.1380 is revised to read as follows:

§ 414.1380 Scoring.

(a) *General.* MIPS eligible clinicians are scored under MIPS based on their performance on measures and activities in four performance categories. MIPS eligible clinicians are scored against performance standards for each performance category and receive a final score, composed of their performance category scores, and calculated according to the final score methodology.

(1) *Performance standards.* (i) For the quality performance category, measures are scored between zero and 10 measure achievement points. Performance is measured against benchmarks. Measure bonus points are available for submitting high-priority measures, submitting measures using end-to-end electronic reporting, and in small practices that submit data on at least 1 quality measure. Beginning with the 2020 MIPS payment year, improvement scoring is available in the quality performance category.

(ii) For the cost performance category, measures are scored between 1 and 10 points. Performance is measured against a benchmark. Starting with the 2024 MIPS payment year, improvement scoring is available in the cost performance category.

(iii) For the improvement activities performance category, each improvement activity is assigned a certain number of points. The points for all submitted activities are summed and scored against a total potential performance category score of 40 points.

(iv) For the Promoting Interoperability performance category, each measure is scored against a maximum number of points. The points for all submitted measures are summed and scored against a total potential performance category score of 100 points.

(2) [Reserved]

(b) *Performance categories.* MIPS eligible clinicians are scored under MIPS in four performance categories.

(1) *Quality performance category.* (i) *Measure achievement points.* For the 2019, 2020, and 2021 MIPS payment years, MIPS eligible clinicians receive between 3 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340. The number of measure achievement points received for each such measure is determined based on the applicable benchmark decile category and the percentile distribution. MIPS eligible clinicians receive zero measure achievement points for each measure required under § 414.1335 on which no data is submitted in accordance with § 414.1325. MIPS eligible clinicians that submit data in accordance with § 414.1325 on a greater number of measures than required under § 414.1335 are scored only on the required measures with the greatest number of measure achievement points. Beginning with the 2021 MIPS payment year, MIPS eligible clinicians that submit data in accordance with § 414.1325 on a single measure via multiple collection types are scored only on the data submission with the greatest number of measure achievement points.

(A) *Lack of benchmark or case minimum.* (*1*) Except as provided in paragraph (b)(1)(i)(A)(*2*) of this section, for the 2019, 2020, and 2021 MIPS payment years, MIPS eligible clinicians receive 3 measure achievement points for each submitted measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement.

(*2*) The following measures are excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points:

(*i*) Each submitted CMS Web Interface-based measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement, or is redesignated as pay-for-reporting for all Shared Savings Program accountable care organizations by the Shared Savings Program; and

(*ii*) Each administrative claims-based measure that does not have a benchmark or meet the case minimum requirement.

(B) *Lack of complete data.* (*1*) Except as provided in paragraph (b)(1)(i)(B)(*2*) of this section, for each submitted measure that does not meet the data completeness requirement:

(*i*) For the 2019 MIPS payment year, MIPS eligible clinicians receive 3 measure achievement points;

(*ii*) For the 2020 and 2021 MIPS payment years, MIPS eligible clinicians other than small practices receive 1 measure achievement point, and small practices receive 3 measure achievement points; and

(*iii*) Beginning with the 2022 MIPS payment year, MIPS eligible clinicians other than small practices receive zero measure achievement points, and small practices receive 3 measure achievement points.

(*2*) MIPS eligible clinicians receive zero measure achievement points for each submitted CMS Web Interface-based measure that does not meet the data completeness requirement.

(ii) *Benchmarks.* Benchmarks will be based on collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

(A) Each benchmark must have a minimum of 20 individual clinicians or groups who reported the measure meeting the case minimum requirement at paragraph (b)(1)(iii) of this section and the data completeness requirement at § 414.1340 and having a performance rate that is greater than zero.

(B) CMS Web Interface collection type uses benchmarks from the corresponding reporting year of the Shared Savings Program.

(iii) *Minimum case requirements.* Except for the all-cause hospital readmission measure, the minimum case requirement is 20 cases. For the all-cause hospital readmission measure, the minimum case requirement is 200 cases.

(iv) *Topped out measures.* CMS will identify topped out measures in the benchmarks published for each Quality Payment Program year.

(A) For the 2020 MIPS payment year, each topped out measure specified by CMS through rulemaking receives no more than 7 measure achievement points, provided that the benchmark for the applicable collection type is identified as topped out in the benchmarks published for the 2018 MIPS performance period.

(B) Beginning with the 2021 MIPS payment year, each measure (except for measures in the CMS Web Interface) for which the benchmark for the applicable collection type is identified as topped out for 2 or more consecutive years receives no more than 7 measure achievement points in the second consecutive year it is identified as topped out, and beyond.

(v) *Measure bonus points.* MIPS eligible clinicians receive measure bonus points for the following measures, except as otherwise required under § 414.1335, regardless of whether the measure is included in the MIPS eligible clinician's total measure achievement points.

(A) *High priority measures.* Subject to paragraph (b)(1)(v)(A)(*1*) of this section, MIPS eligible clinicians receive 2 measure bonus points for each outcome and patient experience measure and 1 measure bonus point for each other high priority measure. Beginning with the 2021 MIPS payment year, MIPS eligible clinicians do not receive such measure bonus points for CMS Web Interface measures.

(*1*) *Limitations.* (*i*) Each high priority measure must have a benchmark at paragraph (b)(1)(ii) of this section, meet the case minimum requirement at (b)(1)(iii) of this section, meet the data completeness requirement at § 414.1340, and have a performance rate that is greater than zero.

(*ii*) For the 2019, 2020, and 2021 MIPS payment years, the total measure bonus points for high priority measures cannot exceed 10 percent of the total available measure achievement points.

(*iii*) Beginning with the 2021 MIPS payment year, MIPS eligible clinicians that collect data in accordance with § 414.1325 on a single measure via multiple collection types receive measure bonus points only once.

(B) *End-to-end electronic reporting.* Subject to paragraph (b)(1)(v)(B)(*1*) of this section, MIPS eligible clinicians receive 1 measure bonus point for each measure (except claims-based measures) submitted with end-to-end electronic reporting for a quality measure under certain criteria determined by the Secretary.

(*1*) *Limitations.* (*i*) For the 2019, 2020, and 2021 MIPS payment years, the total measure bonus points for measures submitted with end-to-end electronic reporting cannot exceed 10 percent of the total available measure achievement points.

(*ii*) Beginning with the 2021 MIPS payment year, MIPS eligible clinicians that collect data in accordance with § 414.1325 on a single measure via multiple collection types receive measure bonus points only once.

(C) *Small practices.* Beginning with the 2021 MIPS payment year, MIPS eligible clinicians in small practices receive 6 measure bonus points if they submit data to MIPS on at least 1 quality measure.

(vi) *Improvement scoring.* Improvement scoring is available to MIPS eligible clinicians that demonstrate improvement in performance in the current MIPS performance period compared to performance in the performance period immediately prior to the current MIPS performance period based on measure achievement points.

(A) Improvement scoring is available when the data sufficiency standard is met, which means when data are available and a MIPS eligible clinician has a quality performance category achievement percent score for the previous performance period and the current performance period.

(*1*) Data must be comparable to meet the requirement of data sufficiency which means that the quality performance category achievement percent score is available for the current performance period and the previous performance period and quality performance category achievement percent scores can be compared.

(*2*) Quality performance category achievement percent scores are comparable when submissions are received from the same identifier for two consecutive performance periods.

(*3*) If the identifier is not the same for 2 consecutive performance periods, then for individual submissions, the comparable quality performance category achievement percent score is the highest available quality performance category achievement percent score associated with the final score from the prior performance period that will be used for payment for the individual. For group, virtual group, and APM Entity submissions, the comparable quality performance category achievement percent score is the average of the quality performance category achievement percent score associated with the final score from the prior performance period that will be used for payment for each of the individuals in the group.

(*4*) Improvement scoring is not available for clinicians who were scored under facility-based measurement in the performance period immediately prior to the current MIPS performance period.

(B) The improvement percent score may not total more than 10 percentage points.

(C) The improvement percent score is assessed at the performance category level for the quality performance category and included in the calculation of the quality performance category percent score as described in paragraph (b)(1)(vii) of this section.

(*1*) The improvement percent score is awarded based on the rate of increase in the quality performance category achievement percent score of MIPS eligible clinicians from the previous performance period to the current performance period.

(*2*) An improvement percent score is calculated by dividing the increase in the quality performance category achievement percent score from the prior performance period to the current performance period by the prior performance period quality performance category achievement percent score multiplied by 10 percent.

(*3*) An improvement percent score cannot be lower than zero percentage points.

(*4*) For the 2020 and 2021 MIPS payment year, we will assume a quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year.

(*5*) The improvement percent score is zero if the MIPS eligible clinician did not fully participate in the quality performance category for the current performance period.

(D) For the purpose of improvement scoring methodology, the term ''quality performance category achievement percent score'' means the total measure achievement points divided by the total available measure achievement points, without consideration of measure bonus points or improvement percent score.

(E) For the purpose of improvement scoring methodology, the term ''improvement percent score'' means the score that represents improvement for the purposes of calculating the quality performance category percent score as described in paragraph (b)(1)(vii) of this section.

(F) For the purpose of improvement scoring methodology, the term ''fully participate'' means the MIPS eligible

clinician met all requirements in §§ 414.1335 and 414.1340.

(vii) *Quality performance category score.* A MIPS eligible clinician's quality performance category percent score is the sum of all the measure achievement points assigned for the measures required for the quality performance category criteria plus the measure bonus points in paragraph (b)(1)(v) of this section. The sum is divided by the sum of total available measure achievement points. The improvement percent score in paragraph (b)(1)(vi) of this section is added to that result. The quality performance category percent score cannot exceed 100 percentage points.

(A) Beginning with the 2021 MIPS payment year, for each measure that a MIPS eligible clinician submits that is significantly impacted by clinical guideline changes or other changes that CMS believes may result in patient harm or misleading results, the total available measure achievement points are reduced by 10 points.

(B) Beginning with the 2021 MIPS payment year, for groups that submit 5 or fewer measures and register for the CAHPS for MIPS survey but do not meet the minimum beneficiary sampling requirements, the total available measure achievement points are reduced by 10 points.

(viii) *ICD–10 updates.* Beginning with the 2018 MIPS performance period, measures significantly impacted by ICD–10 updates, as determined by CMS, will be assessed based only on the first 9 months of the 12-month performance period. For purposes of this paragraph (b)(1)(viii), CMS will make a determination as to whether a measure is significantly impacted by ICD–10 coding changes during the performance period. CMS will publish on the CMS website which measures require a 9-month assessment process by October 1st of the performance period if technically feasible, but by no later than the beginning of the data submission period at § 414.1325(f)(1).

(2) *Cost performance category.* For each cost measure attributed to a MIPS eligible clinician, the clinician receives one to ten achievement points based on the clinician's performance on the measure during the performance period compared to the measure's benchmark. Achievement points are awarded based on which benchmark decile range the MIPS eligible clinician's performance on the measure is between. CMS assigns partial points based on the percentile distribution.

(i) Cost measure benchmarks are determined by CMS based on cost measure performance during the performance period. At least 20 MIPS eligible clinicians or groups must meet the minimum case volume specified under § 414.1350(c) for a cost measure in order for a benchmark to be determined for the measure. If a benchmark is not determined for a cost measure, the measure will not be scored.

(ii) A MIPS eligible clinician must meet the minimum case volume specified under § 414.1350(c) to be scored on a cost measure.

(iii) The cost performance category percent score is the sum of the following, not to exceed 100 percent:

(A) The total number of achievement points earned by the MIPS eligible clinician divided by the total number of available achievement points; and

(B) The cost improvement score, as determined under paragraph (b)(2)(iv) of this section.

(iv) The cost improvement score is determined for a MIPS eligible clinician that demonstrates improvement in performance in the current MIPS performance period compared to their performance in the immediately preceding MIPS performance period.

(A) The cost improvement score is determined at the measure level for the cost performance category.

(B) The cost improvement score is calculated only when data sufficient to measure improvement is available. Sufficient data is available when a MIPS eligible clinician or group participates in MIPS using the same identifier in 2 consecutive performance periods and is scored on the same cost measure(s) for 2 consecutive performance periods. If the cost improvement score cannot be calculated because sufficient data is not available, then the cost improvement score is zero.

(C) The cost improvement score is determined by comparing the number of measures with a statistically significant change (improvement or decline) in performance; a change is determined to be significant based on application of a t-test. The number of cost measures with a significant decline is subtracted from the number of cost measures with a significant improvement, with the result divided by the number of cost measures for which the MIPS eligible clinician or group was scored for 2 consecutive performance periods. The resulting fraction is then multiplied by the maximum cost improvement score.

(D) The cost improvement score cannot be lower than zero percentage points.

(E) The maximum cost improvement score for the 2020, 2021, 2022, and 2023 MIPS payment years is zero percentage points.

(v) A cost performance category percent score is not calculated if a MIPS eligible clinician or group is not attributed any cost measures for the performance period because the clinician or group has not met the minimum case volume specified by CMS for any of the cost measures or a benchmark has not been created for any of the cost measures that would otherwise be attributed to the clinician or group.

(3) *Improvement activities performance category.* Subject to paragraphs (b)(3)(i) and (ii) of this section, the improvement activities performance category score equals the total points for all submitted improvement activities divided by 40 points, multiplied by 100 percent. MIPS eligible clinicians (except for non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs) receive 10 points for each medium-weighted improvement activity and 20 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325. Non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325.

(i) For MIPS eligible clinicians participating in APMs, the improvement activities performance category score is at least 50 percent.

(ii) For MIPS eligible clinicians in a practice that is certified or recognized as a patient-centered medical home or comparable specialty practice, as determined by the Secretary, the improvement activities performance category score is 100 percent. For the 2019 MIPS payment year, at least one practice site within a group's TIN must be certified or recognized as a patient-centered medical home or comparable specialty practice. For the 2020 MIPS payment year and future years, at least 50 percent of the practice sites within a group's TIN must be recognized as a patient-centered medical home or comparable specialty practice. MIPS eligible clinicians that wish to claim this status for purposes of receiving full credit in the improvement activities performance category must attest to their status as a patient-centered medical home or comparable specialty practice in order to receive this credit. A practice is certified or recognized as

a patient-centered medical home if it meets any of the following criteria:

(A) The practice has received accreditation from one of four accreditation organizations that are nationally recognized;

(*1*) The Accreditation Association for Ambulatory Health Care;

(*2*) The National Committee for Quality Assurance (NCQA);

(*3*) The Joint Commission; or

(*4*) The Utilization Review Accreditation Commission (URAC).

(B) The practice is participating in a Medicaid Medical Home Model or Medical Home Model.

(C) The practice is a comparable specialty practice that has received the NCQA Patient-Centered Specialty Recognition.

(D) The practice has received accreditation from other certifying bodies that have certified a large number of medical organizations and meet national guidelines, as determined by the Secretary. The Secretary must determine that these certifying bodies must have 500 or more certified member practices, and require practices to include the following:

(*1*) Have a personal physician/clinician in a team-based practice.

(*2*) Have a whole-person orientation.

(*3*) Provide coordination or integrated care.

(*4*) Focus on quality and safety.

(*5*) Provide enhanced access.

(4) *Promoting Interoperability performance category.* (i) For the 2019 and 2020 MIPS payment years, a MIPS eligible clinician's Promoting Interoperability performance category score equals the sum of the base score, performance score, and any applicable bonus scores, not to exceed 100 percentage points. A MIPS eligible clinician cannot earn a performance score or bonus score unless they have earned a base score.

(A) A MIPS eligible clinician earns a base score by reporting for each base score measure, as applicable: The numerator (of at least one) and denominator, or a yes/no statement, or an exclusion.

(B) A MIPS eligible clinician earns a performance score by reporting on the performance score measures specified by CMS. A MIPS eligible clinician may earn up to 10 or 20 percentage points as specified by CMS for each performance score measure reported.

(C) A MIPS eligible clinician may earn the following bonus scores:

(*1*) A bonus score of 5 percentage points for reporting to one or more additional public health agencies or clinical data registries.

(*2*) A bonus score of 10 percentage points for attesting to completing one or more improvement activities specified by CMS using CEHRT.

(*3*) For the 2020 MIPS payment year, a bonus score of 10 percentage points for submitting data for the measures for the base score and the performance score generated solely from CEHRT as defined in § 414.1305 for 2019 and subsequent years.

(ii) For the 2021 and 2022 MIPS payment years, a MIPS eligible clinician's Promoting Interoperability performance category score equals the sum of the scores for each of the six required measures and any applicable bonus scores, not to exceed 100 points.

(A) A MIPS eligible clinician earns a score for each measure by reporting, as applicable: the numerator (of at least one) and denominator, or a yes/no statement. If an exclusion is reported for a measure, the points available for that measure are redistributed to another measure(s).

(B) Each required measure is worth 10, 20, or 40 points, as specified by CMS.

(C) Each optional measure is worth five bonus points.

(c) *Final score calculation.* Each MIPS eligible clinician receives a final score of 0 to 100 points for a performance period for a MIPS payment year calculated as follows. If a MIPS eligible clinician is scored on fewer than 2 performance categories, he or she receives a final score equal to the performance threshold.

For the 2019 MIPS payment year:

Final score = [(quality performance category percent score × quality performance category weight) + (cost performance category percent score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)], not to exceed 100 points.

For the 2020 MIPS payment year:

Final score = [(quality performance category percent score × quality performance category weight) + (cost performance category percent score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)] × 100 + [the complex patient bonus + the small practice bonus], not to exceed 100 points.

Beginning with the 2021 MIPS payment year:

Final score = [(quality performance category percent score × quality performance category weight) + (cost performance category percent score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)] × 100 + the complex patient bonus, not to exceed 100 points.

(1) *Performance category weights.* The weights of the performance categories in the final score are as follows, unless a different scoring weight is assigned under paragraph (c)(2) of this section:

(i) Quality performance category weight is defined under § 414.1330(b).

(ii) Cost performance category weight is defined under § 414.1350(d).

(iii) Improvement activities performance category weight is defined under § 414.1355(b).

(iv) Promoting Interoperability performance category weight is defined under § 414.1375(a).

(2) *Reweighting the performance categories.* (i) In accordance with paragraph (c)(2)(ii) of this section, a scoring weight different from the weights specified in paragraph (c)(1) of this section will be assigned to a performance category, and its weight as specified in paragraph (c)(1) of this section will be redistributed to another performance category or categories, in the following circumstances:

(A) CMS determines based on the following circumstances that there are not sufficient measures and activities applicable and available under section 1848(q)(5)(F) of the Act.

(*1*) For the quality performance category, CMS cannot calculate a score for the MIPS eligible clinician because there is not at least one quality measure applicable and available to the clinician.

(*2*) For the cost performance category, CMS cannot reliably calculate a score for the cost measures that adequately captures and reflects the performance of the MIPS eligible clinician.

(*3*) Beginning with the 2021 MIPS payment year, for the quality, cost, improvement activities, and Promoting

Interoperability performance categories, the MIPS eligible clinician joins an existing practice during the final 3 months of the performance period year that is not participating in MIPS as a group or joins a practice that is newly formed during the final 3 months of the performance period year.

(*4*) For the Promoting Interoperability performance category beginning with the 2021 MIPS payment year, the MIPS eligible clinician is a physical therapist, occupational therapist, clinical psychologist, qualified audiologist, qualified speech-language pathologist, or a registered dietitian or nutrition professional. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*5*) For the Promoting Interoperability performance category for the 2019, 2020, and 2021 MIPS payment years, the MIPS eligible clinician is a nurse practitioner, physician assistant, clinical nurse specialist, or certified registered nurse anesthetist. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*6*) Beginning with the 2020 MIPS payment year, for the quality, cost, and improvement activities performance categories, the MIPS eligible clinician demonstrates through an application submitted to CMS that they were subject to extreme and uncontrollable circumstances that prevented the clinician from collecting information that the clinician would submit for a performance category or submitting information that would be used to score a performance category for an extended period of time. Beginning with the 2021 MIPS payment year, in the event that a MIPS eligible clinician submits data for the quality, cost, or improvement activities performance categories, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*7*) For the 2019 MIPS payment year, for the quality and improvement activities performance categories, the MIPS eligible clinician was located in an area affected by extreme and uncontrollable circumstances as identified by CMS. In the event that a MIPS eligible clinician submits data for a performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*8*) Beginning with the 2020 MIPS payment year, for the quality, cost, and improvement activities performance categories, the MIPS eligible clinician was located in an area affected by extreme and uncontrollable circumstances as identified by CMS. In the event that a MIPS eligible clinician submits data for the quality or improvement activities performance categories, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(B) Under section 1848(q)(5)(E)(ii) of the Act, CMS estimates that the proportion of MIPS eligible clinicians who are physicians as defined in section 1861(r) of the Act and earn a Promoting Interoperability performance category score of at least 75 percent is 75 percent or greater. The estimation is based on data from the performance period that occurs four years before the MIPS payment year and does not include physicians for whom the Promoting Interoperability performance category is weighted at zero percent.

(C) Under section 1848(o)(2)(D) of the Act, a significant hardship exception or other type of exception is granted to a MIPS eligible clinician based on the following circumstances for the Promoting Interoperability performance category. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*1*) The MIPS eligible clinician demonstrates through an application submitted to CMS that they lacked sufficient internet access during the performance period, and insurmountable barriers prevented the clinician from obtaining sufficient internet access.

(*2*) The MIPS eligible clinician demonstrates through an application submitted to CMS that they were subject to extreme and uncontrollable circumstances that caused their CEHRT to be unavailable.

(*3*) The MIPS eligible clinician was located in an area affected by extreme and uncontrollable circumstances as identified by CMS.

(*4*) The MIPS eligible clinician demonstrates through an application submitted to CMS that 50 percent or more of their outpatient encounters occurred in practice locations where they had no control over the availability of CEHRT.

(*5*) The MIPS eligible clinician is a non-patient facing MIPS eligible clinician as defined in § 414.1305.

(*6*) The MIPS eligible clinician is a hospital-based MIPS eligible clinician as defined in § 414.1305.

(*7*) The MIPS eligible clinician is an ASC-based MIPS eligible clinician as defined in § 414.1305.

(*8*) Beginning with the 2020 MIPS payment year, the MIPS eligible clinician demonstrates through an application submitted to CMS that their CEHRT was decertified either during the performance period for the MIPS payment year or during the calendar year preceding the performance period for the MIPS payment year, and the MIPS eligible clinician made a good faith effort to adopt and implement another CEHRT in advance of the performance period. In no case may a MIPS eligible clinician be granted this exception for more than 5 years.

(*9*) Beginning with the 2020 MIPS payment year, the MIPS eligible clinician demonstrates through an application submitted to CMS that they are in a small practice as defined in § 414.1305, and overwhelming barriers prevent them from complying with the requirements for the Promoting Interoperability performance category.

(ii) A scoring weight different from the weights specified in paragraph (c)(1) of this section will be assigned to a performance category, and its weight as specified in paragraph (c)(1) of this section will be redistributed to another performance category or categories, as follows:

(A) For the 2019 MIPS payment year:

Performance category (%)	Weighting for the 2019 MIPS payment year (%)	Reweight scenario if no promoting interoperability performance category score (%)	Reweight scenario if no quality performance category percent score (%)	Reweight scenario if no improvement activities performance category score (%)
Quality	60	85	0	75
Cost	0	0	0	0
Improvement Activities	15	15	50	0

Performance category (%)	Weighting for the 2019 MIPS payment year (%)	Reweight scenario if no promoting interoperability performance category score (%)	Reweight scenario if no quality performance category percent score (%)	Reweight scenario if no improvement activities performance category score (%)
Promoting Interoperability	25	0	50	25

(B) For the 2020 MIPS payment year:

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Reweighting Needed:				
—Scores for all four performance categories	50	10	15	25
Reweight One Performance Category:				
—No Cost	60	0	15	25
—No Promoting Interoperability	75	10	15	0
—No Quality	0	10	45	45
—No Improvement Activities	65	10	0	25
Reweight Two Performance Categories:				
—No Cost and no Promoting Interoperability	85	0	15	0
—No Cost and no Quality	0	0	50	50
—No Cost and no Improvement Activities	75	0	0	25
—No Promoting Interoperability and no Quality	0	10	90	0
—No Promoting Interoperability and no Improvement Activities	90	10	0	0
—No Quality and no Improvement Activities	0	10	0	90

(C) For the 2021 MIPS payment year:

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Reweighting Needed:				
—Scores for all four performance categories	45	15	15	25
Reweight One Performance Category:				
—No Cost	60	0	15	25
—No Promoting Interoperability	70	15	15	0
—No Quality	0	15	40	45
—No Improvement Activities	60	15	0	25
Reweight Two Performance Categories:				
—No Cost and no Promoting Interoperability	85	0	15	0
—No Cost and no Quality	0	0	50	50
—No Cost and no Improvement Activities	75	0	0	25
—No Promoting Interoperability and no Quality	0	15	85	0
—No Promoting Interoperability and no Improvement Activities	85	15	0	0
—No Quality and no Improvement Activities	0	15	0	85

(iii) For MIPS eligible clinicians submitting data as a group or virtual group, in order for the Promoting Interoperability performance category to be reweighted in accordance with paragraph (c)(2)(ii) of this section, all of the MIPS eligible clinicians in the group must qualify for reweighting based on the circumstances described in paragraph (c)(2)(i) of this section.

(3) *Complex patient bonus.* For the 2020 and 2021 MIPS payment years, provided that a MIPS eligible clinician, group, virtual group or APM entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, as follows:

(i) For MIPS eligible clinicians and groups, the complex patient bonus is calculated as follows: [The average HCC risk score assigned to beneficiaries (pursuant to the HCC risk adjustment model established by CMS pursuant to section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by clinicians in a group] + [the dual eligible ratio × 5].

(ii) For APM entities and virtual groups, the complex patient bonus is calculated as follows: [The beneficiary weighted average HCC risk score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM entity or virtual group, respectively] + [the average dual eligible ratio for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM entity or virtual group, respectively, × 5].

(iii) The complex patient bonus cannot exceed 5.0.

(4) *Small practice bonus.* A small practice bonus of 5 points will be added to the final score for the 2020 MIPS payment year for MIPS eligible clinicians, groups, virtual groups, and APM Entities that meet the definition of a small practice as defined at § 414.1305 and participate in MIPS by submitting

data on at least one performance category in the 2018 MIPS performance period.

(d) *Scoring for APM Entities.* MIPS eligible clinicians in APM Entities that are subject to the APM scoring standard are scored using the methodology under § 414.1370.

(e) *Scoring for facility-based measurement.* For the payment in 2021 MIPS payment year and subsequent years and subject to paragraph (e)(6)(vi) of this section, a MIPS eligible clinician or group will be scored under the quality and cost performance categories using the methodology described in this paragraph (e).

(1) *General.* The facility-based measurement scoring standard is the MIPS scoring methodology applicable for MIPS eligible clinicians identified as meeting the requirements in paragraph (e)(2) of this section.

(i) The measures used for facility-based measurement are the measure set finalized for the fiscal year value-based purchasing program for which payment begins during the applicable MIPS performance period.

(ii) Beginning with the 2021 MIPS payment year, the scoring methodology applicable for MIPS eligible clinicians scored with facility-based measurement is the Total Performance Score methodology adopted for the Hospital VBP Program, for the fiscal year for which payment begins during the applicable MIPS performance period.

(2) *Eligibility for facility-based measurement.* MIPS eligible clinicians are eligible for facility-based measurement for a MIPS payment year if they are determined to be facility-based as an individual clinician or as part of a group, as follows:

(i) *Facility-based individual determination.* A MIPS eligible clinician is facility-based if the clinician meets all of the following criteria:

(A) Furnishes 75 percent or more of his or her covered professional services in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, or emergency room setting based on claims for a 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the performance period with a 30-day claims run out.

(B) Furnishes at least 1 covered professional service in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, or emergency room setting.

(C) Can be attributed, under the methodology specified in paragraph (e)(5) of this section, to a facility with a value-based purchasing score for the applicable period.

(ii) *Facility-based group determination.* A facility-based group is a group in which 75 percent or more of its eligible clinician NPIs billing under the group's TIN meet the requirements under paragraph (e)(2)(i) of this section.

(3) [Reserved]

(4) *Data submission for facility-based measurement.* There are no data submission requirements for individual clinicians to be scored under facility-based measurement. A group must submit data in the improvement activities or Promoting Interoperability performance categories in order to be scored as a facility-based group.

(5) *Determination of applicable facility score.* (i) A facility-based clinician is scored with facility-based measurement using the score derived from the value-based purchasing score for the facility at which the clinician provided services to the most Medicare beneficiaries during the period the claims are drawn from in paragraph (e)(2) of this section. If there is an equal number of Medicare beneficiaries treated at more than one facility, the value-based purchasing score for the highest scoring facility is used.

(ii) A facility-based group is scored with facility-based measurement using the score derived from the value-based purchasing score for the facility at which the plurality of clinicians identified as facility-based would have had their score determined under paragraph (e)(5)(i) of this section.

(6) *MIPS performance category scoring under the facility-based measurement scoring standard*—(i) *Measures.* The quality and cost measures are those adopted under the value-based purchasing program of the facility for the year described in paragraph (e)(1)(i) of this section.

(ii) *Benchmarks.* The benchmarks are those adopted under the value-based purchasing program of the facility program for the year described in paragraph (e)(1) of this section.

(iii) *Performance period.* The performance period for facility-based measurement is the performance period for the measures adopted under the value-based purchasing program of the facility program for the year described in paragraph (e)(1) of this section.

(iv) *Quality.* The quality performance category percent score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(1) of this section and awarding a score associated with that same percentile performance in the MIPS quality performance category percent score for those MIPS-eligible clinicians who are not eligible to be scored using facility-based measurement for the MIPS payment year. A clinician or group receiving a facility-based performance score will not earn improvement points based on prior performance in the MIPS quality performance category

(v) *Cost.* The cost performance category percent score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(1) of this section and awarding a score associated with that same percentile performance in the MIPS cost performance category percent score for those MIPS eligible clinicians who are not eligible to be scored using facility-based measurement for the MIPS payment year. A clinician or group receiving a facility-based performance score will not earn improvement points based on prior performance in the MIPS cost category.

(A) *Other cost measures.* MIPS eligible clinicians who are scored under facility-based measurement are not scored on cost measures described in paragraph (b)(2) of this section.

(B) [Reserved]

(vi) *Use of score from facility-based measurement.* The MIPS quality and cost performance category scores will be based on the facility-based measurement scoring methodology described in paragraph (e)(6) of this section unless a clinician or group receives a higher combined MIPS quality and cost performance category score through another MIPS submission.

■ 37. Section 414.1395 is amended by revising paragraphs (b) and (c) to read as follows:

§ 414.1395 Public reporting.

* * * * *

(b) *Maintain existing public reporting standards.* With the exception of data that must be mandatorily reported on Physician Compare, for each program year, CMS relies on established public reporting standards to guide the information available for inclusion on Physician Compare. The public reporting standards require data included on Physician Compare to be statistically valid, reliable, and accurate; comparable across collection types; and meet the reliability threshold. And, to be included on the public facing profile pages, the data must also resonate with website users, as determined by CMS.

(c) *First year measures.* For each program year, CMS does not publicly report any first year measure for the first 2 years, meaning any measure in its first 2 years of use in the quality and cost performance categories. After the first 2 years, CMS reevaluates measures to determine when and if they are suitable for public reporting.

* * * * *

■ 38. Section 414.1400 is revised to read as follows:

§ 414.1400 Third party intermediaries.

(a) *General.* (1) MIPS data may be submitted on behalf of a MIPS eligible clinician, group, or virtual group by any of the following third party intermediaries:

(i) A QCDR;

(ii) A qualified registry;

(iii) A health IT vendor; or

(iv) A CMS-approved survey vendor.

(2) QCDRs, qualified registries, and health IT vendors may submit MIPS data for any of the following MIPS performance categories:

(i) Quality, except for data on the CAHPS for MIPS survey;

(ii) Improvement activities; or

(iii) Promoting Interoperability, if the MIPS eligible clinician, group, or virtual group is using CEHRT.

(3) CMS-approved survey vendors may submit data on the CAHPS for MIPS survey for the MIPS quality performance category.

(4) To be approved as a third party intermediary, an entity must agree to meet the applicable requirements of this section, including, but not limited to, the following:

(i) A third party intermediary's principle place of business and retention of any data must be based in the U.S.

(ii) If the data is derived from CEHRT, a QCDR, qualified registry, or health IT vendor must be able to indicate its data source.

(iii) All data must be submitted in the form and manner specified by CMS.

(iv) If the clinician chooses to opt-in in accordance with § 414.1310, the third party intermediary must be able to transmit that decision to CMS.

(5) All data submitted to CMS by a third party intermediary on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge. Such certification must be made in a form and manner and at such time as specified by CMS.

(b) *QCDR approval criteria*—(1) *QCDR self-nomination.* For the 2020 and 2021 MIPS payment years, entities seeking to qualify as a QCDR must self-nominate September 1 until November 1 of the CY preceding the applicable performance period. For the 2022 MIPS payment year and future years, entities seeking to qualify as a QCDR must self-nominate during a 60-day period during the CY preceding the applicable performance period (beginning no earlier than July 1 and ending no later than September 1). Entities seeking to qualify as a QCDR for a performance period must provide all information required by CMS at the time of self-nomination and must provide any additional information requested by CMS during the review process. For the 2021 MIPS payment year and future years, existing QCDRs that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period.

(2) *Establishment of a QCDR entity.* (i) Beginning with the 2022 MIPS Payment Year, the QCDR must have at least 25 participants by January 1 of the year prior to the applicable performance period.

(ii) If the entity uses an external organization for purposes of data collection, calculation, or transmission, it must have a signed, written agreement with the external organization that specifically details the responsibilities of the entity and the external organization. The written agreement must be effective as of September 1 of the year preceding the applicable performance period.

(3) *QCDR measures for the quality performance category.* (i) For purposes of QCDRs submitting data for the MIPS quality performance category, CMS considers the following types of quality measures to be QCDR measures:

(A) Measures that are not included in the MIPS final list of quality measures described in § 414.1330(a)(1) for the applicable MIPS payment year; and

(B) Measures that are included in the MIPS final list of quality measures described in § 414.1330(a)(1) for the applicable MIPS payment year, but have undergone substantive changes, as determined by CMS.

(ii) For the 2020 MIPS payment year and future years, an entity seeking to become a QCDR must submit specifications for each measure, activity, and objective that the entity intends to submit to for MIPS (including the information described in paragraphs (b)(3)(ii)(A) and (B) of this section) at the time of self-nomination. In addition, no later than 15 calendar days following CMS approval of any QCDR measure specifications, the entity must publicly post the measure specifications for each QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted.

(A) For QCDR measures, the entity must submit the measure specifications for each QCDR measure, including: Name/title of measures, NQF number (if NQF-endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms.

(B) For MIPS quality measures, the entity must submit the MIPS measure IDs and specialty-specific measure sets, as applicable.

(iii) A QCDR must include the CMS-assigned QCDR measure ID when submitting data on any QCDR measure to CMS.

(c) *Qualified registry approval criteria*—(1) *Qualified registry self-nomination.* For the 2020 and 2021 MIPS payment years, entities seeking to qualify as a qualified registry must self-nominate from September 1 until November 1 of the CY preceding the applicable performance period. For the 2022 MIPS payment year and future years, entities seeking to qualify as a qualified registry must self-nominate during a 60-day period during the CY preceding the applicable performance period (beginning no earlier than July 1 and ending no later than September 1). Entities seeking to qualify as a qualified registry for a performance period must provide all information required by CMS at the time of self-nomination and must provide any additional information requested by CMS during the review process. For the 2021 MIPS payment year and future years, existing qualified registries that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period.

(2) *Establishment of a qualified registry entity.* Beginning with the 2022 MIPS Payment Year, the qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period.

(d) *Health IT vendor approval criteria.* Health IT vendors must meet the criteria specified at paragraph (a)(4) of this section.

(e) *CMS-approved survey vendor approval criteria.* Entities seeking to be a CMS-approved survey vendor for any MIPS performance period must submit a survey vendor application to CMS in a form and manner specified by CMS for each MIPS performance period for

which it wishes to transmit such data. The application and any supplemental information requested by CMS must be submitted by deadlines specified by CMS. For an entity to be a CMS-approved survey vendor, it must meet the following criteria:

(1) The entity must have sufficient experience, capability, and capacity to accurately report CAHPS data, including:

(i) At least 3 years of experience administering mixed-mode surveys (that is, surveys that employ multiple modes to collect date), including mail survey administration followed by survey administration via Computer Assisted Telephone Interview (CATI);

(ii) At least 3 years of experience administering surveys to a Medicare population;

(iii) At least 3 years of experience administering CAHPS surveys within the past 5 years;

(iv) Experience administering surveys in English and at least one other language for which a translation of the CAHPS for MIPS survey is available;

(v) Use equipment, software, computer programs, systems, and facilities that can verify addresses and phone numbers of sampled beneficiaries, monitor interviewers, collect data via CATI, electronically administer the survey and schedule call-backs to beneficiaries at varying times of the day and week, track fielded surveys, assign final disposition codes to reflect the outcome of data collection of each sampled case, and track cases from mail surveys through telephone follow-up activities; and

(vi) Employment of a program manager, information systems specialist, call center supervisor and mail center supervisor to administer the survey.

(2) The entity has certified that it has the ability to maintain and transmit quality data in a manner that preserves the security and integrity of the data.

(3) The entity has successfully completed, and has required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors.

(4) The entity has submitted a quality assurance plan and other materials relevant to survey administration, as determined by CMS, including cover letters, questionnaires and telephone scripts.

(5) The entity has agreed to participate and cooperate, and has required its subcontractors to participate and cooperate, in all oversight activities related to survey administration conducted by CMS or its contractors.

(6) The entity has sent an interim survey data file to CMS that establishes the entity's ability to accurately report CAHPS data.

(f) *Remedial action and termination of third party intermediaries.* (1) If CMS determines that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, or has submitted data that is inaccurate, unusable, or otherwise compromised, CMS may take one or more of the following remedial actions after providing written notice to the third party intermediary:

(i) Require the third party intermediary to submit a corrective action plan (CAP) to CMS to address the identified deficiencies or data issue, including the actions it will take to prevent the deficiencies or data issues from recurring. The CAP must be submitted to CMS by a date specified by CMS.

(ii) Publicly disclose the entity's data error rate on the CMS website until the data error rate falls below 3 percent.

(2) CMS may immediately or with advance notice terminate the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the following reasons:

(i) CMS has grounds to impose remedial action;

(ii) CMS has not received a CAP within the specified time period or the CAP is not accepted by CMS; or

(iii) The third party intermediary fails to correct the deficiencies or data errors by the date specified by CMS.

(3) For purposes of paragraph (f) of this section, CMS may determine that submitted data is inaccurate, unusable, or otherwise compromised if the submitted data:

(i) Includes, without limitation, TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies; and

(ii) Affects more than 3 percent of the total number of MIPS eligible clinicians or group for which data was submitted by the third party intermediary.

(g) *Auditing of entities submitting MIPS data.* Any third party intermediary must comply with the following procedures as a condition of its qualification and approval to participate in MIPS as a third party intermediary.

(1) The entity must make available to CMS the contact information of each MIPS eligible clinician or group on behalf of whom it submits data. The contact information must include, at a minimum, the MIPS eligible clinician or group's practice phone number, address, and, if available, email.

(2) The entity must retain all data submitted to CMS for purposes of MIPS for 6 years from the end of the MIPS performance period.

(3) For the purposes of auditing, CMS may request any records or data retained for the purposes of MIPS for up to 6 years from the end of the MIPS performance period.

■ 39. Section 414.1405 is amended by—

■ a. Adding paragraphs (b)(6) and (d)(5);

■ b. Revising paragraph (e); and

■ c. Adding paragraph (f).

The additions and revision read as follows:

§ 414.1405 Payment.

* * * * *

(b) * * *

(6) The performance threshold for the 2021 MIPS payment year is 30 points.

* * * * *

(d) * * *

(5) The additional performance threshold for the 2021 MIPS payment year is 75 points.

(e) *Application of adjustments to payments.* Except as specified in paragraph (f) of this section, in the case of covered professional services (as defined in section 1848(k)(3)(A) of the Act) furnished by a MIPS eligible clinician during a MIPS payment year beginning with 2019, the amount otherwise paid under Part B with respect to such covered professional services and MIPS eligible clinician for such year, is multiplied by 1, plus the sum of the MIPS payment adjustment factor divided by 100, and as applicable, the additional MIPS payment adjustment factor divided by 100.

(f) *Exception to application of MIPS payment adjustment factors to model-specific payments under section 1115A APMs.* Effective for the 2019 MIPS payment year, the payment adjustment factors specified under paragraph (e) of this section are not applicable to payments that meet all of the following conditions:

(1) Are made only to participants in a model tested under section 1115A of the Act;

(2) Would otherwise be subject to the requirement to apply the MIPS payment adjustment factors if the payment is made with respect to a MIPS eligible clinician participating in a section 1115A model; and

(3) Either have a specified payment amount or are paid according to a methodology for calculating a model-specific payment that is applied in a consistent manner to all model participants, such that application of the MIPS payment adjustment factors would potentially interfere with CMS's ability to effectively evaluate the impact of the APM.

■ 40. Section 414.1415 is amended, effective January 1, 2019, by revising paragraphs (a)(1)(i) and (ii), (b)(1), (c) introductory text, (c)(3)(i)(A), and (c)(6) to read as follows:

§ 414.1415 Advanced APM criteria.

(a) * * *

(1) * * *

(i) Require at least 50 percent, or for QP Performance Periods beginning in 2019, 75 percent of eligible clinicians in each participating APM Entity group, or for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or health care providers; or

(ii) For QP Performance Periods prior to 2019, for the Shared Savings Program, apply a penalty or reward to an APM Entity based on the degree of the use of CEHRT of the eligible clinicians in the APM Entity.

(b) * * *

(1) To be an Advanced APM, an APM must include quality measure performance as a factor when determining payment to participants for covered professional services under the terms of the APM.

* * * * *

(c) *Financial risk.* To be an Advanced APM, except as described in paragraph (c)(6) of this section, an APM must either meet the financial risk standard under paragraph (c)(1) or (2) of this section and the nominal amount standard under paragraph (c)(3) or (4) of this section or be an expanded Medical Home Model under section 1115A(c) of the Act.

* * * * *

(3) * * *

(i) * * *

(A) For QP Performance Periods beginning in 2017, through 2024, 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities; or

* * * * *

(6) *Capitation.* A full capitation arrangement meets this Advanced APM criterion. For purposes of this part, a full capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement is performed to reconcile or share losses incurred or savings earned by the APM Entity. Arrangements between CMS and Medicare Advantage Organizations under the Medicare Advantage program (42 U.S.C. 422) are not considered capitation arrangements for purposes of this paragraph (c)(6).

* * * * *

■ 41. Section 414.1415 is further amended (effective January 1, 2010) by revising paragraphs (b)(2) and (3) to read as follows:

§ 414.1415 Advanced APM criteria.

* * * * *

(b) * * *

(2) At least one of the quality measures used in the payment arrangement as specified in paragraph (b)(1) of this section must:

(i) For QP Performance Periods before January 1, 2020, have an evidence-based focus, be reliable and valid, and meet at least one of the following criteria:

(A) Used in the MIPS quality performance category, as described in § 414.1330;

(B) Endorsed by a consensus-based entity;

(C) Developed under section 1848(s) of the Act;

(D) Submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or

(E) Any other quality measures that CMS determines to have an evidence-based focus and to be reliable and valid; and

(ii) For QP Performance Periods beginning on or after January1, 2020, be:

(A) Finalized on the MIPS final list of measures, as described in § 414.1330;

(B) Endorsed by a consensus-based entity; or

(C) Determined by CMS to be evidenced-based, reliable, and valid.

(3) In addition to the quality measure described under paragraph (b)(2) of this section, the quality measures upon which an Advanced APM bases the payment in paragraph (b)(1) of this section must include at least one additional measure that is an outcome measure unless CMS determines that there are no available or applicable outcome measures included in the MIPS final quality measures list for the Advanced APM's first QP Performance Period. Beginning January 1, 2020, the included outcome measure must satisfy the criteria in paragraph (b)(2) of this section.

* * * * *

■ 42. Section 414.1420 is amended effective January 1, 2019, by revising paragraphs (d) introductory text, (d)(3)(i), and (d)(7) to read as follows:

§ 414.1420 Other payer advanced APM criteria.

* * * * *

(d) *Financial risk.* To be an Other Payer Advanced APM, except as described in paragraph (d)(7) of this section, a payment arrangement must meet either the financial risk standard under paragraph (d)(1) or (2) of this section and the nominal amount standard under paragraph (d)(3) or (4) of this section, or be a Medicaid Medical Home Model with criteria comparable to an expanded Medical Home Model under section 1115A(c) of the Act.

* * * * *

(3) * * *

(i) For QP Performance Periods 2019 through 2024, 8 percent of the total combined revenues from the payer to providers and other entities under the payment arrangement if financial risk is expressly defined in terms of revenue; or, 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement.

* * * * *

(7) *Capitation.* A full capitation arrangement meets this Other Payer Advanced APM criterion. For purposes of paragraph (d)(3) of this section, a full capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the payment arrangement for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement is performed for the purpose of reconciling or sharing losses incurred or savings earned by the participant. Arrangements made directly between CMS and Medicare Advantage Organizations under the Medicare Advantage program (42 U.S.C. 422) are not considered capitation arrangements for purposes of this paragraph (c)(7).

* * * * *

■ 43. Section 414.1420 is further amended (effective January 1, 2020) by revising paragraphs (b), (c)(2) and (3) to read as follows:

§ 414.1420 Other payer advanced APM criteria.

* * * * *

(b) *Use of CEHRT.* To be an Other Payer Advanced APM, CEHRT must be used by at least 50 percent, or for QP Performance Periods on or after January 1, 2020, 75 percent of participants in each participating APM Entity group, or each hospital if hospitals are the APM Entities, in the other payer arrangement to document and communicate clinical care.

(c) * * *

(2) At least one of the quality measures used in the payment arrangement as specified in paragraph (c)(1) of this section must:

(i) For QP Performance Period before January 1, 2020, have an evidence-based focus, be reliable and valid, and meet at least one of the following criteria:

(A) Used in the MIPS quality performance category, as described in § 414.1330;

(B) Endorsed by a consensus-based entity;

(C) Developed under section 1848(s) of the Act;

(D) Submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or

(E) Any other quality measures that CMS determines to have an evidence-based focus and to be reliable and valid; and

(ii) For QP Performance Periods beginning on or after January 1, 2020, be:

(A) Finalized on the MIPS final list of measures, as described in § 414.1330;

(B) Endorsed by a consensus-based entity; or

(C) Determined by CMS to be evidenced-based, reliable, and valid.

(3) To meet the quality measure use criterion under paragraph (c)(1) of this section, a payment arrangement must:

(i) For QP Performance Periods before January 1, 2020, use an outcome measure if there is an applicable outcome measure on the MIPS quality measure list. This criterion also applies for payment arrangements determined to be Other Payer Advanced APMs on or before January 1, 2020, but only for the Other Payer Advanced APM determination made with respect to the arrangement for the CY 2020 QP Performance Period (regardless of whether that determination is a single- or multi-year determination).

(ii) For QP Performance Periods on or after January 1, 2020, in addition to the quality measure described under paragraph (c)(2) of this section, use at least one additional measure that is an outcome measure and meets the criteria in paragraph (c)(2)(ii) of this section if there is such an applicable outcome measure on the MIPS quality measure list.

* * * * *

■ 44. Section 414.1440 is amended by revising paragraphs (d)(1) through (3) to read as follows:

§ 414.1440 Qualifying APM participant determination: All-payer combination option.

* * * * *

(d) * * *

(1) CMS performs QP determinations following the QP Performance Period using payment amount and/or patient count information submitted from January 1 through each of the respective QP determination dates: March 31, June 30, and August 31. CMS will use data for the same time periods for the Medicare and other payer portions of Threshold Score calculations under the All-Payer Combination Option. CMS will use the payment amount or patient count method, applying the more advantageous of the two for both the Medicare and other payer portions of the Threshold score calculation, regardless of the method used for the Medicare Threshold Score calculation.

(2) An APM Entity may request that CMS make QP determinations at the APM Entity level, an eligible clinician may request that CMS make QP determinations at the eligible clinician level, and an eligible clinician or an APM Entity may request that CMS makes QP determinations at the TIN-level in instances where all clinicians who reassigned billing rights to the TIN are participating in a single APM Entity. CMS makes QP determinations at either the APM Entity, eligible clinician, or TIN level. Eligible clinicians assessed at the eligible clinician level under the Medicare Option at § 414.1425(b)(2) will be assessed at the eligible clinician level only under the All-Payer Combination Option. Eligible Clinicians may meet the Medicare and the All-Payer Combination Option thresholds using the payment amount method for both thresholds, the patient account method for both thresholds, or the payment amount method for one threshold and the patient account method for the other threshold.

(3) CMS uses data at the same level for the Medicare and other payer portions of Threshold Score calculations under the All-Payer Combination Option. When QP determinations are made at the eligible clinician or, at the TIN level when all clinicians who have reassigned billing rights to the TIN are included in a single APM Entity; and if the Medicare Threshold score for the APM Entity group is higher than when calculated for the eligible clinician or TIN, CMS makes QP determinations using a weighted Medicare Threshold Score that is factored into an All-Payer Combination Option Threshold Score.

* * * * *

■ 45. Section 414.1445 is amended by revising paragraph (b)(1), adding paragraph (c)(2)(i), and reserving paragraph (c)(2)(ii) to read as follows:

§ 414.1445 Determination of other payer advanced APMs.

* * * * *

(b) * * *

(1) *Payer initiated Other Payer Advanced APM determination process.* Beginning in 2018, and each year thereafter, at a time determined by CMS a payer with a Medicare Health Plan payment arrangement may request, in a form and manner specified by CMS, that CMS determine whether a Medicare Health Plan payment arrangement meets the Other Payer Advanced APM criteria set forth in § 414.1420. A payer with a Medicare Health Plan payment arrangement must submit its requests by the annual Medicare Advantage bid deadline of the year prior to the relevant QP Performance Period. A Medicare Health Plan is a Medicare Advantage plan, a section 1876 cost plan, a PACE organization operated under section 1894, and any similar plan which provides Medicare benefits under demonstration or waiver authority (other than an APM as defined in section 1833(z)(3)(C) of the Act).

* * * * *

(c) * * *

(2) * * *

(i) Based on the submission by an eligible clinician or payer of evidence that CMS determines sufficiently demonstrates that CEHRT is used as specified in § 414.1420(b) by participants in the payment arrangement, CMS will consider the CEHRT criterion in § 414.1420(b) is satisfied for that payment arrangement.

(ii) [Reserved]

* * * * *

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 46. The authority citation for part 415 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 47. Section 415.172 is amended by revising paragraph (b) to read as follows:

§ 415.172 Physician fee schedule payment for services of teaching physicians.

* * * * *

(b) *Documentation.* Except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document the teaching physician was present at the time the service is furnished. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by a physician, resident, or nurse.

* * * * *

■ 48. Section 415.174 is amended—
■ a. In paragraph (a)(3)(iii) by removing ''; '' and adding in its place ''; and'';
■ b. In paragraph (a)(3)(iv) by removing ''; and'' and adding in its place ''.'';
■ c. By removing paragraph (a)(3)(v); and
■ d. By adding paragraph (a)(6).

The addition reads as follows:

§ 415.174 Exception: Evaluation and management services furnished in certain centers.

(a) * * *

(6) The medical records must document the extent of the teaching physician's participation in the review and direction of services furnished to each beneficiary. The extent of the teaching physician's participation may be demonstrated by the notes in the medical records made by a physician, resident, or nurse.

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 49. The authority citation for part 425 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 50. Section 425.20 is amended—
■ a. By revising the definition of ''Agreement period'';
■ b. By adding in alphabetical order definitions for ''Certified Electronic Health Record Technology (CEHRT)'' and ''Eligible clinician''; and
■ c. By revising the definition of ''Performance year''.

The revisions and additions read as follows:

§ 425.20 Definitions.

* * * * *

Agreement period means the term of the participation agreement.

* * * * *

Certified Electronic Health Record Technology (CEHRT) has the same meaning given this term under § 414.1305 of this chapter.

* * * * *

Eligible clinician has the same meaning given this term under § 414.1305 of this chapter.

* * * * *

Performance year means the 12-month period beginning on January 1 of each year during the agreement period, unless otherwise specified in § 425.200(c) or noted in the participation agreement.

* * * * *

§ 425.100 [Amended]

■ 51. Section 425.100 is amended—
■ a. In paragraph (b) by removing the phrase ''under § 425.604, § 425.606 or § 425.610'' and adding in its place the phrase ''under § 425.604, § 425.606, § 425.609 or § 425.610''; and
■ b. In paragraph (c) by removing the phrase ''under § 425.606 or § 425.610'' and adding in its place the phrase ''under § 425.606, § 425.609 or § 425.610''.

■ 52. Section 425.200 is amended—
■ a. By revising paragraph (a);
■ b. By revising the heading of paragraph (b);
■ c. By removing paragraph (b)(2) introductory text, adding a heading for paragraph (b)(2), and revising paragraph (b)(2)(ii); and
■ d. By removing paragraph (b)(3) introductory text, adding a heading for paragraph (b)(3); and
■ e. By revising paragraphs (c) and (d).

The revisions and additions read as follows:

§ 425.200 Participation agreement with CMS.

(a) *General.* In order to participate in the Shared Savings Program, an ACO must enter into a participation agreement with CMS for a period of not less than the number of years specified in this section.

(b) *Agreement period.** * *

(2) *For 2013 and through 2016.** * *

(ii) The term of the participation agreement is 3 years unless all of the following conditions are met to extend the participation agreement by 6 months:

(A) The ACO entered an agreement period starting on January 1, 2016.

(B) The ACO elects to extend its agreement period until June 30, 2019.

(*1*) The ACO's election to extend its agreement period is made in the form and manner and according to the timeframe established by CMS; and

(*2*) An ACO executive who has the authority to legally bind the ACO must certify the election described in paragraph (b)(2)(ii)(B) of this section.

(3) *For 2017 and all subsequent years.* * * *

(c) *Performance year.* The ACO's performance year under the participation agreement is the 12 month period beginning on January 1 of each year during the term of the participation agreement unless otherwise noted in its participation agreement, and except as follows:

(1) For an ACO with a start date of April 1, 2012, or July 1, 2012, the ACO's first performance year is defined as 21 months or 18 months, respectively.

(2) For an ACO that entered a first or second agreement period with a start date of January 1, 2016, and that elects to extend its agreement period by a 6-month period under paragraph (b)(2)(ii)(B) of this section, the ACO's fourth performance year is the 6-month period between January 1, 2019, and June 30, 2019.

(d) *Submission of measures.* For each performance year of the agreement period, ACOs must submit measures in the form and manner required by CMS according to § 425.500(c), and as applicable according to §§ 425.608 and 425.609.

* * * * *

§ 425.221 [Amended]

■ 53. Section 425.221 is amended—
■ a. In paragraph (b)(1)(i) by removing the phrase ''December 31st of such performance year'' and adding in its place the phrase ''the last calendar day of the performance year''; and
■ b. In paragraph (b)(2) by removing the phrase ''December 31 of a performance year'' and adding in its place the phrase ''the last calendar day of a performance year''.

■ 54. Section 425.302 is amended—
■ a. In paragraph (a)(3)(i) by removing the phrase ''requirements; and'' and adding in its place the phrase ''requirements;'';
■ b. In paragraph (a)(3)(ii) by removing the phrase ''owed to CMS.'' and adding in its place the phrase ''owed to CMS; and''; and
■ c. Adding paragraph (a)(3)(iii).

The addition reads as follows:

§ 425.302 Program requirements for data submission and certifications.

(a) * * *

(3) * * *

(iii) That the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage specified by CMS at § 425.506(f).

* * * * *

§ 425.315 [Amended]

■ 55. Section 425.315 is amended in paragraph (a)(1)(ii) by removing the phrase ''§ 425.604(f), § 425.606(h) or § 425.610(h)'' and adding in its place the phrase ''§ 425.604(f), § 425.606(h), § 425.609(e) or § 425.610(h)''.

■ 56. Section 425.400 is amended by—
■ a. Revising paragraph (a)(1)(ii);
■ b. Revising paragraphs (c)(1)(iv) introductory text, (c)(1)(iv)(A), (c)(1)(iv)(B) introductory text, and (c)(1)(iv)(B)(*5*); and
■ c. Adding paragraphs (c)(1)(iv)(B)(*6*) and (*7*).

The revisions and additions read as follows:

§ 425.400 General.

(a)(1) * * *

(ii) CMS applies a step-wise process based on the beneficiary's utilization of primary care services provided under Title XVIII by a physician who is an ACO professional during each performance year for which shared savings are to be determined and, with respect to ACOs participating in a 6-month performance year during CY 2019, during the entirety of CY 2019 as specified in § 425.609.

* * * * *

(c) * * *

(1) * * *

(iv) For performance years starting on January 1, 2019, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*2*) 99304 through 99318 (codes for professional services furnished in a nursing facility; services identified by these codes furnished in a SNF are excluded).

(*3*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*4*) 99341 through 99350 (codes for evaluation and management services furnished in a patients' home for claims identified by place of service modifier 12).

(*5*) 99487, 99489 and 99490 (codes for chronic care management).

(*6*) 99495 and 99496 (codes for transitional care management services).

(*7*) 99497 and 99498 (codes for advance care planning).

(*8*) 96160 and 96161 (codes for administration of health risk assessment).

(*9*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)).

(*10*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(B) HCPCS codes:

* * * * *

(*5*) G0444 (codes for annual depression screening service).

(*6*) G0442 (code for alcohol misuse screening service).

(*7*) G0443 (code for alcohol misuse counseling service).

■ 57. Section 425.401 is amended by revising paragraph (b) introductory text to read as follows:

§ 425.401 Criteria for a beneficiary to be assigned to an ACO.

* * * * *

(b) A beneficiary is excluded from the prospective assignment list of an ACO that is participating under prospective assignment under § 425.400(a)(3) at the end of a performance or benchmark year and quarterly during each performance year consistent with § 425.400(a)(3)(ii), or at the end of CY 2019 as specified in § 425.609(b)(1)(ii), if the beneficiary meets any of the following criteria during the performance or benchmark year:

* * * * *

■ 58. Section 425.402 is amended by revising paragraph (e)(2) to read as follows:

§ 425.402 Basic assignment methodology.

* * * * *

(e) * * *

(2) Beneficiaries are added to the ACO's list of assigned beneficiaries if all of the following conditions are satisfied:

(i) For performance year 2018:

(A) The beneficiary must have had at least one primary care service during the assignment window as defined under § 425.20 with a physician who is an ACO professional in the ACO who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in paragraph (c) of this section.

(B) The beneficiary meets the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b). The exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for alignment to ACOs under all tracks based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section.

(C) The beneficiary must have designated an ACO professional who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at paragraph (c) of this section, or a nurse practitioner, physician assistant, or clinical nurse specialist as responsible for coordinating their overall care.

(D) If a beneficiary has designated a provider or supplier outside the ACO who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at paragraph (c) of this section, or a nurse practitioner, physician assistant, or clinical nurse specialist, as responsible for coordinating their overall care, the beneficiary is not added to the ACO's list of assigned beneficiaries under the assignment methodology in paragraph (b) of this section.

(ii) For performance years starting on January 1, 2019, and subsequent performance years:

(A) The beneficiary meets the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b). The exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for alignment to an ACO based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section, regardless of the ACO's assignment methodology selection under § 425.400(a)(4)(ii).

(B) The beneficiary must have designated an ACO professional as responsible for coordinating their overall care.

(C) If a beneficiary has designated a provider or supplier outside the ACO as responsible for coordinating their overall care, the beneficiary is not added under the assignment methodology in paragraph (b) of this section to the ACO's list of assigned beneficiaries for a 12-month performance year or the ACO's list of assigned beneficiaries for a 6-month performance year, which is based on the entire CY 2019 as provided in § 425.609.

(D) The beneficiary is not assigned to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services and for which there has been a determination by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model.

* * * * *

§ 425.404 [Amended]

■ 59. Section 425.404 is amended in paragraph (b) by removing the phrase ''For performance year 2019 and subsequent performance years'' and adding in its place the phrase ''For performance years starting on January 1, 2019, and subsequent performance years''.

■ 60. Section 425.502 is amended—

■ a. In paragraph (e)(4)(vi) by removing the phrase ''For performance year 2017'' and adding in its place the phrase ''For performance year 2017 and subsequent performance years'';

■ b. By adding a new paragraph (e)(4)(vii);

■ c. By revising paragraph (f) introductory text;

■ d. By redesignating paragraphs (f)(1) and (2) as paragraphs (f)(2)(i) and (ii);
■ e. By adding a new paragraph (f)(1);
■ f. By adding a new paragraph (f)(2) introductory text;
■ g. In newly redesignated paragraph (f)(2)(i) by removing the phrase ''for performance year 2017'' and adding in its place the phrase ''for the relevant performance year'';
■ h. By removing paragraph (f)(4); and
■ i. By redesignating paragraph (f)(5) as paragraph (f)(4).

The revisions and additions read as follows:

§ 425.502 Calculating the ACO quality performance score.

* * * * *

(e) * * *

(4) * * *

(vii) For performance year 2017 and subsequent performance years, if an ACO receives the mean Shared Savings Program ACO quality score under paragraph (f) of this section, in the next performance year for which the ACO receives a quality performance score based on its own quality reporting, quality improvement is measured based on a comparison between the performance in that year and the most recently available prior performance year in which the ACO reported quality.

(f) *Extreme and uncontrollable circumstances.* For performance year 2017 and subsequent performance years, including the applicable quality data reporting period for the performance year if the quality reporting period is not extended, CMS uses an alternative approach to calculating the quality score for ACOs affected by extreme and uncontrollable circumstances instead of the methodology specified in paragraphs (a) through (e) of this section as follows:

(1) CMS determines the ACO was affected by an extreme and uncontrollable circumstance based on either of the following:

(i) Twenty percent or more of the ACO's assigned beneficiaries reside in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance.

(A) Assignment is determined under subpart E of this part.

(B) In making this determination for performance year 2017, CMS uses the final list of beneficiaries assigned to the ACO for the performance year. For performance year 2018 and subsequent performance years, CMS uses the list of assigned beneficiaries used to generate the Web Interface quality reporting sample.

(ii) The ACO's legal entity is located in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance. An ACO's legal entity location is based on the address on file for the ACO in CMS' ACO application and management system.

(2) If CMS determines the ACO meets the requirements of paragraph (f)(1) of this section, CMS calculates the ACO's quality score as follows:

* * * * *

■ 61. Section 425.506 is amended—
■ a. In paragraph (b) by removing the phrase ''As part of the quality performance score'' and adding in its place the phrase ''For performance years 2012 through 2018, as part of the quality performance score'';
■ b. In paragraph (c) by removing the phrase ''Performance on this measure'' and adding in its place the phrase ''For performance years 2012 through 2018, performance on this measure'';
■ c. In paragraph (e) introductory text by removing the phrase ''For 2017 and subsequent years'' and adding in its place the phrase ''For 2017 and 2018''; and
■ d. By adding paragraph (f).

The addition reads as follows:

§ 425.506 Incorporating reporting requirements related to adoption of certified electronic health record technology.

* * * * *

(f) For performance years starting on January 1, 2019, and subsequent performance years, ACOs in a track that—

(1) Does not meet the financial risk standard to be an Advanced APM must certify annually that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds 50 percent; or

(2) Meets the financial risk standard to be an Advanced APM must certify annually that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold established under § 414.1415(a)(1)(i) of this chapter.

■ 62. Section 425.602 is amended by adding paragraph (c) to read as follows:

§ 425.602 Establishing, adjusting, and updating the benchmark for an ACO's first agreement period.

* * * * *

(c) *January 1, 2019 through June 30, 2019 performance year.* In determining performance for the January 1, 2019 through June 30, 2019 performance year described in § 425.609(b) CMS does all of the following:

(1) When adjusting the benchmark using the methodology set forth in paragraph (a)(9) of this section and § 425.609(b), CMS adjusts for severity and case mix between BY3 and CY 2019.

(2) When updating the benchmark using the methodology set forth in paragraph (b) of this section and § 425.609(b), CMS updates the benchmark based on growth between BY3 and CY 2019.

■ 63. Section 425.603 is amended by adding paragraph (g) to read as follows:

§ 425.603 Resetting, adjusting, and updating the benchmark for a subsequent agreement period.

* * * * *

(g) In determining performance for the January 1, 2019 through June 30, 2019 performance year described in § 425.609(b) CMS does all of the following:

(1) When adjusting the benchmark using the methodology set forth in paragraph (c)(10) of this section and § 425.609(b), CMS adjusts for severity and case mix between BY3 and CY 2019.

(2) When updating the benchmark using the methodology set forth in paragraph (d) of this section and § 425.609(b), CMS updates the benchmark based on growth between BY3 and CY 2019.

■ 64. Section 425.604 is amended by adding paragraph (g) to read as follows:

§ 425.604 Calculation of savings under the one-sided model.

* * * * *

(g) *January 1, 2019 through June 30, 2019 performance year.* Shared savings for the January 1, 2019 through June 30, 2019 performance year are calculated as described in § 425.609.

■ 65. Section 425.606 is amended—
■ a. In paragraph (i) introductory text by removing the phrase ''For performance year 2017'' and adding in its place the phrase ''For performance year 2017 and subsequent performance years'';
■ b. In paragraph (i)(1) remove the phrase ''2017''; and
■ c. By adding paragraph (j).

The addition reads as follows:

§ 425.606 Calculation of shared savings and losses under Track 2.

* * * * *

(j) *January 1, 2019 through June 30, 2019.* Shared savings or shared losses for the January 1, 2019 through June 30, 2019 performance year are calculated as described in § 425.609.

■ 66. Section 425.609 is added to read as follows:

§ 425.609 Determining performance for a 6-month performance year during CY 2019.

(a) *General.* An ACO's financial and quality performance for a 6-month performance year during 2019 are determined as described in this section.

(b) *January 2019 through June 2019.* For ACOs participating in a 6-month performance year from January 1, 2019, through June 30, 2019, under § 425.200(b)(2)(ii)(B), CMS reconciles the ACO for the period from January 1, 2019, through June 30, 2019, after the conclusion of CY 2019, based on the 12-month calendar year and pro-rates shared savings or shared losses to reflect the ACO's participation from January 1, 2019, through June 30, 2019. CMS does all of the following to determine financial and quality performance:

(1) Uses the ACO participant list in effect for the performance year beginning January 1, 2019, to determine beneficiary assignment, using claims for the entire calendar year, as specified in §§ 425.402 and 425.404, and according to the ACO's track as specified in § 425.400.

(i) For ACOs under preliminary prospective assignment with retrospective reconciliation the assignment window is CY 2019.

(ii) For ACOs under prospective assignment—

(A) Medicare fee-for-service beneficiaries are prospectively assigned to the ACO based on the beneficiary's use of primary care services in the most recent 12 months for which data are available; and

(B) Beneficiaries remain prospectively assigned to the ACO at the end of CY 2019 if they do not meet any of the exclusion criteria under § 425.401(b) during the calendar year.

(2) Uses the ACO's quality performance for the 2019 reporting period to determine the ACO's quality performance score as specified in § 425.502. The ACO's latest certified ACO participant list is used to determine the quality reporting samples for the 2019 reporting year for an ACO that extends its participation agreement for the 6-month performance year from January 1, 2019, through June 30, 2019, under § 425.200(b)(2)(ii)(B).

(3) Uses the methodology for calculating shared savings or shared losses applicable to the ACO under the terms of the participation agreement that was in effect on January 1, 2019.

(i) The ACO's historical benchmark is determined according to either § 425.602 (first agreement period) or § 425.603 (second agreement period) except as follows:

(A) The benchmark is adjusted for changes in severity and case mix between BY3 and CY 2019 using the methodology that accounts separately for newly and continuously assigned beneficiaries using prospective HCC risk scores and demographic factors as described under §§ 425.604(a)(1) through (3), 425.606(a)(1) through (3), and 425.610(a)(1) through (3).

(B) The benchmark is updated to CY 2019 according to the methodology described under § 425.602(b), § 425.603(b), or § 425.603(d), based on whether the ACO is in its first or second agreement period, and for an ACO in a second agreement period, the date on which that agreement period began.

(ii) The ACO's financial performance is determined based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.604, § 425.606 or § 425.610), unless otherwise specified. In determining ACO financial performance, CMS does all of the following:

(A) Average per capita Medicare Parts A and B fee-for-service expenditures for CY 2019 are calculated for the ACO's performance year assigned beneficiary population identified in paragraph (b)(1) of this section.

(B) Expenditures calculated in paragraph (b)(3)(ii)(A) of this section are compared to the ACO's updated benchmark determined according to paragraph (b)(3)(i) of this section.

(C)(*1*) The ACO's performance year assigned beneficiary population identified in paragraph (b)(1) of this section is used to determine the MSR for Track 1 ACOs and the variable MSR/MLR for ACOs in a two-sided model that selected this option at the start of their agreement period. For two-sided model ACOs that selected a fixed MSR/MLR at the start of the ACO's agreement period, this fixed MSR/MLR is applied. In the event an ACO's performance year assigned population identified in paragraph (b)(1) of this section is below 5,000 beneficiaries, the MSR/MLR is determined according to § 425.110(b).

(*2*) To qualify for shared savings an ACO must do all of the following:

(*i*) Have average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for CY 2019 below its updated benchmark costs for the year by at least the MSR established for the ACO based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.604, § 425.606 or § 425.610) and paragraph (b)(3)(ii)(C)(*1*) of this section.

(*ii*) Meet the minimum quality performance standards established under § 425.502 and according to paragraph (b)(2) of this section.

(*iii*) Otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(*3*) To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for CY 2019 must be above its updated benchmark costs for the year by at least the MLR established for the ACO based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.606 or § 425.610) and paragraph (b)(3)(ii)(C)(*1*) of this section.

(D) For an ACO that meets all the requirements to receive a shared savings payment under paragraph (b)(3)(ii)(C)(*2*) of this section—

(*1*) The final sharing rate, determined based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.604, § 425.606 or § 425.610), is applied to all savings under the updated benchmark specified under paragraph (b)(3)(i) of this section, not to exceed the performance payment limit for the ACO based on its track; and

(*2*) After applying the applicable performance payment limit, CMS pro-rates any shared savings amount determined under paragraph (b)(3)(ii)(D)(*1*) of this section by multiplying the amount by one-half, which represents the fraction of the calendar year covered by the period from January 1, 2019, through June 30, 2019.

(E) For an ACO responsible for shared losses under paragraph (b)(3)(ii)(C)(*3*) of this section—

(*1*) The shared loss rate, determined based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.606 or § 425.610), is applied to all losses under the updated benchmark specified under paragraph (b)(3)(i) of this section, not to exceed the loss recoupment limit for the ACO based on its track; and

(*2*) After applying the applicable loss recoupment limit, CMS pro-rates any shared losses amount determined under paragraph (b)(3)(ii)(E)(*1*) of this section by multiplying the amount by one-half, which represents the fraction of the calendar year covered by the period from January 1, 2019, through June 30, 2019.

(c) [Reserved]

(d) *Extreme and uncontrollable circumstances.* For ACOs affected by extreme and uncontrollable circumstances during CY 2019—

(1) In calculating the amount of shared losses owed, CMS makes adjustments to the amount determined in paragraph (b)(3)(ii)(E)(*1*) of this section, as specified in § 425.606(i) or § 425.610(i), as applicable; and

(2) In determining the ACO's quality performance score for the 2019 quality reporting period, CMS uses the alternative scoring methodology specified in § 425.502(f).

(e) *Notification of savings and losses.* CMS notifies the ACO of shared savings or shared losses for the January 1, 2019 through June 30, 2019 performance year, consistent with the notification requirements specified in §§ 425.604(f), 425.606(h), and 425.610(h), as applicable:

(1) CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due.

(2) CMS provides written notification to an ACO of the amount of shared losses, if any, that it must repay to the program.

(3) If an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

■ 67. Section 425.610 is amended—

■ a. In paragraph (i) introductory text by removing the phrase ''For performance year 2017'' and adding in its place the phrase ''For performance year 2017 and subsequent performance years'';

■ b. In paragraph (i)(1) by removing the phrase ''2017''; and

■ c. By adding paragraph (j).

The addition reads as follows:

§ 425.610 Calculation of shared savings and losses under Track 3.

* * * * *

(j) *January 1, 2019 through June 30, 2019 performance year.* Shared savings or shared losses for the January 1, 2019 through June 30, 2019 performance year are calculated as described in § 425.609.

■ 68. Section 425.702 is amended by adding paragraph (d) to read as follows:

§ 425.702 Aggregate reports.

* * * * *

(d) For an ACO eligible to be reconciled under § 425.609(b), CMS shares with the ACO quarterly aggregate reports as provided in paragraphs (b) and (c)(1)(ii) of this section for CY 2019.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 69. The authority citation for part 495 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 70. Section 495.4 is amended in the definition of ''EHR reporting period'' by adding paragraph (1)(v) to read as follows:

§ 495.4 Definitions.

* * * * *

EHR reporting period. * * *

(1) * * *

(v) Under the Medicaid Promoting Interoperability Program, for the CY 2021 payment year:

(A) For the EP first demonstrating he or she is a meaningful EHR user, any continuous 90-day period within CY 2021 that ends before October 31, 2021, or that ends before an earlier date in CY 2021 that is specified by the state and approved by CMS in the State Medicaid HIT plan described at § 495.332.

(B) For the EP who has successfully demonstrated he or she is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2021 that ends before October 31, 2021, or that ends before an earlier date in CY 2021 that is specified by the state and approved by CMS in the State Medicaid HIT plan described at § 495.332.

* * * * *

■ 71. Section 495.24 is amended by revising paragraphs (d)(6)(i)(B) and (d)(8)(i)(B)(*2*) to read as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2019 and subsequent years.

* * * * *

(d) * * *

(6) * * *

(i) * * *

(B) *Measures.* In accordance with paragraph (a)(2) of this section, an EP must satisfy 2 out of the 3 following measures in paragraphs (d)(6)(i)(B)(*1*) through (*3*) of this section except those measures for which an EP qualifies for an exclusion under paragraph (a)(3) of this section.

(*1*) During the EHR reporting period, more than 5 percent of all unique patients (or their authorized representatives) seen by the EP actively engage with the electronic health record made accessible by the provider and do either of the following:

(*i*) View, download or transmit to a third party their health information;

(*ii*) Access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or

(*iii*) A combination of paragraphs (d)(6)(i)(B)(*1*)(*i*) and (*ii*) of this section.

(*2*) A secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient, for more than 5 percent of all unique patients seen by the EP during the EHR reporting period.

(*3*) Patient generated health data or data from a nonclinical setting is incorporated into the CEHRT for more than 5 percent of all unique patients seen by the EP during the EHR reporting period.

* * * * *

(8) * * *

(i) * * *

(B) * * *

(*2*) *Syndromic surveillance reporting.* The EP is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting, or from any other setting from which ambulatory syndromic surveillance data are collected by the state or a local public health agency.

* * * * *

■ 72. Section 495.332 is amended by adding paragraphs (f)(3), (4), and (5) to read as follows:

§ 495.332 State Medicaid health information technology (HIT) plan requirements.

* * * * *

(f) * * *

(3) An alternative date within CY 2021 by which all ''EHR reporting periods'' (as defined under § 495.4) for the CY 2021 payment year for Medicaid EPs demonstrating they are meaningful EHR users must end. The alternative date selected by the state must be earlier than October 31, 2021, and must not be any earlier than the day prior to the attestation deadline for Medicaid EPs attesting to that state.

(4) An alternative date within CY 2021 by which all clinical quality measure reporting periods for the CY 2021 payment year for Medicaid EPs demonstrating they are meaningful EHR users must end. The alternative date selected by the state must be earlier than October 31, 2021, and must not be any earlier than the day prior to the attestation deadline for Medicaid EPs attesting to that state.

(5) For the CY 2019 payment year and beyond, a state-specific listing of which clinical quality measures selected by CMS are considered to be high priority measures for purposes of Medicaid EP clinical quality measure reporting.

* * * * *

Dated: October 26, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 30, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Appendix 1: Finalized MIPS Quality Measures

Note: Except as otherwise finalized in this final rule, previously finalized measures and specialty measure sets will continue to apply for the 2021 MIPS payment year and future years.

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TABLE Group A: Finalized New Quality Measures for Inclusion in MIPS for the 2021 MIPS Payment Year and Future Years

A.1. Continuity of Pharmacotherapy for Opioid Use Disorder

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	468
Description:	Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.
Measure Steward:	University of Southern California
Numerator:	Adults in the denominator who have at least 180 days of continuous pharmacotherapy with a medication prescribed for OUD without a gap of more than 7 days.
Denominator:	Adults aged 18 years and older who had a diagnosis of OUD.
Exclusions:	Pharmacotherapy for OUD initiated after June 30th of performance period.
Measure Type:	Process
Measure Domain:	Effective Clinical Care
High Priority Measure:	Yes (Appropriate Use and Opioid-Related)
Collection Type:	MIPS CQMs Specifications
Rationale:	We are adopting this measure because the opioid epidemic is immensely affecting the nation and it is imperative to measure opioid use. This clinical concept is currently not represented within MIPS. There are three existing opioid use related measures for MIPS but none cover the topic of pharmacotherapy. This measure captures patients diagnosed with opioid use disorder (OUD) who are receiving and adhering to the prescribed therapy. The performance data provided by the measure steward supports there is opportunity for improvement. Based on the measure steward research, only about a quarter to a third of individuals with commercial insurance or Medicaid coverage taking medication for OUD remained on the medication for at least 180 days without a gap of more than 7 days. The MAP acknowledged the public health importance of measures that address opioid use disorder and noted the gap in this area. However, the MAP recognized that the current measure is specified and tested at the health plan and state level and recommended the measure be refined and resubmitted prior to rulemaking because the measure has not been tested or endorsed at the clinician or clinician group level. While we agree that the measure should be tested at the clinician level, we believe there is an urgent need for measures that address the opioid epidemic affecting the nation. We believe that the health plan level version of the measure can be adapted to the clinician level by revising the measure analytics to assess the proportion of patients with opioid use disorder that achieve continuity of pharmacotherapy aggregated at the clinician level. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

Comment: One commenter supported adoption of new measure Q468: Continuity of Pharmacotherapy for Opioid Use Disorder, but has concerns about the potential for confounders in the measure data sources. The commenter urged CMS to consider, and account for the possibilities of confounders as the agency determines whether and how to adopt this measure.

Response: We thank the commenter for their support. We will work with the measure steward to consider accounting for confounders when implementing this measure, but maintain the notion that the measure is appropriate for implementation. This measure also addresses an at-risk population not addressed within MIPS measures which outweighs the risk of potential variables.

FINAL ACTION: We are finalizing the *Continuity of Pharmacotherapy for Opioid Use Disorder* measure as proposed for the 2019 Performance Period and future years.

A.2. Average Change in Functional Status Following Lumbar Spine Fusion Surgery

Category	Description
NQF #:	2643
Quality #:	469
Description:	For patients age 18 and older undergoing lumbar spine fusion surgery, the average change from pre-operative functional status to 1 year (9 to 15 months) post-operative functional status using the Oswestry Disability Index (ODI version 2.1a) patient reported outcome tool.
Measure Steward:	Minnesota Community Measurement
Numerator:	The average change (preoperative to 1 year post-operative) in functional status for all patients in the denominator. There is not a traditional numerator for this measure; the measure calculating the average change in functional status score from pre-operative to post-operative functional status score. The measure is NOT aiming for a numerator target value for a post-operative ODI score. The average change is calculated as follows: Change is first calculated for each patient and then changed scores are summed and then an average is determined. Measure calculation takes into account those patients that have an improvement and those patients whose function decreases post-operatively. For example: Patient Pre-op ODI :I Post-op ODI :I Change in ODI Patient A: I 47 :I 18 :I 29 Patient B: I 45 :I 52 :I -7 Patient C: I 56 :I 12 :I 44 Patient D: I 62 :I 25 :I 37 Patient E: I 42 :I 57 :I -15 Patient F: I 51 :I 10 :I 41 Patient G: I 62 :I 25 :I 37 Patient H: I 43 :I 20 :I 23 Patient I: I 74 :I 35 :I 39 Patient J: I 59 :I 23 :I 36 Average change in ODI 1 year post-op 26.4 points on a 100 point scale
Denominator:	Eligible Population: Patients with lumbar spine fusion procedures (Arthrodesis Value Set) occurring during a 12-month period for patients age 18 and older at the start of that period. Denominator: Patients within the eligible population whose functional status was measured by the Oswestry Disability Index, version 2.1a (ODI, v2.1a) within 3 months preoperatively AND at 1 year (+/- 3 months) postoperatively. *The measure of average change in function can only be calculated if both a pre-operative and post-operative PRO assessment are completed
Exclusions:	The following exclusions must be applied to the eligible population: Patient had cancer (Spine Cancer Value Set), fracture (Spine Fracture Value Set) or infection (Spine Infection Value Set) related to the spine. Patient had idiopathic or congenital scoliosis (Congenital Scoliosis Value Set)
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes
High Priority Measure:	Yes (Patient Reported Outcome)
Collection Type:	MIPS CQMs Specifications
Rationale:	We are adopting this measure because it measures an important patient reported outcome evaluating the functional status change from pre- to post-operative. Results of the measure can be used by clinicians in evaluating whether the patient's functional status has improved post-operatively. The MAP supported this measure for rulemaking and recognized that improvement in functional status is an important outcome to patients and was encouraged by the potential addition of more patient-reported outcome measures to the MIPS set. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

Comment: One commenter supported this new measure and applauded CMS for proposing to adopt four patient-reported outcome measures. The commenter stated that patient-reported outcomes reflect issues that are important to patients and provide a valuable perspective on care that cannot be obtained from other data sources (for example, severity of pain, physical functioning). Another commenter is pleased this measure emphasizes the change in functional status.

Response: We thank the commenters for their support.

Comment: One commenter recommended using the Patient-Reported Outcome Measurement Information System (PROMIS) as an alternative to the Oswestry Disability Index (ODI) as the functional status assessment basis for this quality measure.

Response: The measure steward has developed and tested this measure using the ODI tool to assess the change in functional status. We do not believe that the PROMIS scale will add value to this quality measure. Rather, we believe that the addition of the PROMIS scale introduces variability and would not provide a standardized tool to assess functional status. We do not own this measure and encourage the commenter to collaborate with the measure steward to expand the assessment tools.

Comment: One commenter did not support the addition of this measure, stating that the validity, reliability, and informativeness of PROMs are uncertain.

Response: Although we agree PROMs can be challenging to implement, the measure steward has fully tested this measure for validity and reliability to obtain NQF

Category	Description
	endorsement. PROMs have been deemed one of our priorities as it is important to ensure patients are engaged in their care and are an important component in evaluating outcomes. The Oswestry Disability Index is a standardized tool that will allow eligible clinicians to track the progress of their patient's functional improvement. Therefore, we respectfully disagree that PROMs are not informative for improving patient outcomes and clinician quality performance. **FINAL ACTION:** We are finalizing the *Average Change in Functional Status Following Lumbar Spine Fusion Surgery* measure as proposed for the 2019 Performance Period and future years.

A.3. Average Change in Functional Status Following Total Knee Replacement Surgery

Category	Description
NQF #:	2653
Quality #:	470
Description:	For patients age 18 and older undergoing total knee replacement surgery, the average change from pre-operative functional status to 1 year (9 to 15 months) post-operative functional status using the Oxford Knee Score (OKS) patient reported outcome tool.
Measure Steward:	Minnesota Community Measurement
Numerator:	There is not a traditional numerator for this measure; the measure is calculating the average change in functional status score from pre-operative to post-operative functional status score. The measure is NOT aiming for a numerator target value for a post-operative OKS score. For example: The average change in knee function was an increase of 15.9 points 1 year post-operatively on a 48 point scale. The average change is calculated as follows: Change is first calculated for each patient and then changed scores are summed and then an average is determined. Measure calculation takes into account patients who have an improvement and patients whose function decreases post-operatively. For example: Patient Pre-op OKS:I Postop OKS:I Change in OKS Patient A: I 33 :I 45 :I 12 Patient B: I 17 :I 39 :I 22 Patient C: I 16 :I 31 :I 15 Patient D: I 23 :I 40 :I 17 Patient E: I 34 :I 42 :I 8 Patient F: I 10 :I 42 :I 32 Patient G: I 14 :I 44 :I 30 Patient H: I 32 :I 44 :I 12 Patient I: I 19 :I 45 :I 26 Patient J: I 26 :I 19 :I -7 Patient K: I 24 :I 43 :I 19 Patient L: I 29 :I 34 :I 5 Patient M : I 23 :I 39 :I 16 Patient N: I 29 :I 45 :I 16 Patient O: I 29 :I 45 :I 16 Patient P: I 34 :I 41 :I 7 Patient Q: I 11 :I 14 :I 3 Patient R: I 13 :I 39 :I 26 Patient S: I18 :I 45 :I 27 Average change in OKS 1 year post-op 15.9 points on a 48 point scale
Denominator:	Eligible Population: Patients with total knee replacement procedures (Primary TKR Value Set, Revision TKR Value Set) occurring during a 12-month period for patients age 18 and older at the start of that period. Denominator: Patients within the eligible population whose functional status was measured by the Oxford Knee Score within 3 months preoperatively AND at 1 year (+/- 3 months) postoperatively *The measure of average change in function can only be calculated if both a pre-operative and post-operative PRO assessment are completed
Exclusions:	None
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes
High Priority Measure:	Yes (Patient Reported Outcome)
Collection Type:	MIPS CQMs Specifications
Rationale:	We are adopting this measure because it measures an important patient reported outcome evaluating the functional status change from pre- to post-operative. Results can be used by clinicians in evaluating whether the patient's functional status has improved post-operatively. The MAP supported this measure for rulemaking and recognized that improvement in functional status is an important outcome to patients and was encouraged by the potential addition of more patient-reported outcome measures to the MIPS set. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

Comment: One commenter supported this new measure and applauded CMS for proposing to adopt four patient-reported outcome measures. They stated that patient-reported outcomes reflect issues that are important to patients and provide a valuable perspective on care that cannot be obtained from other data sources (for example, severity of pain, physical functioning). Several commenters are pleased this measure emphasizes the change in functional status and said that CMS should consider development of additional short and long-term outcomes measures for total joint procedures.

Response: We thank the commenters for their support.

Comment: One commenter recommended using the Patient-Reported Outcome Measurement Information System (PROMIS) as an alternative to the Oxford Knee Score (OKS) as the functional status assessment basis for this quality measure. A second commenter expressed concern that the OKS is a proprietary tool and that there are a number of validated tools available. Another commenter recommended the use of KOOS Jr and other potential measuring surveys to be available for use. The commenter also stated that KOOS Jr. and HOOS Jr. tools were selected as the preferred measurement instruments by the national orthopaedic specialty societies due to the ease of the tools.

Response: We thank the commenters for their input. The measure steward has developed and tested this measure using the OKS tool to assess the change in functional status. We do not believe that the introduction of additional tools (PROMIS, KOOS Jr, HOOS Jr.) will add value to this quality measure. Rather, we believe that the addition tools introduce variability and would not provide a standardized tool to assess functional status. We do not own this measure and encourage the commenter to collaborate with the measure steward to expand the assessment tools. In addition, it would not be appropriate to include the

Category	Description
HOOS Jr. survey since the patient population within this measure includes patients that have had a total knee replacement procedure. The HOOS Jr. is used to assess hip injuries and osteoarthritis. **Comment:** One commenter did not support the addition of this measure, stating that the validity, reliability, and informativeness of PROMs are uncertain. **Response:** Although we agree PROMs can be challenging to implement, the measure steward has fully tested this measure for validity and reliability to obtain NQF endorsement. PROMs have been deemed one of our priorities as it is important to ensure patients are engaged in their care and are an important component in evaluating outcomes. Therefore, we respectfully disagree that PROMs are not informative for improving patient outcomes and clinician quality performance. **FINAL ACTION:** We are finalizing the *Average Change in Functional Status Following Total Knee Replacement Surgery* measure as proposed for the 2019 Performance Period and future years.	

A.4. Average Change in Functional Status Following Lumbar Discectomy Laminotomy Surgery

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	471
Description:	For patients age 18 and older undergoing lumbar discectomy laminotomy surgery, the average change from pre-operative functional status to 3 months (6 to 20 weeks) post-operative functional status using the Oswestry Disability Index (ODI version 2.1a) patient reported outcome tool.
Measure Steward:	Minnesota Community Measurement
Numerator:	The average change (preoperative to 3 months post-operative) in functional status for all patients in the denominator. There is not a traditional numerator for this measure; the measure is calculating the average change in functional status score from pre-operative to post-operative functional status score. The measure is NOT aiming for a numerator target value for a post-operative ODI score. The average change is calculated as follows: Change is first calculated for each patient and then changed scores are summed and then an average is determined. Measure calculation takes into account those patients that have an improvement and those patients whose function decreases post-operatively. For example: Patient Pre-op ODI :I Post-op ODI :I Change in ODI Patient A: I 47 :I 18 :I 29 Patient B: I 45 :I 52 :I -7 Patient C: I 56 :I 12 :I 44 Patient D: I 62 :I 25 :I 37 Patient E: I 42 :I 57 :I -15 Patient F: I 51 :I 10 :I 41 Patient G: I 62 :I 25 :I 37 Patient H: I 43 :I 20 :I 23 Patient I: I 74 :I 35 :I 39 Patient J: I 59 :I 23 :I 36 Average change in ODI 3 months post-op 26.4 points on a 100-point scale
Denominator:	Eligible Population: Patients with lumbar discectomy laminotomy procedure (Single Disc-Lami Value Set) for a diagnosis of disc herniation (Disc Herniation Value Set)) occurring during a 12-month period for patients age 18 and older at the start of that period. Denominator: Patients within the eligible population whose functional status was measured by the Oswestry Disability Index, version 2.1a (ODI, v2.1a) within 3 months preoperatively AND at 3 months (6 to 20 weeks) postoperatively. *The measure of average change in function can only be calculated if both a pre-operative and post-operative PRO assessment are completed.
Exclusions:	The following exclusions must be applied to the eligible population: Patient had any additional spine procedures performed on the same date as the lumbar discectomy laminotomy.
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes
High Priority Measure:	Yes (Patient Reported Outcome)
Collection Type:	MIPS CQMs Specifications
Rationale:	We are adopting this measure because it measures an important patient reported outcome evaluating the functional status change from pre- to post-operative. The results of the measure can be used by clinicians in evaluating whether the patient's functional status has improved post-operatively. The MAP conditionally supported this measure pending NQF endorsement. While we agree with MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

Comment: One commenter supported this new measure and applauded CMS for proposing to adopt four patient-reported outcome measures. They stated that patient-reported outcomes reflect issues that are important to patients and provide a valuable perspective on care that cannot be obtained from other data sources (for example, severity of pain, physical functioning). Another commenter is pleased this measure emphasizes the change in functional status.

Response: We thank the commenters for their support.

Comment: One commenter recommended using the Patient-Reported Outcome Measurement Information System (PROMIS) as an alternative to the Oswestry Disability Index (ODI) as the functional status assessment basis for this quality measure.

Response: The measure steward has developed and tested this measure using the ODI tool to assess the change in functional status. We do not believe that the PROMIS scale will add value to this quality measure. Rather, we believe that the addition of the PROMIS scale introduces variability and would not provide a standardized tool to assess functional status. We do not own this measure and encourage the commenter to collaborate with the measure steward to expand the assessment tools.

Comment: One commenter did not support the addition of this measure, stating that the validity, reliability, and informativeness of PROMs are uncertain.

Category	Description
Response: Although we agree PROMs can be challenging to implement, the measure steward has fully tested this measure for validity and reliability to obtain NQF endorsement. PROMs have been deemed one of our priorities as it is important to ensure patients are engaged in their care and are an important component in evaluating outcomes. Therefore, we respectfully disagree that PROMs are not informative for improving patient outcomes and clinician quality performance. **FINAL ACTION:** We are finalizing the *Average Change in Functional Status Following Lumbar Discectomy Laminotomy Surgery* measure as proposed for the 2019 Performance Period and future years.	

A.5. Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	472
Description:	Percentage of female patients aged 50 to 64 without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Female patients who received an order for at least one DXA scan in the measurement period.
Denominator:	Female patients ages 50 to 64 years with an encounter during the measurement period.
Exclusions:	Exclude from the denominator patients with a combination of risk factors (as determined by age) or one of the independent risk factors: • Ages: 50-54 (>=4 combo risk factors) or 1 independent risk factor • Ages: 55-59 (>=3 combo risk factors) or 1 independent risk factor • Ages: 60-64 (>=2 combo risk factors) or 1 independent risk factor Combination risk factors (The following risk factors are all combination risk factors; they are grouped by when they occur in relation to the measurement period): The following risk factors may occur any time in the patient's history but must be active during the measurement period: • White (race) • BMI <= 20 kg/m2 (must be the first BMI of the measurement period) • Smoker (current during the measurement period) • Alcohol consumption (> two units per day (one unit is 12 oz. of beer, 4 oz. of wine, or 1 oz. of liquor)) The following risk factor may occur any time in the patient's history and must not start during the measurement period: • Osteopenia The following risk factors may occur at any time in the patient's history or during the measurement period: • Rheumatoid arthritis • Hyperthyroidism • Malabsorption syndromes: celiac disease, inflammatory bowel disease, ulcerative colitis, Crohn's disease, cystic fibrosis, malabsorption • Chronic liver disease • Chronic malnutrition The following risk factors may occur any time in the patient's history and do not need to be active at the start of the measurement period: • Documentation of history of hip fracture in parent • Osteoporotic fracture • Glucocorticoids (>= 5 mg/per day) [cumulative medication duration >= 90 days] Independent risk factors (The following risk factors are all independent risk factors; they are grouped by when they occur in relation to the measurement period): The following risk factors may occur at any time in the patient's history and must not start during the measurement period: • Osteoporosis The following risk factors may occur at any time in the patient's history prior to the start of the measurement period, but do not need to be active during the measurement period: • Gastric bypass • FRAX[R] 10-year probability of all major osteoporosis related fracture >= 9.3 percent • Aromatase inhibitors The following risk factors may occur at any time in the patient's history or during the measurement period: • Type I diabetes • End stage renal disease • Osteogenesis imperfecta • Ankylosing spondylitis • Psoriatic arthritis • Ehlers-Danlos syndrome • Cushing's syndrome • Hyperparathyroidism • Marfan syndrome • Lupus
Measure Type:	Process
Measure Domain:	Efficiency and Cost Reduction
High Priority measure:	Yes (Appropriate Use)
Collection Type:	eCQM Specifications
Rationale:	We are adopting this measure because it will serve as a counterbalance to the existing measure of appropriate use (that is, Screening for Osteoporosis for Women Aged 65-85 Years of Age (Quality ID #039)). This measure addresses the inappropriate use of DXA scans for

Category	Description
	women age 50 – 64 years without risk factors for osteoporosis. The MAP recognized the need for early detection of osteoporosis but reiterated the importance of appropriate use of this screening technique and noted this measure could be complementary to the existing osteoporosis screening measure (Quality ID #039). The MAP recognized the potential need for a balancing measure to prevent the potential underuse of DXA scans. The MAP conditionally supported this measure pending NQF endorsement. While we agree with MAP that NQF endorsement of measures is preferred, it is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

Comment: One commenter supported the addition of this measure.

Response: We thank the commenter for their support.

Comment: One commenter expressed that clinicians may not be aware of the distinction between screening DXA scans and those appropriately performed as medically necessary follow-up care in a diagnosed individual to ascertain response to pharmacological interventions. The commenter urged CMS to clarify this distinction within its final rule and consider augmenting the pharmacologic therapy quality measure with a subpart that captures appropriate DXA re-testing to ascertain response to treatment. A second commenter urged CMS to defer implementing any quality measures that might deter osteoporosis screening until most men and women who are at heightened risk of fragility fractures receive testing and pharmacotherapy within the standard of care.

Response: Thank you for your comment and support of the DXA screening measure. We affirm that the intent of this measure is to encourage screening in the population at greatest risk for osteoporosis and assess progress toward appropriate screening. We appreciate your suggestion for an additional measure on appropriate screening as a follow-up to pharmacologic therapy in the treatment of osteoporosis and will give consideration to developing such a measure. This measure includes a number of applicable risk factors that would remove the at-risk patient from the denominator. The intended patient population is not considered high risk where a DXA scan is not appropriate. This measure does not deter appropriate osteoporotic screening for patients that meet the risks factors.

FINAL ACTION: We are finalizing the *Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture* measure as proposed for the 2019 Performance Period and future years.

A.6. Average Change in Leg Pain Following Lumbar Spine Fusion Surgery

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	473
Description:	For patients age 18 and older undergoing lumbar spine fusion surgery, the average change from pre-operative leg pain to 1 year (9 to 15 months) post-operative leg pain using the Visual Analog Scale (VAS) patient reported outcome tool.
Measure Steward:	Minnesota Community Measurement
Numerator:	The average change (preoperative to 1 year post-operative) in leg pain for all patients in the denominator. There is not a traditional numerator for this measure; the measure is calculating the average change in leg pain score from pre-operative to post-operative leg pain score. The measure is NOT aiming for a numerator target value for a post-operative pain score. The average change is calculated as follows: Change is first calculated for each patient and then changed scores are summed and then an average is determined. Measure calculation takes into account those patients that have an improvement and those patients whose pain increases post-operatively. For example: Patient I: Pre-op VAS I: Post-op VAS I:(Pre-op minus Post-op) Patient A: I: 8.5 I: 3.5 I: 5.0 Patient F I: 7.5 I: 1.5 I: 6.0 Patient B: I: 9.0 I: 2.5 I: 6.5 Patient G I: 9.0 I: 4.5 I: 4.5 Patient C: I: 7.0 I: 0.5 I: 6.5 Patient H I: 5.5 I: 7.5 I: -2.0 Patient D: I: 6.5 I: 8.0 I: -1.5 Patient I I: 9.0 I: 5.0 I: 4.0 Patient E I: 8.5 I: 2.0 I: 6.5 Patient J I: 7.0 I: 2.5 I: 4.5 Average change in VAS points 4.0 Average change in leg pain 1 year post-op 4.0 points on a 10 point scale.
Denominator:	Eligible Population: Patients with lumbar spine fusion procedures (Arthrodesis Value Set) occurring during a 12-month period for patients age 18 and older at the start of that period. Denominator: Patients within the eligible population whose leg pain was measured by the Visual Analog Scale (VAS) within 3 months preoperatively AND at 1 year (+/- 3 months) postoperatively. *The measure of average change in function can only be calculated if both a pre-operative and post-operative PRO assessment are completed
Exclusions:	The following exclusions must be applied to the eligible population: Patient had cancer (Spine Cancer Value Set), fracture (Spine Fracture Value Set) or infection (Spine Infection Value Set) related to the spine. Patient had idiopathic or congenital scoliosis (Congenital Scoliosis Value Set)
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes
High priority measure:	Yes (Patient Reported Outcome)
Collection Type:	MIPS CQMs Specifications
Rationale:	We are adopting this measure because it evaluates the management of pain from pre- to post-operative, which represents an important patient reported outcome. The results can be used by clinicians in evaluating whether the patient's pain has reduced post-operatively. The MAP conditionally supported this measure pending NQF endorsement. While we agree with MAP that NQF endorsement of measures is preferred, it is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

Comment: One commenter supported this new measure and applauded CMS for proposing to adopt four patient-reported outcome measures. The commenter stated that patient-reported outcomes reflect issues that are important to patients and provide a valuable perspective on care that cannot be obtained from other data sources (for example, severity of pain, physical functioning).

Response: We thank the commenter for their support.

Comment: One commenter did not support the addition of this measure, stating that the validity, reliability, and informativeness of PROMs are uncertain.

Response: Although we agree PROMs can be challenging to implement, the measure steward has fully tested this measure for validity and reliability to obtain NQF endorsement. PROMs have been deemed one of our priorities as it is important to ensure patients are engaged in their care and are an important component in evaluating outcomes. Therefore, we respectfully disagree that PROMs are not informative for improving patient outcomes and clinician quality performance.

FINAL ACTION: We are finalizing the *Average Change in Leg Pain Following Lumbar Spine Fusion Surgery* measure as proposed for the 2019 Performance Period and future years.

A.7. Ischemic Vascular Disease Use of Aspirin or Anti-platelet Medication

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	Not Applicable (N/A)
Description:	The percentage of patients 18-75 years of age who had a diagnosis of ischemic vascular disease (IVD) and were on daily aspirin or anti-platelet medication, unless allowed contraindications or exceptions are present.
Measure Steward:	Minnesota Community Measurement
Numerator:	Denominator patients with documentation that the patient was on daily aspirin or anti-platelet medication during the measurement period, unless allowed contraindications or exceptions are present.
Denominator:	18 years or older at the start of the measurement period AND less than 76 years at the end of the measurement period. AND Patient had a diagnosis of ischemic vascular disease (Ischemic Vascular Disease Value Set) with any contact during the current or prior measurement period OR had ischemic vascular disease (Ischemic Vascular Disease Value Set) present on an active problem list at any time during the measurement period. AND At least one established patient office visit (Established Pt Diabetes & Vasc Value Set) for any reason during the measurement period
Exclusions:	The following exclusions are allowed to be applied to the eligible population: • Patient was a permanent nursing home resident at any time during the measurement period. • Patient was in hospice or receiving palliative care at any time during the measurement period. • Patient died prior to the end of the measurement period. • Patient had only urgent care visits during the measurement period.
Measure Type:	Process
Measure Domain:	Effective Clinical Care
High priority measure:	No
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Rationale:	We proposed this measure because the measure exclusions are more appropriate than those in the currently adopted Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic (Quality ID #204) measure. The measure accounts for history of gastrointestinal bleeding, intracranial bleeding, bleeding disorder, allergy to aspirin or anti-platelets, or use of non-steroidal anti-inflammatory agents. The MAP acknowledged both that clinicians may still report Aspirin or Anti-platelet Medication measures separately from the composite to drive quality improvement. The MAP conditionally supported this measure with the condition that there are no competing measures in the program. We refer readers to Table C where we are removing Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic (Quality ID #204). Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

Comment: A commenter recommended utilizing the Core Quality Measure Collaborative (CQMC) to evaluate both the Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet measure and the measure CMS proposed to replace it with a new measure: Ischemic Vascular Disease: Use of Aspirin or Antiplatelet Medication, during their maintenance review of the ACO/PMH/PC Core Measure Set. This will allow payers, clinicians, and other stakeholders to weigh in on the measures' exclusion criteria and other characteristics. Another commenter encouraged CMS to continue alignment of the MIPS measure set with those recommended by the CQMC. Another commenter opposed the proposed adoption of this measure because they believe that it is already captured in the Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) measure and recommended not including such a measure in the program where it could displace reporting of the higher-value composite measure.

Response: We appreciate the suggestion to allow stakeholders to weigh in on the exclusion criteria; however, we do not steward either of the measures and may not have the flexibility to revise the measures based on payers, clinicians or other stakeholders' feedback. Engaging the CQMC is beneficial to obtaining stakeholder feedback, but we encourage the commenter to provide this feedback to the CQMC. We are aware that this new measure is captured in the composite measure Q441 and that the composite measure is more robust. Although we believe Q441 may be burdensome to some eligible clinicians, we also believe it is a more meaningful measure than this new IVD measure. Therefore, to be consistent with our policy to remove measures that are duplicative to other measures and to ensure measures are more meaningful, we have decided to not finalize inclusion of this new IVD measure.

FINAL ACTION: We are not finalizing the *Ischemic Vascular Disease Use of Aspirin or Anti-platelet Medication* measure as proposed for the 2019 Performance Period.

A.8. Zoster (Shingles) Vaccination

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	474
Description:	The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.
Measure Steward:	PPRNet
Numerator:	Patients with a shingles vaccine ever recorded.
Denominator:	Patients 50 years of age and older.
Exclusions:	None
Measure Type:	Process
Measure Domain:	Community/Population Health
High priority measure:	No
Collection Type:	MIPS CQMs Specifications
Rationale:	We are adopting this measure because there are no measures currently in MIPS that address shingles vaccination for patients 50 years and older as recommended by the CDC. The MAP concluded that this measure would address the important topic of adult immunization. It discussed the new guidelines under development for the Zoster vaccination that could impact the amount of doses, the age of administration, and the specific vaccine that is used, but also noted that guidelines are constantly evolving and measures should be routinely updated based on changing guidelines. The MAP conditionally supported this measure pending NQF endorsement, and specifically requested evaluating the measure to ensure it has appropriate exclusions and reflects the most current CDC guidelines given the concerns about the cost of the vaccine and potential concerns about administering to immunocompromised patients. While we agree with MAP that NQF endorsement of measures is preferred, it is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

Comment: One commenter did not support the proposed adoption of this measure because it needs to be updated to reflect the most recent clinical guidelines.

Response: The measure steward has aligned this measure with the most current clinical guidelines and it will be implemented as such. As indicated in our rationale, the measure will address the impacts to the amount of doses, the age of administration and the specific vaccine utilized. This measure addresses an important gap in adult immunization.

Comment: Several commenters noted that the proposed rule rationale of "60 years and older" should be "50 years and older."

Response: We thank the commenters for their concerns regarding the age criteria with the rationale. The correct age was included in the description and denominator within the proposed rule, but did not align with the rationale. We agree with the denominator including patients over the age of 50 years and aligned the rationale with the measure's age criteria.

Comment: One commenter supported the proposed new measure for Zoster (Shingles) Vaccination. The commenter also supported broader adoption of a herpes zoster measure across specialty sets to reduce the number of missed immunization opportunities for this debilitating condition. The commenter supported the alignment of reporting mechanisms and believed doing so will strengthen and enhance the development and implementation of adult immunization quality measures.

Response: We thank the commenter for their support of the new measure, Zoster (Shingles) Vaccination.

FINAL ACTION: We are finalizing the *Zoster (Shingles) Vaccination* measure as proposed for the 2019 Performance Period and future years. The rationale is updated to state "patients 50 years and older" which aligns with the description and denominator age criteria.

A.9. HIV Screening

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	475
Description:	Percentage of patients 15-65 years of age who have ever been tested for human immunodeficiency virus (HIV).
Measure Steward:	Centers for Disease Control and Prevention
Numerator:	Patients with documentation of the occurrence of an HIV test between their 15th and 66th birthdays and before the end of the measurement period.
Denominator:	Patients 15 to 65 years of age who had an outpatient visit during the measurement period.
Exclusions:	Patients diagnosed with HIV prior to the start of the measurement period.
Measure Type:	Process
Measure Domain:	Community/Population Health
High priority measure:	No
Collection Type:	eCQM Specifications
Rationale:	We are adopting this measure because HIV screening is a national and global priority. While there are three currently adopted HIV measures in MIPS, they do not include screening the general population. The MAP acknowledged the importance of HIV screening from a population health perspective, but also questioned whether encouraging HIV screening through the MIPS program is the most effective strategy for improving this population health goal. It also expressed concern about how this measure under consideration identified individuals who may have a HIV screening in the community. Additionally, several MAP members expressed concern regarding the specifications requiring one time lifetime screening. The MAP conditionally supported this measure pending NQF endorsement. While we agree with MAP that NQF endorsement of measures is preferred, it is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

Comment: One commenter did not support the proposed adoption of this measure because they stated that there is no demonstrated performance gap (measure testing results showed very high performance overall) and the measure still needs to be tested at the clinician-level.

Response: We believe it is important to implement an HIV screening measure as it addresses an important national and global priority. This measure has been developed as an eCQM Specification and should have little burden in the submission of this measure. The version of this measure proposed has been tested at the clinician-level. The measure steward developed and tested a previous version of this measure at the community center-level. The NQF Health and Well-Being 2015-2017 Committee reviewed this facility-level version of the measure and voted to pass the measure on evidence and performance gap, but decided the measure did not meet the scientific acceptability criteria. The NQF standing committee noted that when this previous version of the measure was tested at the facility-level a performance gap was demonstrated, performance at four community health centers ranged from 20.6 to 31.1 percent and performance at a fifth community health center serving a high-risk population was 65.3 percent (NQF, Health and Well-Being 2015-2017: Technical Report, April 17, 2017, http://www.qualityforum.org/Projects/h/Health_and_Well_Being_2015-2017/Final_Report.aspx). Since then, the measure steward modified the measure and tested it at the clinician-level. As we indicated in our proposal, the MAP reviewed this clinician-level version of the measure in 2018 and conditionally supported it pending NQF review and endorsement. The steward plans to seek NQF endorsement on this clinician-level measure. We believe implementing this measure at the clinician-level will raise awareness and improve patient care leading to improvement in population health.

FINAL ACTION: We are finalizing the *HIV Screening* measure as proposed for the 2019 Performance Period and future years.

A.10. Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Category	Description
NQF #:	0101
Quality #:	Not Applicable (N/A)
Description:	This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates: **Screening for Future Fall Risk:** Percentage of patients aged 65 years and older who were screened for future fall risk at least once within 12 months. **Falls Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months. **Plan of Care for Falls:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.
Measure Steward:	National Committee for Quality Assurance
Numerator:	This measure has three rates. The numerators for the three rates are as follows: A) Screening for Future Fall Risk: Patients who were screened for future fall* risk** at last once within 12 months. B) Falls Risk Assessment: Patients who had a risk assessment*** for falls completed within 12 months. C) Plan of Care for Falls: Patients with a plan of care**** for falls documented within 12 months. *A fall is defined as a sudden, unintentional change in position causing an individual to land at a lower level, on an object, the floor, or the ground, other than as a consequence of a sudden onset of paralysis, epileptic seizure, or overwhelming external force. **Risk of future falls is defined as having had had 2 or more falls in the past year or any fall with injury in the past year. ***Risk assessment is comprised of balance/gait assessment AND one or more of the following assessments: postural blood pressure, vision, home fall hazards, and documentation on whether medications are a contributing factor or not to falls within the past 12 months. ****Plan of care must include consideration of vitamin D supplementation AND balance, strength and gait training.
Denominator:	A) Screening for Future Fall Risk: All patients aged 65 years and older seen by an eligible provider in the past year. B & C) Falls Risk Assessment & Plan of Care for Falls: All patients aged 65 years and older seen by an eligible provider in the past year with a history of falls (history of falls is defined as 2 or more falls in the past year or any fall with injury in the past year).
Exclusions:	Patients who have documentation of medical reason(s) for not screening for future fall risk, undergoing a risk-assessment or having a plan of care (for example, patient is not ambulatory) are excluded from this measure.
Measure Type:	Process
Measure Domain:	Patient Safety
High Priority Measure:	Yes
Collection Type:	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Rationale:	We are adopting this measure because it is a combined version of three of the currently adopted measures 154: Falls: Risk Assessment, 155: Falls: Plan of Care and 318: Falls: Screening for Future Fall Risk. The new combined Falls measure (based on specifications in NQF 0101) is more robust and will include strata components for Future Falls Risk, Falls Risk Assessment, and Falls Risk Plan of Care which creates a more comprehensive screening measure. As noted in Table C, we are proposing to remove 154: Falls: Risk Assessment, 155: Falls: Plan of Care and 318: Falls: Screening for Future Fall Risk because they will be subsumed by this new measure. While we note that has not been put forth through the MAP for consideration in MIPS, the three individual measures have been NQF endorsed as one measure.

Comment: We received a number of comments opposing the new composite measure. Comments included a need for more clinical review, that vendors need time to develop and certify the respective replacement measures, and that CMS does not describe a benchmark for the composite measure.
Several commenters were in support of the new composite measure stating that that it is a more robust and more comprehensive screening measure.

Response: We thank all of the commenters for expressing the opposition of combining three measures to create a composite measure. We agree with the feedback provided and will postpone the implementation of the Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls measure until the measure can be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population.

FINAL ACTION: We are not finalizing the *Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls* measure for the 2019 Performance Period.

TABLE Group B: Finalized New and Modified MIPS Specialty Measure Sets for the 2021 MIPS Payment Year and Future Years

Note: In the CY 2019 PFS proposed rule (83 FR 35704), we proposed to modify the specialty measure sets below based upon review of updates made to existing quality measure specifications, the proposal of adding new measures for inclusion in MIPS, and the feedback provided by specialty societies. In the first column, existing measures with substantive changes are noted with an asterisk (*), core measures that align with Core Quality Measure Collaborative (CQMC) core measure set(s) are noted with the symbol (§) and high priority measures are noted with an exclamation point (!). In addition, the Indicator column includes a "high priority type" in parentheses after each high priority indicator (!) to fully represent the regulatory definition of high priority measures.

As discussed in section III.I.3.h.(2)(b)(i) of this final rule, we are amending the definition of high priority at §414.1305 to include opioid-related measures. We define high priority measure to mean an outcome, appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. Outcome measures include outcome, intermediate outcome, and patient reported outcome. A high priority indicator (an exclamation point (!)) in the Indicator column has been added for all opioid-related measures.

The following specialty measure sets have been excluded from this final rule, because we did not propose any changes to these sets: Allergy/Immunology, Electro-Physiology Cardiac Specialist, Plastic Surgery, Interventional Radiology, Dentistry and Hospitalists. Therefore, we refer readers to these finalized specialty sets in the CY 2018 Quality Payment Program final rule (82 FR 53976 through 54146). Note: In the proposed rule, we inadvertently included the Dentistry specialty set even though no changes were proposed for this specialty set; therefore, we removed the Dentistry specialty set from this final rule because we did not receive any comments specific to the Dentistry specialty set from previous final rules or the proposed rule.

B.1. Anesthesiology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Anesthesiology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 426 and 427.

B.1. Anesthesiology

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0236	044	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery:** Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC)-Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists
! (Outcome)	N/A	404	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Anesthesiology Smoking Abstinence:** The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists
! (Outcome)	2681	424	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Perioperative Temperature Management:** Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was achieved within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists
! (Patient Safety)	N/A	430	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively or intraoperatively.	American Society of Anesthesiologists
	N/A	463	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Prevention of Post-Operative Vomiting (POV) - Combination Therapy (Pediatrics):** Percentage of patients aged 3 through 17 years of age, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
We did not receive specific comments regarding the measures included in this specialty measure set. **FINAL ACTION:** We are finalizing the *Anesthesiology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.								

B.1. Anesthesiology (continued)

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, the following measure(s) are removed from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	426	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU):** Percentage of patients, regardless of age, who are under the care of an anesthesia practitioner and are admitted to a PACU or other non-ICU location in which a post-anesthetic formal transfer of care protocol or checklist which includes the key transfer of care elements is utilized.	American Society of Anesthesiologists	This measure is removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future."
N/A	427	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU):** Percentage of patients, regardless of age, who undergo a procedure under anesthesia and are admitted to an Intensive Care Unit (ICU) directly from the anesthetizing location, who have a documented use of a checklist or protocol for the transfer of care from the responsible anesthesia practitioner to the responsible ICU team or team member.	American Society of Anesthesiologists	This measure is removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

We did not receive specific comments regarding the proposed removal of measures from this specialty measure set.

FINAL ACTION: We are finalizing the removal of measures from the *Anesthesiology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.2. Cardiology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Cardiology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 204 and 373.

B.2. Cardiology

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	0081	005	CMS135 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40 percent who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Stable Coronary Artery Disease: Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070	007	CMS145 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40** percent**):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have prior MI OR a current or prior LVEF < 40 percent who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0083	008	CMS144 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40 percent who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan	National Committee for Quality Assurance
§	0066	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Stable Coronary Artery Disease: ACE Inhibitor or ARB Therapy--Diabetes or Left Ventricular Systolic Dysfunction (LVEF <40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40 percent who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
*	0421	128	CMS69v	Medicare Part	Process	Community/	**Preventive Care and Screening: Body Mass**	Centers for

B.2. Cardiology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§			7	B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications		Population Health	**Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Medicare & Medicaid Services
! (Patient Safety)	0419	130	CMS68v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§	0028	226	CMS138 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Outcome)	0018	236	CMS165 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Inter-mediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
! (Patient Safety)	0022	238	CMS156 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance

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MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0643	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP).	Centers for Medicare & Medicaid Services
! (Efficiency)	N/A	322	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low risk surgery patients 18 years or older for preoperative evaluation during the 12-month reporting period.	American College of Cardiology
! (Efficiency)	N/A	323	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI):** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status.	American College of Cardiology
! (Efficiency)	N/A	324	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment.	American College of Cardiology
§	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with a diagnosis of nonvalvular atrial fibrillation (AF) or atrial flutter whose assessment of the specified	American Heart Association

B.2. Cardiology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Specifications			thromboembolic risk factors indicate one or more high-risk factors or more than one moderate risk factor, as determined by CHADS2 risk stratification, who are prescribed warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism.	
! (Outcome)	N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery**.**	Society for Vascular Surgeons
! (Care Coordination)	N/A	374	CMS50v 7	eCQM Specifications, MIPS CQMs Specifications	Process	Communicati on and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Population/ Community	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI)
	N/A	438	CMS347 v2	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermedi ate Outcome	Effective Clinical Care	**Ischemic Vascular Disease All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must	Wisconsin Collaborativ e for Healthcare Quality

B.2. Cardiology

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- And • Most recent tobacco status is Tobacco Free -- And • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- And • Statin Use Unless Contraindicated	(WCHQ)
§	0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Persistent Beta Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who received were prescribed persistent beta-blocker treatment for 6 months after discharge.	National Committee for Quality Assurance

Comment: One commenter supported the inclusion of measure Q243: Cardiac Rehabilitation Patient Referral from an Outpatient Setting measure in this measure set. The commenter noted that the inclusion of the performance measure, in the MIPS Cardiology Specialty Measure Sets is a first and important step in improving physician referral habits; however, the commenter stated that it will also be important to include the corresponding measure, Cardiac Rehabilitation Patient Referral from an Inpatient Setting as well.

Response: We encourage the commenter to work with measures' developers to submit new measures through the Call for Measures process to include the measure related to the inpatient setting.

FINAL ACTION: We are finalizing the *Cardiology Specialty Measure Set* as proposed for the 2019 Performance Period and future years with the exception of Ischemic Vascular Disease Use of Aspirin or Anti-platelet Medication. We are no longer finalizing the inclusion of this measure as it is duplicative of a component within Q441: Ischemic Vascular Disease All or None Outcome Measure (Optimal Control).

B.2. Cardiology

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0068	204	CMS164v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet:** Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period.	National Committee for Quality Assurance	This measure is removed from the 2019 program based on the detailed below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	373	CMS65v8	eCQM Specifications	Intermediate Outcome	Effective Clinical Care	**Hypertension: Improvement in Blood Pressure:** Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.	Centers for Medicare & Medicaid Services	This measure is removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

We did not receive specific comments regarding the proposed removal of measures from this specialty measure set.

FINAL ACTION: We are finalizing the removal of measures from the *Cardiology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.3. Gastroenterology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Gastroenterology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we are not finalizing our proposal to remove Quality ID: 185 (MIPS CQMs Specifications) from the specialty set, but we are finalizing our proposal to remove Quality ID: 185 (Medicare Part B Claims Measure Specifications). Therefore, Q185 is now included in this measure set table for the final rule with MIPS CQMs Specifications as the collection type.

B.3. Gastroenterology

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421	128	CMS69v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	CMS68v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§ !	0659	185	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior adenomatous polyp(s) in previous colonoscopy findings, who had an interval of 3 or more years since their last colonoscopy.	American Gastroenterological Association
§	0028	226	CMS138v7	Medicare Part B Claims Measure	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:**	Physician Consortium for

B.3. Gastroenterology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications			a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Performance Improvement Foundation (PCPI®)
§	N/A	271	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment:** Percentage of patients with an inflammatory bowel disease encounter who were prescribed prednisone equivalents greater than or equal to 10 mg/day for 60 or greater consecutive days or a single prescription equating to 600 mg prednisone or greater for all fills and were documented for risk of bone loss once during the reporting year or the previous calendar year. Individuals who received an assessment for bone loss during the prior or current year are considered adequately screened.	American Gastro-enterological Association
§	N/A	275	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastro-enterological Association
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	0658	320	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 50 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.	American Gastroentero logical Association
§ ! (Outcome)	N/A	343	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Screening Colonoscopy Adenoma Detection Rate Measure:** The percentage of patients age 50 years or	American Society for Gastrointesti

B.3. Gastroenterology

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							older with at least one conventional adenoma or colorectal cancer detected during screening colonoscopy.	nal Endoscopy
! (Care Coordination)	N/A	374	CMS50v7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	390	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient. To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment.	American Gastroentero logical Association
§	N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis**: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroentero logical Association
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	N/A	425	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Photodocumentation of Cecal Intubation:** The rate of screening and surveillance colonoscopies for which photodocumentation of at least two landmarks of cecal intubation is performed to establish a complete examination.	American Society for Gastrointesti nal Endoscopy
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening	Physician Consortium for Performance Improvement Foundation

B.3. Gastroenterology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	(PCPI®)
§ ! (Efficiency)	N/A	439	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Age Appropriate Screening Colonoscopy:** The percentage of patients greater than 85 years of age who received a screening colonoscopy from January 1 to December 31.	American Gastroenterological Association

Comment: A few commenters did not support removal of measure Q185: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use. One commenter noted that updated guidelines on the appropriate follow-up interval for patients with a history of adenomatous polyps are set to be released in the near future. This commenter noted that it is likely that the measure specifications will be updated at that point, which may alter clinician performance. This commenter recommended that CMS retain the measure in MIPS until it is able to review other stakeholder concerns about measure performance, and that CMS work with the measure developer to update the MIPS measure specifications when new guidelines are released.

Response: We agree that updated guidelines could affect the performance of this measure causing the measure to have a substantive change, and therefore, may no longer have a benchmark that is considered to be topped out. We note this measure shows a 97.7 percent average performance for Medicare Part B Claims Measure Specifications while the MIPS CQMs Specification (registry) version shows less than 97 percent average performance rate. Based on our extremely topped out measure removal policy, we are only finalizing the removal of this measure from the Medicare Part B Claims Measure Specification collection type for the 2019 performance period. We will not finalize the removal of MIPS CQM s Specification collection type. We will work with the measure steward to update for the new clinical guidelines once they are released and continue to monitor the performance of the MIPS CQM Measure Specification in the future.

Comment: One commenter expressed concern about the scoring methodology of measure Q343: Screening Colonoscopy Adenoma Detection Rate as a performance rate near 100 percent would not indicate better care. The commenter stated that in a typical population about 25 percent of colonoscopies should find an adenoma to set a benchmark of 25 percent for all populations. From a clinical and performance measure perspective, while it may be true that a 0 percent or 5 percent rate would be worrisome, the commenter stated there is no reason to believe that a rate of 20 percent is worse than 30 percent or that 40 percent is better than 35 percent or 45 percent. A rate of 90 percent would be suspicious.

Response: We will explore options to alter the scoring methodology to assign higher deciles to the 25th to 35th percentiles or consider removing the measure in future rulemaking. We encourage measure stewards to explore options that address appropriate adenoma detection and submit measures for consideration to the annual Call for Measures.

Comment: One commenter indicated that the measure steward listed in the proposed rule for measure Q343: Screening Colonoscopy Adenoma Detection Rate is incorrect and asked that the measure steward be corrected.

Response: We agree with the commenter that the measure steward was incorrectly listed as the American Gastroenterological Association. This has been updated to the American Society for Gastrointestinal Endoscopy.

FINAL ACTION: We are finalizing the *Gastroenterology Specialty Measure Set* as proposed for the 2019 Performance Period and future years. As noted above, we are not finalizing the removal of measure Q185 (MIPS CQM specification) from the *Gastroenterology Specialty Measure Set* for the 2019 Performance Period and future years; therefore, measure Q185 has been added back into this measure specialty set.

B.4. Dermatology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Dermatology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measure from the specialty set: Quality ID: 224.

B.4. Dermatology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419	130	CMS68v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	137	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12-month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.	American Academy of Dermatology
! (Care Coordination)	N/A	138	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma: Coordination of Care:** Percentage of patients visits, regardless of age, with a new occurrence of melanoma, who have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within 1 month of diagnosis.	American Academy of Dermatology
§	0028	226	CMS138v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Care Coordination)	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician.	American Academy of Dermatology

B.4. Dermatology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
	N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology
! (Care Coordination)	N/A	374	CMS50v7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Outcome)	N/A	410	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver Centered Experience and Outcomes	**Psoriasis: Clinical Response to Systemic Medications:** Percentage of psoriasis vulgaris patients receiving systemic therapy who meet minimal physician-or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician- and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment	American Academy of Dermatology
! (Care Coordination)	N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma: Biopsy Reporting Time – Pathologist to Clinician:** Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma (SCC): Biopsy Reporting Time – Pathologist to Clinician: Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC) (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology

Comment: One commenter was pleased this measure set includes measures Q337: Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier and Q410: Psoriasis Clinical Response to Systemic Medication. Inclusion of these measures will advance psoriatic disease care and help to ensure that clinicians are accountable for meaningful measures that have the greatest impact on patient care.

A second commenter appreciated that CMS accepted its recommendations to update the description and expand the measure numerator and denominator.

Response: We thank the commenter for their support of these measures.

FINAL ACTION: We are finalizing the *Dermatology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.4 Dermatology (continued)

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	224	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Melanoma: Avoidance of Overutilization of Imaging Studies:** Percentage of patients, regardless of age, with a current diagnosis of stage 0 through IIC melanoma or a history of melanoma of any stage, without signs or symptoms suggesting systemic spread, seen for an office visit during the one-year measurement period, for whom no diagnostic imaging studies were ordered.	American Academy of Dermatology	This measure is removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

We did not receive specific comments regarding the proposed removal of measures from this specialty measure set.

FINAL ACTION: We are finalizing the removal of measures from the *Dermatology Measure Set* as proposed for the 2019 Performance Period and future years.

B.5. Family Medicine

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Family Medicine specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 163, 204, 334, 373, and 447.

B.5. Family Medicine

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059	001	CMS122 v7	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications, eCQM Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0 percent during the measurement period.	National Committee for Quality Assurance
§	0081	005	CMS135 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40 percent who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Stable Coronary Artery Disease: Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070	007	CMS145 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have prior MI OR a current or prior LVEF < 40 percent who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0083	008	CMS144 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40 percent who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0105	009	CMS128 v7	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on antidepressant medication treatment.	National Committee for Quality Assurance

B.5. Family Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							Two rates are reported: a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	
! (Care Coordination)	N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
! (Appropriate Use)	0069	065	CMS154v7	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months through 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or 3 days after the episode.	National Committee for Quality Assurance
! (Appropriate Use)	N/A	066	CMS146v7	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an	National Committee for Quality Assurance

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MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							antibiotic and received a group A streptococcus (strep) test for the episode.	
! (Appropriate Use)	0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology - Head and Neck Surgery
	0104	107	CMS161 v7	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Patient Experience)	N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons
	0041	110	CMS147 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
§	2372	112	CMS125 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 51 - 74 years of age who had a mammogram to screen for breast cancer.	National Committee for Quality Assurance
§	0034	113	CMS130 v7	Medicare Part B Claims Measure	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50 - 75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality

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MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications				Assurance
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.	National Committee for Quality Assurance
* §	0055	117	CMS131 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance
§	0062	119	CMS134 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy –Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	0421	128	CMS69v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	CMS68v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	0418	134	CMS2v8	Medicare Part B Claims Measure Specifications, eCQM	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the	Centers for Medicare & Medicaid Services

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MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications			encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	NA	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§	0028	226	CMS138v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Outcome)	0018	236	CMS165v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
! (Patient Safety)	0022	238	CMS156v7	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
! (Care	0643	243	N/A	MIPS CQMs Specifications	Process	Communication and Care	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:**	American Heart

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MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
Coordination)						Coordination	Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	Association
! (Opioid)	0004	305	CMS137 v7	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment within 14 days of the diagnosis. • Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance
§	0032	309	CMS124 v7	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21–64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21–64 who had cervical cytology performed every 3 years • Women age 30–64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	National Committee for Quality Assurance
	N/A	317	CMS22v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
	0101	318	CMS139 v7	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Patient Experience)	0005 & 0006	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ) Centers for Medicare & Medicaid Services

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MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							• Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	
§	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA- approved anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology -Head and Neck Surgery
! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery
	N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test	American Academy of Dermatology
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load	Health Resources and Services

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MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							less than 200 copies/mL at last HIV viral load test during the measurement year.	Administration
! (Outcome)	N/A	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization
* § ! (Outcome)	0710	370	CMS159 v7	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
*	0712	371	CMS160 v7	eCQM Specifications	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** The percentage of adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) with a diagnosis of major depression or dysthymia who have a completed PHQ-9 or PHQ-9M tool during the measurement period.	MN Community Measurement
! (Care Coordination)	N/A	374	CMS50v 7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	377	CMS90v 8	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Congestive Heart Failure:** Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	Health Services Advisory Group
	N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients regardless of age who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	1407	394	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three	Minnesota Community Measurement

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MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							age appropriate patient reported outcome tools.	
§	N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who had a follow-up evaluation conducted at least every 3 months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than 6 weeks duration evaluated for risk of opioid misuse using a brief validated instrument (for example Opioid Risk Tool, SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the 6 months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the 6 months after the fracture.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least	Physician Consortium for Performance Improvement Foundation

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MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	(PCPI®)
	N/A	438	CMS347 v2	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg; and • Most recent tobacco status is Tobacco Free; and • Daily Aspirin or Other Antiplatelet Unless Contraindicated; and • Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality (WCHQ)
§	0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Persistent Beta Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who received were prescribed persistent beta-blocker treatment for 6 months after discharge.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
§ ! (Efficiency)	N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma (MMA):** The percentage of patients 5-64 years of age during the measurement year who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75 percent of their	National Committee for Quality Assurance

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MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							treatment period.	
! (Patient Safety)	0657	464	N/A	MIPS CQMs Specifications	Process	Patient Safety, Efficiency, and Cost Reduction	**Otitis Media with Effusion (OME): Systemic Antimicrobials- Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder:** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
! (Appropriate Use)	N/A	472	CMS249 v1	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients aged 50 to 64 without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
	N/A	474	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet
	N/A	475	CMS349 v1	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients 15-65 years of age who have ever been tested for human immunodeficiency virus (HIV).	Centers for Disease Control and Prevention

Comment: One commenter indicated that opportunities to assess the immunization status of Medicare beneficiaries for should be done by the range of clinicians who care for them, including primary care and specialty clinicians. Taking advantage of each and every patient encounter to ensure that counseling and education on vaccines, based on their age and health status, and a strong clinician recommendation have been found to improve the likelihood of a patient being immunized. The commenter supported the inclusion of measure Q110: Preventive Care and Screening Influenza Immunization and measure Q111: Pneumococcal Vaccination Status for Older Adults into a number of primary care and specialty quality measure sets. Prioritizing quality measures around immunizations will help close existing measure gaps, improve upon immunization rates and health outcomes for the millions of Medicare beneficiaries. A second commenter supported inclusion of measures Q110, Q111, Q394: Immunizations for Adolescents.

Response: We thank the commenters for their support of measures Q110, Q111, and Q394.

FINAL ACTION: We are finalizing the *Family Medicine Specialty Measure Set* as proposed for the 2019 Performance Period and future year with the exception of the following newly proposed measures: Ischemic Vascular Disease Use of Aspirin or Anti-platelet Medication and Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. We are no longer finalizing the inclusion of this IVD measure as it is duplicative of a component within Q441: Ischemic Vascular Disease All or None Outcome Measure (Optimal Control). We are no longer finalizing the inclusion of the composite falls measure because it must be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population. In addition, as noted in our responses to public comments in Table C, measures Q048, Q154, Q155, and Q318 are not finalized for removal from this measure set as proposed; therefore, they will be retained in this measure set for the 2019 Performance Period and future years.

B.5. Family Medicine

MEASURES FINALIZED FOR REMOVAL

Note: In this this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0056	163	CMS123 v7	eCQM Specifications	Process	Effective Clinical Care	**Comprehensive Diabetes Care: Foot Exam:** The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the measurement year.	National Committee for Quality Assurance	This measure is removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
0068	204	CMS164 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet:** Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period.	National Committee for Quality Assurance	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	334	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis.	American Academy of Otolaryngology-Otolaryngology- Head and Neck Surgery	This measure is removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	373	CMS65v 8	eCQM Specifications	Intermediate Outcome	Effective Clinical Care	**Hypertension: Improvement in Blood Pressure:** Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.	Centers for Medicare & Medicaid Services	This measure is removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	447	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Chlamydia Screening and Follow Up:** The percentage of female adolescents 16 years of age who had a chlamydia screening test with proper follow-up during the measurement period.	National Committee for Quality Assurance	This measure is removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

We did not receive specific comments regarding the proposed removal of measures from this specialty measure set.

FINAL ACTION: We are finalizing the removal of measures from the *Family Medicine Specialty Measure Set* as proposed for the 2019 Performance Period and future years. However, as noted in our responses to public comments in Table C, we are not finalizing the following measures for removal from this measure set: Q048, Q154, Q155, and Q318.

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In addition to the considerations discussed in the introductory language of Table B in this final rule, the Internal Medicine specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 163, 204, 276, 278, 334, 373, and 447.

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MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059	001	CMS122v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0 percent during the measurement period.	National Committee for Quality Assurance
§	0081	005	CMS135v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40 percent who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Stable Coronary Artery Disease: Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070	007	CMS145v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have prior MI OR a current or prior LVEF < 40 percent who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0083	008	CMS144v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40 percent who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium For Performance Improvement
	0105	009	CMS128v7	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on	National Committee for Quality Assurance

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MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							antidepressant medication treatment. Two rates are reported: a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	
! (Care Coord-ination)	N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordinatio n)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
! (Appropriat e Use)	0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology -Head and Neck Surgery
! (Appropriat	0654	093	N/A	Medicare Part B Claims	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of**	American Academy of

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MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
e Use)				Measure Specifications, MIPS CQMs Specifications			**Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	Otolaryngology -Head and Neck Surgery
	0041	110	CMS147v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance
§ ! (Appropriat e Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** Percentage of adults 18-64 years of age with a diagnosis of acute bronchitis who were not dispensed an antibiotic prescription	National Committee for Quality Assurance
* §	0055	117	CMS131v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam**: Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance
§	0062	119	CMS134v 7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy –Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	0421	128	CMS69v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services

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MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419	130	CMS68v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	0418	134	CMS2v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§	0028	226	CMS138v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Outcome)	0018	236	CMS165v7	Medicare Part B Claims Measure	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose	National Committee for Quality

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MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications			blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	Assurance
! (Patient Safety)	0022	238	CMS156v 7	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
! (Care Coordinatio n)	0643	243	N/A	MIPS CQMs Specifications	Process	Communicatio n and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/ diagnosis who were referred to a CR program.	American Heart Association
	N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
	N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
! (Opioid)	0004	305	CMS137v 7	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment within 14 days of the diagnosis. • Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance
§	0032	309	CMS124v 7	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21–64 years of age who were screened for cervical cancer using either of the following criteria:	National Committee for Quality Assurance

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MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							• Women age 21–64 who had cervical cytology performed every 3 years • Women age 30–64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
	0101	318	CMS139v 7	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Patient Experience)	0005	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) •• Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ) Centers for Medicare & Medicaid Services
§	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA- approved anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology -Head and Neck Surgery
!	N/A	332	N/A	MIPS CQMs	Process	Efficiency and	**Adult Sinusitis: Appropriate Choice of**	American

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MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
(Appropriate Use)				Specifications		Cost Reduction	**Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without Clavulanate, as a first line antibiotic at the time of diagnosis.	Academy of Otolaryngology -Head and Neck Surgery
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery
	N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test	American Academy of Dermatology
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
! (Outcome)	N/A	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization
* § ! (Outcome)	0710	370	CMS159v7	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	MN Community Measurement
*	0712	371	CMS160v7	eCQM Specifications	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** The percentage of adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) with a diagnosis of major depression or dysthymia who have a completed PHQ-9 or PHQ-9M tool during the measurement period.	MN Community Measurement
! (Care Coordination)	N/A	374	CMS50v7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

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MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A	377	CMS90v8	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Congestive Heart Failure:** Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	Health Services Advisory Group
	N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients regardless of age who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools.	Minnesota Community Measurement
§	N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastro-enterological Association/ American Society for Gastro-intestinal Endoscopy/ American College of Gastro-enterology
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

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MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who had a follow-up evaluation conducted at least every 3 months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than 6 weeks duration evaluated for risk of opioid misuse using a brief validated instrument (for example Opioid Risk Tool, SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the 6 months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the 6 months after the fracture.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	438	CMS347v 2	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients: all considered at high risk of cardiovascular events who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease(ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none	Wisconsin Collaborative for Healthcare Quality (WCHQ)

B.6. Internal Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg; and • Most recent tobacco status is Tobacco Free; and • Daily Aspirin or Other Antiplatelet Unless Contraindicated; and • Statin Use Unless Contraindicated.	
§	0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Persistent Beta Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who received were prescribed persistent beta-blocker treatment for 6 months after discharge.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
§ ! (Efficiency)	N/A	444	NA	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma (MMA):** The percentage of patients 5-64 years of age during the measurement year who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75 percent of their treatment period.	National Committee for Quality Assurance
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder:** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
! (Appropriate Use)	N/A	472	CMS249v1	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients aged 50 to 64 without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
	N/A	474	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet
	N/A	475	CMS349v1	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients 15-65 years of age who have ever been tested for human immunodeficiency virus (HIV).	Centers for Disease Control and Prevention

Comment: One commenter supported measure Q277: Sleep Apnea: Severity Assessment at Initial Diagnosis and measure Q279: Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy in this measure set.

Response: We thank the commenter for their support.

FINAL ACTION: We are finalizing the *Internal Medicine Specialty Measure Set* as proposed for the 2019 Performance Period and future year with the exception of the following newly proposed measures: Ischemic Vascular Disease Use of Aspirin or Anti-platelet Medication and Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. We are no longer finalizing the inclusion of this IVD measure as it is duplicative of a component within Q441: Ischemic Vascular Disease All or None Outcome Measure (Optimal Control). We are no longer finalizing the inclusion of the composite falls measure because it must be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population. In addition, as noted in our responses to public comments in Table C, measures Q048, Q154, Q155, and Q318 are not finalized for removal from this measure set as proposed; therefore, they will be retained in this measure set for the 2019 Performance Period and future years. Please note that measures Q468, Q472, Q474, and Q475 were included in the proposed rule for this specialty set; however, they did not have Quality # IDs at the time they were published in the proposed rule because they were new measures. They were included at the beginning of this specialty measure set table in the proposed rule with "TBD" as the Quality # IDs. Therefore, in this final rule, we replaced "TBD" with the assigned Quality # IDs Q468, Q472, Q474, and Q475, which were established for these new measures subsequent to the proposed rule publication and included these measures at the end of this measure set table in ascending order.

B.14. Physical Medicine

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Physical Medicine specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This measure set does not have any measures removed from prior years.

B.14. Physical Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Experience)	N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons
* §	0421	128	CMS69 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	CMS68 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
!	0101	155	N/A	Medicare Part	Process	Communication	**Falls: Plan of Care:**	National

B.14. Physical Medicine

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
(Care Coordination)				B Claims Measure Specifications, MIPS CQMs Specifications		and Care Coordination	Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	Committee for Quality Assurance
! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
§	0028	226	CMS13 8v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	317	CMS22 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who had a follow-up evaluation conducted at least every 3 months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the	American Academy of Neurology

B.14. Physical Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							medical record.	
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than 6 weeks duration evaluated for risk of opioid misuse using a brief validated instrument (for example, Opioid Risk Tool, SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder:** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
We did not receive specific comments regarding the measures included in this specialty measure set. **FINAL ACTION:** We are finalizing the *Physical Medicine Specialty Measure Set* as proposed for the 2019 Performance Period and future years with the exception of the newly proposed composite measure: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. We are no longer finalizing the inclusion of the composite falls measure because it must be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population. In addition, as noted in our responses to public comments in Table C, measures Q154 and Q155 are not finalized for removal from this measure set as proposed; therefore, they will be retained in this measure set for the 2019 Performance Period and future years.								

B.15. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Preventive Medicine specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 014.

B.15. Preventive Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059	001	CMS122 v7	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications, eCQM Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0 percent during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs	Process	Person and Caregiver-Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons

B.15. Preventive Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Specifications				
	0041	110	CMS147 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
§	2372	112	CMS125 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 51 - 74 years of age who had a mammogram to screen for breast cancer.	National Committee for Quality Assurance
§	0034	113	CMS130 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50 - 75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** Percentage of adults 18-64 years of age with a diagnosis of acute bronchitis who were not dispensed an antibiotic prescription.	National Committee for Quality Assurance
§	0062	119	CMS134 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy –Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

B.15. Preventive Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0421	128	CMS69v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	CMS68v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	0418	134	CMS2v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
§	0028	226	CMS138v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.15. Preventive Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							identified as a tobacco user.	
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	438	CMS347v2	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	/Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
	N/A	474	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet
	N/A	475	CMS349v1	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients 15-65 years of age who have ever been tested for human immunodeficiency virus (HIV).	Centers for Disease Control and Prevention

We did not receive specific comments regarding the measures included in this specialty measure set.

FINAL ACTION: We are finalizing the *Preventive Medicine Specialty Measure Set* as proposed for the 2019 Performance Period and future years. However, as noted in our responses to public comments in Table C, we are not finalizing the following measures for removal from this measure set: Q048. Q154, Q155. Therefore, measures Q048. Q154, Q155 are retained for the 2019 Performance Period and future years. These measures were previously included within the 2018 specialty measure set and therefore they will continue to be included in this measure set. To this end, we have deleted the Removal table in this final rule.

B.16. Neurology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Neurology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This measure set does not have any measures removed from prior years.

B.16. Neurology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Safety)	0419	130	CMS68v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	0418	134	CMS2v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	NA	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§	0028	226	CMS138 v7	Medicare Part B Claims	Process	Community/ Population	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:**	Physician Consortium

B.16. Neurology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications		Health	a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	for Performance Improvement Foundation (PCPI®)
		268	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** All female patients of childbearing potential (12 - 44 years old) diagnosed with epilepsy who were counseled or referred for counseling for how epilepsy and its treatment may affect contraception OR pregnancy at least once a year.	American Academy of Neurology
	2872	281	CMS149 v7	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association and American Academy of Neurology
	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented symptoms screening for behavioral and psychiatric symptoms, including depression, AND for whom, if symptoms screening was positive, there was also documentation of recommendations for symptoms management in the last 12 months.	American Psychiatric Association and American Academy of Neurology
! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others; and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association and American Academy of Neurology
! (Care Coordination)	N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12-month period.	American Psychiatric Association and American Academy of Neurology

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MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A	290	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for psychiatric symptoms in the past 12 months.	American Academy of Neurology
	N/A	291	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction in the past 12 months.	American Academy of Neurology
!	N/A	293	N/A	Registry	Process	Communication and Care Coordination	**Parkinson's Disease: Rehabilitative Therapy Options:** All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (for example, physical, occupational, or speech therapy) discussed in the last 12 months.	American Academy of Neurology
	N/A	317	CMS22v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP).	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v 7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
!	N/A	386	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (for example, advance directives, invasive ventilation, hospice) at least once annually.	American Academy of Neurology
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who had a follow-up evaluation conducted at least every 3 months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology

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MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than 6 weeks duration evaluated for risk of opioid misuse using a brief validated instrument (for example, Opioid Risk Tool, SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
! (Efficiency) *	N/A	419	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Overuse of Imaging for the Evaluation of Primary Headache:** Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.	American Academy of Neurology
	2152	431	N/A	MIPS CQMs Specifications	Process	Population/ Community	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI)
! (Outcome)	N/A	435	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Patient Reported Outcome	Effective Clinical Care	**Quality Of Life Assessment For Patients With Primary Headache Disorders:** Percentage of patients with a diagnosis of primary headache disorder whose health related quality of life (HRQoL) was assessed with a tool(s) during at least two visits during the 12-month measurement period AND whose health related quality of life score stayed the same or improved	American Academy of Neurology

Comment: One commenter supported the inclusion of measure Q134: Preventive Care and Screening: Screening for Clinical Depression and Follow-up Plan. Comorbid depression is a frequent concern for patients with neurologic conditions.

Response: We thank the commenter for their support of measure Q134: Preventive Care and Screening: Screening for Clinical Depression and Follow-up Plan.

Comment: Two commenters do not support removal of Q386: Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences from this measure set. The commenters appreciated the effort to decrease redundancy between this measure and the Q047 Advance Care Plan measure. While these measures do overlap, the commenters noted that ALS measure specification recognizes the likely earlier age of onset of this devastating diagnosis and the need to have earlier planning conversations around palliative and end of life care by having no minimum age requirement. For this reason, the commenter believed the measure should be retained.

Response: We agree with the commenters concerns about removing measure Q386 and will not finalize this measure for removal. Specifically, we agree that patients with ALS are often younger than those in the denominator for measure Q047, which includes patients age 65 and older. For this reason, we concur with commenters that a separate measure applying to all patients with a diagnosis of ALS is clinically indicated.

Comment: One commenter requested that CMS consider adding the measure Q370: Depression Remission at Twelve Months to this measure set because they stated that comorbid depression is a frequent concern for patients with neurologic conditions.

Response: We note that this measure set does include Q134, which screens for depression and would address the commenter's concern of identifying comorbid depression. Prior to rulemaking, we solicit feedback from stakeholders with regards to measures that should be added or removed to existing specialty sets or the development of new specialty sets. The suggestion to add the measure to the Neurology specialty measure set was not provided as part of the feedback received from specialty stakeholders for the 2019 performance period. We ask the commenter to submit their feedback during this solicitation process for future consideration in rulemaking.

FINAL ACTION: We are finalizing the *Neurology Specialty Measure Set* as proposed for the 2019 Performance Period and future years with the exception of the newly proposed composite measure: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. We are no longer finalizing the inclusion of the composite falls measure because it must be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population. In addition, as noted in our responses to public comments in Table C, measures Q154, Q155, and Q386 are not finalized for removal from this measure set as proposed; therefore, they will be retained in this measure set for the 2019 Performance Period and future years.

B.17. Mental/Behavioral Health

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Mental/Behavioral Health specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measure from the specialty set: Quality ID: 367.

B.17. Mental/Behavioral Health

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0105	009	CMS128 v7	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on antidepressant medication treatment. Two rates are reported: a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
	0104	107	CMS161 v7	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	Physician Consortium for Performance Improvement
* §	0421	128	CMS69v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	CMS68v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	0418	134	CMS2v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs	Process	Community / Population Health	**Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services

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MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Specifications				
! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder mal-treatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§	0028	226	CMS138 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	2872	281	CMS149 v7	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association and American Academy of Neurology
	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented symptoms screening for behavioral and psychiatric symptoms, including depression, AND for whom, if symptoms screening was positive, there was also documentation of recommendations for symptoms management in the last 12 months.	American Psychiatric Association and American Academy of Neurology
! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others; and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association and American Academy of Neurology
! (Care Coordination)	N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association and American Academy of Neurology
	N/A	317	CMS22v7	Medicare Part B Claims	Process	Community /	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up**	Centers for Medicare &

B.17. Mental/Behavioral Health

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Measure Specifications, eCQM Specifications, MIPS CQMs Specifications		Population Health	**Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Medicaid Services
! (Care Coordination)	N/A	325	N/A	MIPS CQMs Specifications	Process	Communication/ Care Coordination	**Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions:** Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a specific diagnosed comorbid condition (diabetes, coronary artery disease, ischemic stroke, intracranial hemorrhage, chronic kidney disease [stages 4 or 5], End Stage Renal Disease [ESRD] or congestive heart failure) being treated by another clinician with communication to the clinician treating the comorbid condition.	American Psychiatric Association
	0108	366	CMS136 v8	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* § ! (Outcome)	0710	370	CMS159 v7	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
*	0712	371	CMS160 v7	eCQM Specifications	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** The percentage of adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) with a diagnosis of major depression or dysthymia who have a completed PHQ-9 or PHQ-9M tool during the measurement period.	MN Community Measurement
! (Care Coordination)	N/A	374	CMS50v 7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Safety)	1365	382	CMS177 v7	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Physician Consortium for Performance Improvement Foundation (PCPI®)

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MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	National Committee for Quality Assurance
! (Care Coordination)	0576	391	N/A	MIPS CQMs Specifications	Process	Communication/ Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: ● The percentage of discharges for which the patient received follow-up within 30 days of discharge. ● The percentage of discharges for which the patient received follow-up within 7 days of discharge.	National Committee for Quality Assurance
	N/A	402	NA	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Outcome)	0711	411	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Six Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 6 months (+/- 60 days) after an index event date.	MN Community Measurement
	2152	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder:** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

Comment: One commenter stated that the Mental/Behavioral Health Specialty Measure Set too narrowly defines the measures' denominator populations. This type of highly detailed specification inappropriately limits the users' abilities to apply otherwise applicable and useful measures to a larger percentage of patients. The commenter also stated that considering the frequency of medical comorbidity diagnoses and the fragmented health care delivery for serious mental illness (SMI) patients, it requested that CMS include more cross-cutting measures that address commonly diagnosed medical comorbidities among patients with SMI into the Mental/Behavioral Health Specialty Measure Set. Due to the nature of the encounter, the eligible clinician-psychiatrist might not utilize otherwise appropriate measures because it might be therapeutically inappropriate. The decision to employ a quality measure for all specialties must be made on a case-by-case basis.

Response: Prior to rulemaking, we solicit feedback from stakeholders with regards to measures that should be added or removed to existing specialty sets or the development of new specialty sets. We ask the commenter to submit their feedback during this solicitation process for future consideration in rulemaking. In addition, eligible clinicians are not limited to selecting measures from their specialty measure set, but have the opportunity to select any of the MIPS measure that are applicable to their practice and workflow. We encourage the commenter to collaborate with measure developers to create robust measures that address patient with serious mental illnesses with comorbidities. Once fully tested, we request the measure be submitted to the Call for Measures process for consideration.

Comment: One commenter stated that behavioral health clinicians (psychiatrists, clinical psychologists), while eligible for MIPS, may not have received the direction and

B.17. Mental/Behavioral Health

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**

attention that has been focused on other specialties. The commenter requested that CMS provide background on the development of its measures for these behavioral health clinicians and solicit input from these clinicians as to the appropriateness of those measures.

Response: The measures included within the measure specialty set have been reviewed and developed by specialty societies. Prior to rulemaking, we solicit feedback from stakeholders with regards to measures that should be added or removed to existing specialty sets or the development of new specialty sets. We ask the commenter to submit their feedback during this solicitation process for future consideration in rulemaking. Each of the measures included in the specialty measure sets is developed and stewarded by various measure stewards as indicated in the table. The measure steward revises the quality measure during the annual revision cycle based on their technical expert panel input and direction.

Comment: One commenter did not agree that new measures must be developed to specifically address patients with mental or substance use disorders and medical comorbidities. Measures that already exist for the general population would be adequate to use to monitor these conditions.

Response: We disagree and believe there is a gap in measurement that addresses mental and substance use disorders. Measures applicable to the general population are not appropriate to promote appropriate or adherence of treatment for patient with mental and substance use disorders with comorbidities.

Comment: One commenter requested that CMS test the measure Q105: Anti-Depressant Medication Management at the clinician-level before its continued use in MIPS.

Response: This measure has been in use at the clinician-level for several years without incident so we believe that its continued use in MIPS is appropriate until clinician-level testing is conducted by the steward. We will continue to encourage the steward to expand testing for this measure at the clinician-level.

Comment: One commenter was concerned about the denominator for measure Q107: Adult Major Depressive Disorder (MDD): Suicide Risk Assessment. As currently specified, the denominator limits screening for suicide to patients with new onset or recurrent episodes of Major Depressive Disorder (MDD), instead of applying it to patients with mood disorders, as supported by the measure's rationale and evidence to measure (part of the National Quality Forum's 2018 Spring Behavioral Health Measure Endorsement Cycle). Current evidence supports suicide risk assessments for an even broader population, like patients with other mental illnesses who present an increased safety risk. This measure would be better specified by including patients with comorbid-multiple psychiatric illnesses paired with increased substance use and medical conditions (that is, chronic pain). The commenter requested that CMS work with the measure's developers to also provide a definition of the term "assessment to avoid issues with the measure's reliability and to provide clarity to those clinicians who do not possess expertise in suicide risk assessments. In addition, the commenter recommended that measure Q107 include references on the use of validated rating scales designed for suicide screening and assessment.

Response: This measure was originally developed as part of a suite of measures to improve care for adults with major depressive disorder and was specified and tested for that population. We will give consideration to this suggestion in future updates of the measure. A change in the measure intent as suggested would require additional testing to understand the impact on measure performance, feasibility, reliability, and validity of the measure. A "suicide risk assessment" is defined more explicitly in the Numerator Details section in the human readable format of this measure's technical specifications. The clinical guideline statement also makes reference to key components of a complete assessment. Clinical guidance on how to address and manage patients who screen positive for suicidal ideation is provided in the human readable format of this measure's technical specifications. Use of a standardized tool or instrument to assess suicide risk will meet numerator performance, and can be mapped to a general SNOMED CT code: "Suicide risk assessment (procedure)". We encourage mapping to this concept in order to ensure that the suicide risk assessment was performed. We will work with the measure steward to consider reference to specific suicide risk assessment tools for clinician guidance in future updates of this measure.

Comment: One commenter stated that measure Q105: Anti-Depressant Medication Management consists of a limited denominator. Antidepressants may be prescribed to individuals who do not meet criteria for an MDD diagnosis. According to current evidence, various mental illnesses may be treated with antidepressants; as such, adherence to antidepressants result in more positive health outcomes for those for whom they are appropriately prescribed. Therefore, the commenter requested that CMS engage with the measure's developers and discuss widening the measure's population to consist of anyone prescribed antidepressants as guided by current evidence. Thus, this measure should not be considered for use in the MIPS quality performance category until it is tested and demonstrates valid and reliable measurement characteristics.

Response: This measure is focused on treating patients with major depression disorder. Expanding the denominator to include all patients taking antidepressants would change the intent of this measure. We will give consideration to this suggestion in future updates of the measure. A change in the measure intent as suggested would require additional testing to understand the impact on measure performance, feasibility, reliability, and validity of the measure.

Comment: One commenter appreciated that measure Q325: Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions remains in this measure set. The commenter interpreted the lack of the "Individual Measures List" proposed within the rule to mean that CMS solely supports quality measures as part of specialty measure sets, and the commenter concluded that clinicians would be required to select measures from one of the 33 specialty sets to meet the 6-measure (including one outcome or high priority measure) criteria.

Response: We thank the commenter for their support of measure Q325: Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions. Previously finalized measure sets were not republished in the proposed rule and remain available for applicable specialties.

FINAL ACTION: We are finalizing the *Mental/Behavioral Health Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.17. Mental/Behavioral Health

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	367	CMS169 v7	eCQM Specifications	Process	Effective Clinical Care	**Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use:** Percentage of patients with depression or bipolar disorder with evidence of an initial assessment that includes an appraisal for alcohol or chemical substance use.	Center for Quality Assessment and Improvement in Mental Health	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

Comment: One commenter did not support removal of measure Q367: Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use. The commenter stated that removal would make this measure set lack measures that address unhealthy substance use. The commenter did not agree that measure Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling is duplicative or superior to measure Q367. If the developers were to update the denominator to include the general population and the numerator to include data capture of the follow-up actions related to the appraisal, this measure would be more useful in MIPS than is measure Q431.

Response: Currently, Q367 does not include follow-up actions when there is identified alcohol or substance abuse. The measure steward has not currently specified this for Q367 and although they could add it in the future, it would not be in enough time to implement for the 2019 performance period. Q431 is currently more robust as it includes the requirement of a follow-up action in identified alcohol or substance abuse patients. We agree with the commenter that a measure with a broader denominator to include the general population and the numerator to include data capture of the follow-up actions related to the appraisal would be appropriate. These revisions would require a new measure to be submitted to the Call for Measures process. We encourage the commenter to collaborate with measure developers to create a measure as suggested.

FINAL ACTION: We are finalizing the removal of measures from the *Mental/Behavioral Health Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.18. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Diagnostic Radiology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 359 and 363.

B.18. Diagnostic Radiology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).	American College of Radiology
! (Efficiency)	0508	146	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening:** Percentage of final reports for screening mammograms that are classified as "probably benign."	American College of Radiology
! (Care Coordination)	N/A	147	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy:** Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (for example, x-ray, MRI, CT, etc.) that were performed.	Society of Nuclear Medicine and Molecular Imaging
	0507	195	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiology: Stenosis Measurement in Carotid Imaging Reports:** Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement.	American College of Radiology
!	0509	225	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Radiology: Reminder System for Screening Mammograms:** Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram.	American College of Radiology
! (Patient Safety)	N/A	360	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology
! (Patient Safety)	N/A	361	N/A	MIPS CQMs Specifications	Structure	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry:** Percentage of total computed tomography (CT) studies performed for all patients, regardless of age,	American College of Radiology

B.18. Diagnostic Radiology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							that are reported to a radiation dose index registry that is capable of collecting at a minimum selected data elements.	
!	N/A	362	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes:** Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external healthcare facilities or entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12-month period after the study.	American College of Radiology
* ! (Appropriate Use)	N/A	364	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up (for example, type of imaging or biopsy) or for no follow-up, and source of recommendations (for example, guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).	American College of Radiology
! (Appropriate Use)	N/A	405	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for abdominal imaging studies for asymptomatic patients aged 18 years and older with one or more of the following noted incidentally with follow-up imaging recommended: • Liver lesion ≤ 0.5 cm. • Cystic kidney lesion < 1.0 cm. • Adrenal lesion ≤ 1.0 cm.	American College of Radiology
! (Appropriate Use)	N/A	406	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT), magnetic resonance imaging (MRI) or magnetic resonance angiogram (MRA) studies of the chest or neck or ultrasound of the neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	American College of Radiology
	N/A	436	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques:** Percentage of final reports for patients aged 18 years and older undergoing CT with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control. • Adjustment of the mA and/or kV according to patient size. • Use of iterative reconstruction technique.	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance

B.18. Diagnostic Radiology

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**

Comment: One commenter noted on measure Q436: Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques that there is equivalency of a site-based attestation and an attestation included in the individual radiology report. In practice, these generic attestations included in the report are not dictated case-by-case, but rather automatically added to all CT templates in order to satisfy the measure. Adding additional generic comments necessarily lengthens our reports, making it less likely that the requesting clinician will read the entire report or identify the clinically relevant information. The commenter suggested the following: Site-based attestations be sufficient to meet measure Q436, without requiring documentation in each individual adult CT report.

Response: This measure does not require detailed comments that would lengthen a report, but requires general attestation statement in the final report; however, there would need to be a written policy in place describing the process that ensures dose optimization techniques are used appropriately per instrument/room, as well as a method for validating that their use occurs for each patient. This may include periodic audits.

FINAL ACTION: We are finalizing the *Diagnostic Radiology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.18. Diagnostic Radiology (continued)

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	359	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging:** Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institution's computer systems.	American College of Radiology	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	363	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive:** Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external healthcare facilities or entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed.	American College of Radiology	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

Comment: One commenter did not support removal of measure Q359: Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging. The commenter also did not support the removal of measure Q363: Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive. The commenter indicated that the number of radiology measures is limited, and that additional measures should be added before additional measures are removed, and CMS should also encourage clinicians to take greater advantage of existing studies as a means of reducing unnecessary duplicative exams.

Response: We encourage measure developers to submit additional radiology measures through the Call for Measures process. In the event an eligible clinician reports on less than 6 quality measures, because no other measures in the set are available or applicable to their scope of practice, the quality performance category score will be adjusted accordingly through the measure validation process.

FINAL ACTION: We are finalizing the removal of measures from the *Diagnostic Radiology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.19. Nephrology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Nephrology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 122 and 327.

B.19. Nephrology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059	001	CMS122 v7	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications, eCQM Specifications.	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0 percent during the measurement period.	National Committee for Quality Assurance
§ ! (Care Coordination) *	0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (for example hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	0041	110	CMS147 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs	Process	Community / Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance

B.19. Nephrology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Specifications				
§	0062	119	CMS134 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
! (Patient Safety)	0419	130	CMS68v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordinat ion)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communica tion and Care Coordinatio n	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
	N/A	317	CMS22v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
	0101	318	CMS139 v7	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
! (Outcome)	1667	328	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10 g/dL:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis or peritoneal dialysis have a hemoglobin level < 10 g/dL.	Renal Physicians Association
!	N/A	330	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Adult Kidney Disease: Catheter Use for Greater Than or Equal to 90 Days:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving maintenance hemodialysis for greater than or equal to 90 days whose mode of vascular access is a catheter.	Renal Physicians Association
§	N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-	Physician Consortium for Performance Improvement

B.19. Nephrology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							time screening for hepatitis C virus (HCV) infection.	
! (Patient Experience)	N/A	403	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Adult Kidney Disease: Referral to Hospice:** Percentage of patients aged 18 years and older with a diagnosis of ESRD who withdraw from hemodialysis or peritoneal dialysis who are referred to hospice care.	Renal Physicians Association
	N/A	474	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet
We did not receive specific comments regarding the measures included in this specialty measure set. **FINAL ACTION:** We are finalizing the *Nephrology Specialty Measure Set* as proposed for the 2019 Performance Period and future years with the exception of the newly proposed composite measure: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. We are no longer finalizing the inclusion of the composite falls measure because it must be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population. In addition, as noted in our responses to public comments in Table C, measure Q386 is not finalized for removal from this measure set as proposed; therefore, it will be retained in this measure set for the 2019 Performance Period and future years.								

B.19. Nephrology (continued)

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	122	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Adult Kidney Disease: Blood Pressure Management:** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) with a blood pressure < 140/90 mmHg OR ≥ 140/90 mmHg with a documented plan of care.	Renal Physicians Association	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	327	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Pediatric Kidney Disease: Adequacy of Volume Management:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) undergoing maintenance hemodialysis in an outpatient dialysis facility have an assessment of the adequacy of volume management from a nephrologist.	Renal Physicians Association	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

We did not receive specific comments regarding the proposed removal of measures from this specialty measure set.

FINAL ACTION: We are finalizing the removal of measures from the *Nephrology Specialty Measure Set* as proposed for the 2019 Performance Period and future years. However, as noted in our responses to public comments in Table C, we are not finalizing the following measure proposed for removal from this measure set: Q318.

B.20. General Surgery

In addition to the considerations discussed in the introductory language of Table B in this final rule, the General Surgery specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This measure set does not have any measures removed from prior years.

B.20. General Surgery

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
§ ! (Care Coordination) *	0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (for example, hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421	128	CMS69 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25	Centers for Medicare & Medicaid Services

B.20. General Surgery

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							kg/m2.	
! (Patient Safety)	0419	130	CMS68 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§	0028	226	CMS13 8v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	264	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer:** The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons
	N/A	317	CMS22 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period.	American College of Surgeons
! (Outcome)	N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care	N/A	374	CMS50 v7	eCQM Specifications,	Process	Communication and Care	**Closing the Referral Loop:** Receipt of Specialist Report	Centers for Medicare &

B.20. General Surgery

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
Coordination)				MIPS CQMs Specifications		Coordination	Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

Comment: One commenter noted the inclusion of measure Q264: Sentinel Lymph Node Biopsy for Invasive Breast Cancer measure as a new measure in this measure set in the 2019 performance year. They support the inclusion of this measure in this measure set.

Response: We thank the commenter for their support.

FINAL ACTION: We are finalizing the *General Surgery Specialty Measure Set* as proposed for the 2019 Performance Period and future years. Note: Measure Q263 was incorrectly attributed to this measure set and proposed as a removal from this measure set in the proposed rule; therefore, the removal table that included measure 263 has been deleted from this final rule.

B.21. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Vascular Surgery specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 257 and 423.

B.21. Vascular Surgery

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421	128	CMS69v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	CMS68v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§	0028	226	CMS138	Medicare Part	Process	Community/	**Preventive Care and Screening: Tobacco Use:**	Physician

B.21. Vascular Surgery

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
			v7	B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications		Population Health	**Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Outcome)	0018	236	CMS165 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
! (Outcome)	N/A	258	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Open Elective Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7):** Percent of patients undergoing open repair of small or moderate sized non-ruptured infrarenal abdominal aortic aneurysms who do not experience a major complication (discharge to home no later than post-operative day #7).	Society for Vascular Surgeons
! (Outcome)	N/A	259	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged at Home by Post-Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2).	Society for Vascular Surgeons
! (Outcome)	N/A	260	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CEA who are discharged to home no later than post-operative day #2).	Society for Vascular Surgeons
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services

B.21. Vascular Surgery

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery.	Society for Vascular Surgeons
! (Outcome)	1540	346	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CEA who are stroke free or discharged alive following surgery.	Society for Vascular Surgeons
! (Outcome)	1534	347	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) Who Are Discharged Alive:** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) who are discharged alive.	Society for Vascular Surgeons
! (Outcome)	N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50v7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	1523	417	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Open Repair of Small or Moderate Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive:** Percentage of patients undergoing open repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) who are discharged alive.	Society for Vascular Surgeons
! (Outcome)	N/A	420	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report	Society of Interventional Radiology

B.21. Vascular Surgery

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							an improvement on a disease specific patient reported outcome survey instrument after treatment.	
! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg; and • Most recent tobacco status is Tobacco Free; and • Daily Aspirin or Other Antiplatelet Unless Contraindicated; and • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality (WCHQ)
We did not receive specific comments regarding the measures included in this specialty measure set. **FINAL ACTION:** We are finalizing the *Vascular Surgery Specialty Measure Set* as proposed for the 2019 Performance Period and future years.								

B.21. Vascular Surgery (continued)

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
1519	257	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy at Discharge after Lower Extremity Bypass (LEB):** Percentage of patients aged 18 years and older undergoing infra-inguinal lower extremity bypass who are prescribed a statin medication at discharge.	Society for Vascular Surgeons	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
0465	423	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Perioperative Anti-platelet Therapy for Patients Undergoing Carotid Endarterectomy:** Percentage of patients undergoing carotid endarterectomy (CEA) who are taking an anti-platelet agent within 48 hours prior to surgery and are prescribed this medication at hospital discharge following surgery.	Society for Vascular Surgeons	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

Comment: One commenter stated that measure Q257: Statin Therapy at Discharge after Lower Extremity Bypass (LEB) is not duplicative of the new measure for Ischemic Vascular Disease – Use of Aspirin or Anti-platelet Medication proposed for 2019. An important part of this measure is its timeframe. In many institutions, anti-platelet agents are stopped 7 days prior to any procedure/operation. Ensuring that the patient stays on the antiplatelet agent in the pre-operative period often requires extra effort and coordination so the commenter believed measure Q257 should be maintained for 2019. The benefit of statins has been well-documented.

Response: We agree with the commenter that it is not duplicative of a proposed measure Ischemic Vascular Disease – Use of Aspirin or Anti-platelet Medication. We cited that this measure was duplicative of measure Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease.

FINAL ACTION: We are finalizing the removal of measures from the *Vascular Surgery Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.22. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Thoracic Surgery specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 043, 236, and 441.

B.22. Thoracic Surgery

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Safety)	0419	130	CMS68 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Outcome)	0129	164	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours.	Society of Thoracic Surgeons
! (Outcome)	0130	165	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or	Society of Thoracic Surgeons

B.22. Thoracic Surgery

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							mediastinum requiring operative intervention	
! (Outcome)	0131	166	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Stroke:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (that is, any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours.	Society of Thoracic Surgeons
! (Outcome)	0114	167	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons
! (Outcome)	0115	168	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.	Society of Thoracic Surgeons
§	0028	226	CMS138v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50v7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population	**Tobacco Use and Help with Quitting Among Adolescents:**	National Committee for

B.22. Thoracic Surgery

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
						Health	The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	Quality Assurance
§ !	0119	445	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG):** Percent of patients aged 18 years and older undergoing isolated CABG who die, including both all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure.	Society of Thoracic Surgeons

Comment: One commenter noted that the correct measure steward for the following measures should be the "Society of Thoracic Surgeons": Q164: CABG: Prolonged Intubation; Q165: CABG: Deep Sternal Wound Infection Rate; Q166: CABG: Stroke; Q167: CABG: PostOp Renal Failure

Response: We have updated the measure steward for these measures accordingly.

Comment: The commenter stated that measure Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented is not appropriate for the Thoracic Surgery Specialty Set and requested its removal for CY 2019. The commenter noted that blood pressure management is outside of the scope of practice of cardiothoracic surgeons.

Response: We do not agree to remove the measure from the Thoracic Surgery specialty set because if the patient has an elevated blood pressure at post-op, it is within the thoracic surgeon's scope to recommend a follow-up with the patient's PCP. In addition, we believe that if the thoracic surgeon should assess a patient at pre-operatively or post-operatively, there should be blood pressure screening.

Comment: One commenter supported inclusion of measures Q358: Patient-Centered Surgical Risk Assessment and Communication.

Response: We thank the commenter for their support of measure Q358: Patient-Centered Surgical Risk Assessment and Communication.

FINAL ACTION: We are finalizing the *Thoracic Surgery Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.22. Thoracic Surgery (continued)

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, CMS removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0134	043	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who received an IMA graft.	Society of Thoracic Surgeons	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
0018	236	CMS165 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance	We agree with specialty society feedback to remove this measure from this specialty set because blood pressure control is managed by care team members other than the cardiothoracic surgeon. Blood pressure outcomes are more likely attributed to the primary care provider or cardiologist. These eligible clinicians are part of the core treatment team that is responsible for the ongoing hypertension therapy.
N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg; and • Most recent tobacco status is Tobacco Free; and • Daily Aspirin or Other Antiplatelet Unless Contraindicated; and • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality (WCHQ)	We agree with specialty society feedback to remove this measure from this specialty set because the outcomes and medications within the measure are managed by care team members other than the cardiothoracic surgeon. Blood pressure and tobacco cessation outcomes are more likely attributed to the primary care provider or cardiologist. These eligible clinicians are part of the core treatment team that is responsible for the ongoing ischemic vascular disease care.

Comment: One commenter opposed removal of measure Q043: CABG: Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery due to topped out status. The commenter stated that IMA use is so important to long-term graft patency and if CMS removes this life-saving measure from MIPS, there will be little incentive for clinicians to report it and thus, a natural tendency for performance to slip without anyone's knowledge. The commenter opposed the proposal to modify the existing topped-out measure policy to allow for the immediate removal of highly topped out measures.

Response: This measure leaves little room for improvement as reflected in the 2018 MIPS Benchmark Results as an average performance rate of 99 percent which supports the removal as it is a standard of care. The measure has limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying and restricts the creation of meaningful benchmarks. This provides little incentive for clinicians to report the measure since the performance data does not allow for maximum points to be awarded. We advise the commenter to collaborate with measure developers to submit more robust or outcome measures through

the Call for Measures process.

Comment: One commenter did not see that measure Q441: Ischemic Vascular Disease All or None Outcome Measure (Optimal Control) was in the removal table for Thoracic Surgery in the proposed rule, but supported its removal since not all of the four goals reflected in the measure are appropriate for acute surgical patients.

Response: We thank the commenter for feedback regarding the removal of this measure. We agree with the commenter's assessment that not all of the goals are applicable for this specialty. The measure was inadvertently not included in this specialty measure set tables but it was our intent to remove this measure from this specialty measure set based on similar feedback received prior to the public comment period.

Comment: Several commenters supported the removal of measure Q236: Controlling High Blood Pressure. Blood pressure control is managed by care team members other than the cardiothoracic surgeon.

Response: We thank the commenters for supporting the removal of measure Q236: Controlling High Blood Pressure.

FINAL ACTION: We are finalizing the removal of measures from the *Thoracic Surgery Specialty Measure Set* as proposed for the 2019 Performance Period and future years. Note: We are also including the removal of Q441 based on public comments above supporting removal.

B.23. Urology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Urology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set.

B.23. Urology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Assessment of Presence or Absence Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0389	102	CMS129 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0390	104	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer**: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.	American Urological Association Education and Research

§	0062	119	CMS134 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
* §	0421	128	CMS69v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	CMS68v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services
§	0028	226	CMS138 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
!	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician.	American Academy of Dermatology
	N/A	317	CMS22v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by	American College of Surgeons

							their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	
! (Care Coordination)	N/A	374	CMS50v7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	428	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence:** Percentage of patients undergoing appropriate preoperative evaluation of stress urinary incontinence prior to pelvic organ prolapse surgery per ACOG/AUGS/AUA guidelines.	American Urogynecologic Society
! (Patient Safety)	N/A	429	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement
! (Outcome)	N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing any surgery to repair pelvic organ prolapse who sustains an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A	434	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Ureter Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 30 days after surgery.	American Urogynecologic Society
	N/A	462	CMS645 v2	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

Comment: One commenter noted that the proposed rule Urology Specialty Measure Set listed a measure for Benign Prostatic Hyperplasia and questioned its measure specifications.

Response: This measure was included in error and has been removed from the final rule. The measure will be reviewed for future consideration.

FINAL ACTION: We are finalizing the *Urology Specialty Measure Set* as proposed for the 2019 Performance Period and future years. Note: As noted in our responses to public comments in Table C, measure Q048 is not finalized for removal from this measure set as proposed; therefore, it is retained in this measure set for the 2019 Performance Period and future years.

B.24a. Oncology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Oncology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This measure set does not have any measures removed from prior years.

B.24a. Oncology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0389	102	CMS129v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0041	110	CMS147v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
! (Patient Safety)	0419	130	CMS68v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, andvitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§	0384	143	CMS157v	eCQM	Process	Person and	**Oncology: Medical and Radiation – Pain**	Physician

B.24a. Oncology

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)			7	Specifications, MIPS CQMs Specifications		Caregiver Centered Experience and Outcome	**Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	Consortium for Performance Improvement Foundation (PCPI®)
* ! (Patient Experience)	0383	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcome	**Oncology: Medical and Radiation – Plan of Care for Moderate to Severe Pain:** Percentage of patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having moderate to severe pain with a plan of care to address pain documented on or before the date of the second visit with a clinician.	American Society of Clinical Oncology
§	0028	226	CMS138v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	1853	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Population/ Community	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief**	Physician Consortium

B.24a. Oncology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							Counseling: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	for Performance Improvement Foundation (PCPI)
§ ! (Appropriate Use)	1857	449	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies:** Percentage of female patients (aged 18 years and older) with breast cancer who are human epidermal growth factor receptor 2 (HER2) negative who are not administered HER2-targeted therapies.	American Society of Clinical Oncology
§ ! (Appropriate Use)	1858	450	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Trastuzumab Received By Patients With AJCC Stage I (T1c) –III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy:** Proportion of female patients (aged 18 years and older) with AJCC stage I (T1c) – III, human epidermal growth factor receptor 2 (HER2) positive breast cancer receiving adjuvant chemotherapy who are also receiving trastuzumab.	American Society of Clinical Oncology
§	1859	451	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**KRAS Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy::** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom KRAS gene mutation testing was performed.	American Society of Clinical Oncology
§ ! (Patient Safety)	1860	452	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and KRAS gene mutation spared treatment with anti-EGFR monoclonal antibodies.	American Society of Clinical Oncology
§ ! (Appropriate Use)	0210	453	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving chemotherapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	N/A	454	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer with More than One Emergency Department Visit in the Last 30 Days of Life (lower score – better):** Proportion of patients who died from cancer with more than one emergency room visit in the last 30 days of life.	American Society of Clinical Oncology
§ ! (Outcome	0213	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients Who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life**	American Society of Clinical

B.24a. Oncology

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
)							**(lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	Oncology
§ ! (Appropriate Use)	0215	456	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients Who Died from Cancer Not Admitted To Hospice (lower score – better):** Proportion of patients who died from cancer not admitted to hospice.	American Society of Clinical Oncology
§ ! (Outcome)	0216	457	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better):** Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
	N/A	462	CMS645v2	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute
	N/A	474	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet
We did not receive specific comments regarding the measures included in this specialty measure set. **FINAL ACTION:** We are finalizing the *Oncology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.								

B.24b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Radiation Oncology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measure from the specialty set: Quality ID: 156.

B.24b. Radiation Oncology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0389	102	CMS129 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Patient Experience)	0384	143	CMS157 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcome	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* ! (Patient Experience)	0383	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcome	**Oncology: Medical and Radiation – Plan of Care for Moderate to Severe Pain:** Percentage of patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having moderate to severe pain with a plan of care to address pain documented on or before the date of the second visit with a clinician.	American Society of Clinical Oncology

Comment: One commenter requested that its specialty be able to report the entire specialty specific measure set through a single collection type of their choice. The commenter was concerned that the eCQM reporting mechanism is not available for all three measures within the Radiation Oncology subspecialty measure set, which inhibits complete quality reporting of the subspecialty measure set via an EHR. The commenter urged CMS to continue to work with third-party measure stewards to allow EHR submission of each of the quality measures in the radiation oncology measure set and alleviate reporting burden.

Response: We regularly evaluate to identify measures that could be specified as an eCQM. There are some measures that are currently unable to be captured via an eCQM Specification but we will continue to work with the measure stewards to determine the future implementation of an eCQM Specification for measure Q144.

FINAL ACTION: We are finalizing the *Radiation Oncology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.24b. Radiation Oncology

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	156	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Oncology: Radiation Dose Limits to Normal Tissues:** Percentage of patients, regardless of age, with a diagnosis of breast, rectal, pancreatic or lung cancer receiving 3D conformal radiation therapy who had documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues.	American Society for Radiation Oncology	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

We did not receive specific comments regarding the measures removed from this specialty measure set.

FINAL ACTION: We are finalizing the removal of measures from the *Radiation Oncology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.25. Infectious Disease

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Infectious Disease specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 065, 066, 091, 093, 116, 128, 176, 226, 275, 331, 332, 333, 334, 337, 387, 390, 394, 400, 401, and 447.

B.25. Infectious Disease

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0041	110	CMS147 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
! (Patient Safety)	0419	130	CMS68v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§	0409	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea and syphilis screenings were performed at least once since the diagnosis of HIV infection.	National Committee for Quality Assurance
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
§ ! (Efficiency)	2079	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6-month period of the 24-month measurement period, with a minimum of 60 days between medical	Health Resources and Services Administration

B.25. Infectious Disease

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							visits.	
! (Appropriate Use)	N/A	407	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Treatment of Methicillin-Sensitive Staphylococcus Aureus (MSSA) Bacteremia:** Percentage of patients with sepsis due to MSSA bacteremia who received beta-lactam antibiotic (for example nafcillin, oxacillin or cefazolin) as definitive therapy.	Infectious Diseases Society of America
	N/A	475	CMS349 v1	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients 15-65 years of age who have ever been tested for human immunodeficiency virus (HIV).	Centers for Disease Control and Prevention
	N/A	474	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet
! (Patient Safety)	0657	464	N/A	MIPS CQMs Specifications	Process	Patient Safety, Efficiency, and Cost Reduction	**Otitis Media with Effusion (OME): Systemic Antimicrobials- Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)
We did not receive specific comments regarding the measures included in this specialty measure set. **FINAL ACTION:** We are finalizing the *Infectious Disease Specialty Measure Set* as proposed for the 2019 Performance Period and future years.								

B.25. Infectious Disease

MEASURES FINALIZED FOR REMOVAL Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0069	065	CMS154 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months--18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or 3 days after the episode	National Committee for Quality Assurance	Most infectious disease physicians consult on patients in the inpatient setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess appropriate treatment for children with upper respiratory infections, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease physicians only working within outpatient settings.
N/A	066	CMS146 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance	Most infectious disease physicians consult on patients in the inpatient setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess appropriate testing for children with pharyngitis, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease physicians only working within outpatient settings.
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology -Head and Neck Surgery	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care,

B.25. Infectious Disease

MEASURES FINALIZED FOR **REMOVAL** Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
								pediatricians, or other physicians to assess appropriate topical therapy treatment for patients with acute otitis externa. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology -Head and Neck Surgery	Most infectious disease physicians consult on patients in the inpatient setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess appropriate topical therapy treatment for patients with acute otitis externa, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease physicians only working within outpatient settings.
0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** Percentage of adults 18-64 years of age with a diagnosis of acute bronchitis who were not dispensed an antibiotic prescription.	National Committee for Quality Assurance	Most infectious disease physicians consult on patients in the inpatient setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess the appropriate use of antibiotics for patients with acute bronchitis, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease

B.25. Infectious Disease

MEASURES FINALIZED FOR REMOVAL Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
								physicians only working within outpatient settings.
0421	128	CMS69v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care or other physicians as part of routine preventive care for patients. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Tuberculosis Screening:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 12 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).	American College of Rheumatology	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by rheumatologists or other physicians as part of disease management for rheumatoid arthritis for patients. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
0028	226	CMS138 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation	Physician Consortium for Performance Improvement Foundation (PCPI®)	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care or other physicians as part of preventive care for patients. Most infectious disease physicians consult on

B.25. Infectious Disease

MEASURES FINALIZED FOR REMOVAL Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
						intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.		patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	275	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastro-enterological Association	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by gastroenterologists or other physicians as part of inflammatory bowel disease management. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery	Most infectious disease physicians consult on patients in the inpatient setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess appropriate treatment for patients diagnosed with acute sinusitis, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease physicians only working within outpatient settings.
N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin**	American Academy of Otolaryngology-	Most infectious disease physicians consult on patients in the inpatient

B.25. Infectious Disease

MEASURES FINALIZED FOR REMOVAL Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
						With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use): Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	Head and Neck Surgery	setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess appropriate treatment for patients diagnosed with acute sinusitis, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease physicians only working within outpatient settings.
N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology - Otolaryngology - Head and Neck Surgery	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care, otolaryngologists, or other physicians to assess appropriate treatment for patients diagnosed with acute sinusitis. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	334	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis.	American Academy of Otolaryngology - Otolaryngology - Head and Neck Surgery	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	337	N/A	MIPS CQMs	Process	Effective	**Psoriasis: Tuberculosis (TB)**	American	We agree with specialty

B.25. Infectious Disease

MEASURES FINALIZED FOR REMOVAL Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
			Specifications		Clinical Care	**Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier :** Percentage of patients, regardless of age, with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	Academy of Dermatology	society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by dermatologists, rheumatologists, or other physicians to ensure appropriate testing prior to treatment with a biological immune response modifier. . Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	Physician Consortium for Performance Improvement	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care or other physicians as part of screening process for a high risk patient population. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	390	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient.	American Gastroenterological Association	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care, gastroenterologists, or other physicians to promote shared decision making with patient with hepatitis C.

B.25. Infectious Disease

MEASURES FINALIZED FOR REMOVAL Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
						To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment.		Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
1407	394	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday.	National Committee for Quality Assurance	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians as part of well child care for patients. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care or other physicians to assess the appropriate screening for a high-risk patient population. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with**	American Gastroenterological Association	We agree with specialty society feedback that this measure is neither an

B.25. Infectious Disease

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
						Cirrhosis: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.		applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care, gastroenterologists, or other physicians to ensure appropriate screening for patients with cirrhosis. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	447	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Chlamydia Screening and Follow Up:** The percentage of female adolescents 16 years of age who had a chlamydia screening test with proper follow-up during the measurement period.	National Committee for Quality Assurance	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

Comment: One commenter supported removing measure Q065: Appropriate Treatment for Children with Upper Respiratory Infection, Appropriate Testing for Children with Pharyngitis and Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis from the Infectious Disease set. That set focuses on acute care while these measures focus on primary care.

Response: We thank the commenter for their support on removal of this measure.

Comment: One commenter noted that there will be a negative impact from the removal of measures Q130 and Q226 on quality reporting for Infectious Disease specialists and across all eligible medical specialties. They noted that according to the 2016 PQRS Experience Report the 41 MD/DO specialties listed in Table 14: Top Reported Individual Measures by Specialty or Provider Type (2016) in the 2016 PQRS Experience Report, Q130 was the top measure reported by 29 specialties (70 percent) and Q226 was reported the second most by 21 specialties (51 percent). In addition, across all medical specialties claims-based reporting was the most utilized method of reporting for the 2016 PQRS program. With the above rationale, the commenter asked CMS to consider retaining measure Q130 and Q226 as they would not only affect the opportunities to report for Infectious Disease physicians but most of medical specialties.

Response: To clarify, measure Q130 was not proposed for removal from the Infectious Disease specialty measure set nor from the 2019 Quality Payment Program as a whole, and therefore, will be retained for reporting. Also to clarify further, Q226 was not proposed for removal from the program in general but only proposed to be removed from the Infectious Disease specialty measure set. While we agree that Q226 is a highly reported measure that is applicable to many eligible clinicians, we received specific feedback from specialty societies that this measure was not applicable to most infectious disease physicians as they mostly consult in an inpatient setting. Q226 is specific to the outpatient setting and therefore would not be applicable to most infectious disease physicians.

FINAL ACTION: We are finalizing the removal of measures from the *Infectious Disease Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.26. Neurosurgical

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Neurosurgical specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This measure set does not have any measures removed from prior years.

B.26. Neurosurgical

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications fo a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated i all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis t be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Patient Safety)	0419	130	CMS68v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 2 hours of time last known well and for whom IV t-PA was initiated within 3 hours of time last known well.	American Heart Association
§	0028	226	CMS138 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.26. Neurosurgical

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery.	Society for Vascular Surgeons
! (Outcome)	1540	346	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CEA who are stroke free or discharged alive following surgery.	Society for Vascular Surgeons
! (Outcome)	N/A	409	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
! (Outcome)	N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than 2 hours.	Society of Interventional Radiology
* ! (Outcome)	N/A	459	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Back Pain Following Lumbar Discectomy and/or Laminotomy:** The average change (preoperative to 3 months postoperative) in back pain for patients 18 years of age or older who had lumbar discectomy laminotomy procedure.	MN Community Measurement
* ! (Outcome)	N/A	460	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Back Pain Following Lumbar Fusion:** The average change (preoperative to 1 year postoperative) in back pain for patients 18 years of age or older who had lumbar spine fusion surgery.	MN Community Measurement
* ! (Outcome)	N/A	461	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Leg Pain Following Lumbar Discectomy and/or Laminotomy:** The average change (preoperative to 3 months postoperative) in leg pain for patients 18 years of age or older who had lumbar discectomy laminotomy procedure.	MN Community Measurement
! (Patient Experience)	2643	469	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Functional Status Following Lumbar Spine Fusion Surgery:** For patients aged 18 and older undergoing lumbar spine fusion surgery, the average change from pre-operative functional status to 1 year (9 to 15 months post-operative functional status using the Oswestry Disability Index (ODI version 2.1a) patient reported outcome tool.	Minnesota Community Measurement
! (Patient Experience)	N/A	471	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Functional Status Following Lumbar Discectomy Laminotomy Surgery:** For patients aged 18 and older undergoing lumbar discectomy laminotomy surgery, the average change from pre-operative functional status to 3 months (6 to 20 weeks) post-operative functional status using the Oswestry Disability Index (ODI version 2.1a) patient reported outcome tool.	Minnesota Community Measurement
! (Patient Experience)	N/A	473	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Leg Pain Following Lumbar Spine Fusion Surgery:** For patients aged 18 and older undergoing lumbar spine fusion surgery, the average change from pre-operative leg pain to 1 year (9 to 15 months) post-operative leg pain using the Visual Analog Scale (VAS) patient reported outcome tool.	Minnesota Community Measurement

B.26. Neurosurgical

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**

Comment: One commenter requested for measure Q023: Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients) that the measure be changed to exclude unicompartmental/partial knee replacement in the denominator until the developer can consider the inclusion of ASA for acceptable prophylaxis consistent with current guidelines.

Response: We agree that the measure should align with current clinical guidelines. We will provide this suggestion to the measure steward for future consideration in the annual updates of the measure specifications.

Comment: One commenter supported measure Q187: Stroke and Stroke Rehabilitation: Thrombolytic Therapy in this measure set. The commenter encouraged CMS to continue to consider measurement and payment of high quality, cost effective stroke care in all settings, including in the hospital inpatient setting.

Response: We thank the commenter for their support of measure Q187: Stroke and Stroke Rehabilitation: Thrombolytic Therapy.

Comment: Once commenter expressed concern about the following new measures in this measure set: Q469: Average Change in Functional Status Following Lumbar Spine Fusion Surgery; Q471: Average Change in Functional Status Following Lumbar Discectomy Laminotomy Surgery; and Q473: Average Change in Leg Pain Following Lumbar Spine Fusion Surgery. Although the commenter supported the measures in concept, they noted that the measures require the use of specific tools to capture pain (that is, Visual Analog Scale or VAS) and functional status (that is, Oswestry Disability Index or ODI) despite the existence of equally useful scoring systems. The commenter also noted these measures should provide more flexibility to clinicians by instead focusing more generically on "improvement on a validated pain or disability patient-reported outcome tool." The commenter further expressed concern that they were never consulted about the appropriateness of these measures and would have appreciated an earlier opportunity to provide feedback.

Response: The measure steward has developed and tested these measures using the VAS and ODI tools to assess the change in status. We do not own this measure and encourage the commenter to collaborate with the measure steward to expand the assessment tools. With regard to concerns about measure selection input for this specialty set, prior to rulemaking we solicit feedback from stakeholders with regards to measures that should be added or removed to existing specialty sets or the development of new specialty sets. We ask the commenter to submit their feedback during this solicitation process for future consideration in rulemaking.

FINAL ACTION: We are finalizing the *Neurosurgical Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.27. Podiatry

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Podiatry specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This measure set does not have any measures removed from prior years.

B.27. Podiatry

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy –Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	0416	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention- Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* §	0421	128	CMS69v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
§	0028	226	CMS138v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0101	318	CMS139v7	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.27. Podiatry

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
We did not receive specific comments regarding the measures included in this specialty measure set. **FINAL ACTION:** We are finalizing the *Podiatry Specialty Measure Set* as proposed for the 2019 Performance Period and future years with the exception of the newly proposed composite measure: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. We are no longer finalizing the inclusion of the composite falls measure because it must be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population. In addition, as noted in our responses to public comments in Table C, measures Q154, Q155, and Q318 are not finalized for removal from this measure set as proposed; therefore, they will be retained in this measure set for the 2019 Performance Period and future years.								

B.28. Rheumatology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Rheumatology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This measure set does not have any measures removed from prior years.

B.28. Rheumatology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N	024	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	0041	110	CMS147 v8	Part B Claims Measure Specifications, eCQM Specifications, Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127 v7	Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	0421	128	CMS69v 7	Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services

B.28. Rheumatology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419	130	CMS68v8	Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0420	131	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services
*	N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Tuberculosis Screening:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 12 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).	American College of Rheumatology
*	N/A	177	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity at ≥50 percent of encounters for RA for each patient during the measurement year.	American College of Rheumatology
	N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
	N/A	179	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months.	American College of Rheumatology
	N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
§	0028	226	CMS138v7	Part B Claims Measure Specifications, eCQM Specifications, Web Interface Measure Specifications,	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.28. Rheumatology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				MIPS CQMs Specifications			intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	
§ !! (Outcome)	0018	236	CMS165 v7	Part B Claims Measure Specifications, eCQM Specifications, Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90mmHg) during the measurement period	National Committee for Quality Assurance
! (Patient Safety)	0022	238	CMS156 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 6565 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
	N/A	317	CMS22v 7	Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v 7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
We did not receive specific comments regarding the measures included in this specialty measure set. **FINAL ACTION:** We are finalizing the *Rheumatology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.								

B.29. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Physical Therapy/Occupational Therapy specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This is a new specialty set for 2019; therefore, we are not removing any measures from this specialty set.

B.29. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0421	128	CMS69v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	CMS68v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services
! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Outcome) *	0422	217	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the Knee FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure	Focus on Therapeutic Outcomes, Inc.

B.29. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	
! (Outcome) *	0423	218	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the Hip FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	Focus on Therapeutic Outcomes, Inc.
! (Outcome) *	0424	219	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) assessed using the Foot/Ankle FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	Focus on Therapeutic Outcomes, Inc.
! (Outcome) *	0425	220	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the Low Back FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	Focus on Therapeutic Outcomes, Inc.
! (Outcome) *	0426	221	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.).The measure	Focus on Therapeutic Outcomes, Inc.

B.29. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	
! (Outcome) *	0427	222	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS is assessed using the Elbow/Wrist/Hand FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.) The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	Focus on Therapeutic Outcomes, Inc.
! (Outcome) *	0428	223	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with General Orthopedic Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients aged 14 years+ with general orthopedic impairments (neck, cranium, mandible, thoracic spine, ribs or other general orthopedic impairment). The change in FS is assessed using the General Orthopedic FS PROM (patient reported outcome measure) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	Focus on Therapeutic Outcomes, Inc.

Comment: One commenter supported the creation of the Physical and Occupational Therapy Specialty Measure Set. The commenter encouraged CMS to make two additional measures available to physical therapists (Q126 Diabetic Foot and Ankle Care, Peripheral Neuropathy: Neurological Evaluation; and Q127 Diabetic Foot and Ankle Care, Ulcer Prevention Evaluation of Footwear) and three additional measures available to occupational therapists (Q134 Screening for Depression and Follow-Up Plan); Q181 Elder Maltreatment Screen and Follow-Up Plan); and Q226 Tobacco Use: Screening and Cessation Intervention).

Response: We will provide this recommendation to the measure steward for measures Q126 Diabetic Foot and Ankle Care, Peripheral Neuropathy: Neurological Evaluation, Q127 Diabetic Foot and Ankle Care, Ulcer Prevention Evaluation of Footwear, and Q226 Tobacco Use: Screening and Cessation Intervention. We will evaluate the commenter's request for inclusion for future revisions for measures Q134 Screening for Depression and Follow-Up Plan, Q181 Elder Maltreatment Screen and Follow-Up Plan. We maintain that the measures are still valid as currently specified which includes many clinical settings, but will thoroughly vet the request to include physical and occupational therapy.

FINAL ACTION: We are finalizing the *Physical Therapy/Occupational Therapy Specialty Measure Set* as proposed for the 2019 Performance Period and future years with the exception of the newly proposed composite measure: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. We are no longer finalizing the inclusion of the composite falls measure because it must be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population. .

B.30. Geriatrics

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Geriatrics specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This is a new specialty set for 2019; therefore, we are not removing any measures from this specialty set.

B.30. Geriatrics

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
§ ! (Care Coordination) *	0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (for example hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years and older of age seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is reported as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
	0041	110	CMS147v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement
*	N/A	111	CMS127v7	Medicare Part B Claims Measure Specifications,	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance

B.30. Geriatrics

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				eCQM Specifications, MIPS CQMs Specifications				
! (Patient Safety)	0419	130	CMS68 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0022	238	CMS15 6v7	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 6565 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
	2872	281	CMS14 9v7	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement
	N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology
	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented symptoms screening for behavioral and psychiatric symptoms, including depression, AND for whom, if symptoms screening was positive, there was also documentation of recommendations for symptoms management in the last 12 months.	American Academy of Neurology
! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others; and (2)	American Academy of Neurology

B.30. Geriatrics

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	
! (Care Coordination)	N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology
* § ! (Outcome)	0710	370	CMS159v7	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who had a follow-up evaluation conducted at least every 3 months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than 6 weeks duration evaluated for risk of opioid misuse using a brief validated instrument (for example Opioid Risk Tool, SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
§ ! (Outcome)	0213	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients Who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology
	N/A	474	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet

Comment: One commenter recommended that this measure set be finalized. The commenter appreciated CMS' support of measures for the geriatrics population that CMS expends the most resources. The commenter noted that measure: Q474: Zoster (Shingles) Vaccination is not presently covered under Medicare Part B. The only Part B covered vaccines are influenza, hepatitis, and pneumococcal pneumonia. Because the Zoster (Shingles) vaccine is covered under Part D patients may incur cost-sharing obligations.

Response: This measure is being implemented as a MIPS CQM measure specification which allows all payer data. We appreciate the concern but believe this is a valuable measure that will promote the vaccination and open dialogue between the patient eligible clinician regarding the benefits of this vaccine.

FINAL ACTION: We are finalizing the *Geriatrics Specialty Measure Set* as proposed for the 2019 Performance Period and future years with the exception of the newly proposed composite measure: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. We are no longer finalizing the inclusion of the composite falls measure because it must be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population.

B.31. Urgent Care

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Urgent Care specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This is a new specialty set for 2019; therefore, we are not removing any measures from this specialty set.

B.31. Urgent Care

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0069	065	CMS154 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months-18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or 3 days after the episode.	National Committee for Quality Assurance
! (Appropriate Use)	N/A	066	CMS146 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
! (Appropriate Use)	0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults With Acute Bronchitis:** The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.	National Committee for Quality Assurance
! (Patient Safety)	0419	130	CMS68v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services
§	0028	226	CMS138 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications,	Process	Community /Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older	Physician Consortium for Performance Improvement

B.31. Urgent Care

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				CMS Web Interface Measure Specifications, MIPS CQMs Specifications			who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)
! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement
! (Patient Safety)	0657	464	N/A	MIPS CQMs Specifications	Process	Patient Safety, Efficiency and Cost Reduction	**Otitis Media with Effusion (OME): Systemic Antimicrobials- Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)

B.31. Urgent Care

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
Comment: One commenter thanked CMS for the creation of the Urgent Care specialty set that impacts many specialties. Delineation of a specialty measure set for urgent care medicine will assist physicians and other health care providers who practice in urgent care centers with measure selection, compliance with MIPS requirements, and, most importantly, practice improvement in a setting where tens of millions of patient visits occur annually. **Response:** We thank the commenter for their support of this new measure set. **FINAL ACTION:** We are finalizing the *Urgent Care Specialty Measure Set* as proposed for the 2019 Performance Period and future years.								

B.32. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Skilled Nursing Facility specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This is a new specialty set for 2019; therefore, we are not removing any measures from this specialty set.

B.32. Skilled Nursing Facility

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070	007	CMS145 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI OR a current or prior LVEF <40 percent who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement
§	0083	008	CMS144 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40 percent who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium For Performance Improvemen
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	0041	110	CMS147 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement
§	0066	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40 percent who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
!	0101	154	N/A	Medicare Part	Process	Patient	**Falls: Risk Assessment:**	National

B.32. Skilled Nursing Facility

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
(Patient Safety)				B Claims Measure Specifications, MIPS CQMs Specifications		Safety	Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
§	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
	N/A	474	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet

Comment: One commenter was pleased to see the new proposed Skilled Nursing Facility Specialty Measure Set. The commenter noted this is the first step to delineating the SNF/NF setting as an integral but different area of practice of medicine that deserves its own consideration within MIPS and APM programs. However, the commenter noted that while there are many "reportable" measures included in the MIPS program, some measures are counter to recommendations for the SNF/NF population. The commenter requested CMS consider the following measures for this measure set; Q006: Coronary Artery Disease (CAD): Antiplatelet Therapy; Q007: Coronary Artery Disease (CAD): Beta-Blocker Therapy- Prior Myocardial Infraction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40 percent); Q047: Advance Care Plans; Q110: Preventive Care and Screening: Influenza Immunization; Q118: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40 percent); Q154: Falls: Risk Assessment (Two part measure pair with Q155); Q155: Falls: Plan of Care (Two part measure- pair with Q154); Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented; and Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy. Other commenters were supportive of the addition of the Skilled Nursing Facility measure set.

Response: We agree that this specialty set will assist clinicians who provide care within SNFs to identify measures applicable to their patient population. All of the measures suggested by the commenter (except Q154 and Q155) were proposed for inclusion in this specialty measure set and we agree that they are applicable to Skilled Nursing Facilities. In addition, we agree with the commenter that measures Q154 and Q155 should be included in this measure set for the 2019 Performance Period and future years.

FINAL ACTION: We are finalizing the *Skilled Nursing Facility Specialty Measure Set* as proposed for the 2019 Performance Period and future years with the exception of the newly proposed composite measure: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. We are no longer finalizing the inclusion of the composite falls measure because it must be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population. However, based on public comments, we are finalizing the individual measures Q154: Falls: Risk Assessment and Q155: Falls: Plan of Care as additional measures in this measure set.

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

In this final rule, we removed 26 previously finalized quality measures from the MIPS Program for the 2021 MIPS payment year and future years. These measures are discussed in detail below. As discussed in section III.I.3.h.(2)(b) of the final rule, please note that our measure removal criteria considers the following:

- Whether the removal of the measure impacts the number of measures available to a specific specialty
- Whether the measure addresses a priority area of the Meaningful Measures Initiative
- Whether the measure is linked closely to improved outcomes in patients

Further considerations are given in the evaluation of the measure's performance data, to determine whether there is or no longer is variation in performance. As discussed in section III.I.3.h.(2)(b) of this final rule, we applied additional criteria this year for the removal of measures, such as: extreme topped out measures, which means measures that are topped-out with an average (mean) performance rate between 98-100 percent.

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0088	018	CMS167v 7	eCQM Specifications	Process	Effective Clinical Care	**Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We proposed removal of this measure (finalized in (81 FR 77558 through 77675)) because it is duplicative both in concept and patient population as the currently adopted Measure 019: Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care (finalized in (81 FR 77558 through 77675)). Measure 019 is considered high priority because it promotes communication and care coordination with eligible clinicians managing diabetes care. The numerator of Measure 018 is considered the standard of care as it captures an assessment with no additional clinical action. Measure 018 neither assesses a clinical outcome nor one of the defined MIPS high priority areas.
0134	043	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who received an IMA graft.	Society of Thoracic Surgeons	We proposed removal of this measure (finalized in (81 FR 77558 through 77675)) because there is no longer variation in performance for the measure to be able to evaluate improvement in performance making this measure extremely topped-out as discussed in section III.I.3.h.(2) of this final rule. The average performance for this measure is 99 percent based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip. Therefore, we believe use of IMA has been widely accepted and implemented. The measure neither assesses a clinical outcome nor one of the defined MIPS high priority areas.
N/A	099	N/A	Medicare Part B Claims Measure Specifications,	Process	Effective Clinical Care	**Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category**	College of American Pathologists	We proposed removal of this measure (finalized in (81 FR 77558 through 77675)) because it is considered a standard of care that has

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
			MIPS CQMs Specifications			**(Regional Lymph Nodes) with Histologic Grade:** Percentage of breast cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes), and the histologic grade		a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.I.3.h.(2) of this final rule. The average performance for this measure is 99 percent based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip. In addition, the measure does not assess a clinical outcome nor one of the defined MIPS high priority areas.
N/A0392	100	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade:** Percentage of colon and rectum cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade	College of American Pathologists	We proposed removal of this measure (finalized in (81 FR 77558 through 77675)) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.I.3.h.(2) of this final rule. The average performance for this measure is 99.5 percent based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip. In addition, the measure neither assesses a clinical outcome nor one of the defined MIPS high priority areas.
N/A	122	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Adult Kidney Disease: Blood Pressure Management:** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) with a blood pressure < 140/90 mmHg OR ≥ 140/90 mmHg with a documented plan of care.	Renal Physicians Association	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because the measure has neither been updated nor planned to be updated by the measure steward to reflect the current clinical guidelines as indicated by the measure steward.
0566	140	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) or their caregiver(s) who were	American Academy of Ophthalmology	We proposed removal of this measure (finalized in (81 FR 77558 through 77675)) because the measure neither assesses a clinical outcome nor one of the defined MIPS high priority areas. The measure's quality action that only requires the provision of counseling of AREDS risk factors, but does not require discontinuation of

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NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
						counseled within the 12-month performance period on the benefits and/or risks of the Age-Related Eye Disease Study (AREDS) 2 formulation for preventing progression of AMD.		AREDS if risks/adverse effects are identified.
N/A	156	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Oncology: Radiation Dose Limits to Normal Tissues:** Percentage of patients, regardless of age, with a diagnosis of breast, rectal, pancreatic or lung cancer receiving 3D conformal radiation therapy who had documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues.	American Society for Radiation Oncology	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.I.3.h.(2) of this final rule. The average performance for this measure is 97.5 percent based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip.
0056	163	CMS123v7	eCQM Specifications	Process	Effective Clinical Care	**Comprehensive Diabetes Care: Foot Exam:** The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the measurement year.	National Committee for Quality Assurance	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is duplicative to the currently adopted Measure 126: Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation (finalized in 81 FR 77558 through 77675). However, Measure 163 is designated as a core performance measure by the Core Quality Measures Collaborative (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/CoreCQMs.html). Therefore, we specifically seek comments regarding the impact of removing this measure and replacing it with Measure 126. We strive to not duplicate measures in the program. We believe Measure 126 is a more appropriate measure because it targets an at-risk patient population, is clinically significant, and is in alignment with current clinical guidelines for neurological evaluation of diabetic neuropathy.
0068	204	CMS164v7	Medicare Part B Claims Measure Specifications, eCQM Specifications,	Process	Effective Clinical Care	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet:** Percentage of patients 18 years of age and older who were diagnosed with acute	National Committee for Quality Assurance	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it would be duplicative of a component within the existing measure Q441: Ischemic Vascular Disease: All or

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NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
			CMS Web Interface Measure Specifications, MIPS CQMs Specifications			myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period.		None Outcome Measure We strive to not duplicate measures in the program. In this case, we concluded that measure Q204 is captured within the more robust composite measure Q441.
N/A	224	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Melanoma: Avoidance of Overutilization of Imaging Studies:** Percentage of patients, regardless of age, with a current diagnosis of stage 0 through IIC melanoma or a history of melanoma of any stage, without signs or symptoms suggesting systemic spread, seen for an office visit during the one-year measurement period, for whom no diagnostic imaging studies were ordered.	American Academy of Dermatology	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.I.3.h.(2) of this final rule. The average performance for this measure is 99.5 percent based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip.
N/A	251	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Structure	Effective Clinical Care	**Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients:** This is a measure based on whether quantitative evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) by immunohistochemistry (IHC) uses the system recommended in the current ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in breast cancer	College of American Pathologists	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.I.3.h.(2) of this final rule. The average performance for this measure is 99 percent based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip. In addition, the measure does not assess a clinical outcome or one of the defined MIPS high priority areas.
1519	257	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy at Discharge after Lower Extremity Bypass (LEB):** Percentage of patients aged 18 years and older undergoing infra-inguinal lower extremity bypass who are prescribed a statin	Society for Vascular Surgeons	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because the clinical concept is captured within currently adopted Measure 438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (finalized in 81 FR 77558

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NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
						medication at discharge.		through 77675). Measure 438 captures all patients that require statin therapy. Whereas Measure 257 only captures a subset of the patient population undergoing lower extremity bypass.
N/A	276	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Sleep Symptoms:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of sleep symptoms, including presence or absence of snoring and daytime sleepiness.	American Academy of Sleep Medicine	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is duplicative to the currently adopted Measure 277: Sleep Apnea: Severity Assessment at Initial Diagnosis (finalized in 81 FR 77558 through 77675). Measure 276 only represents a quality action to assess for the sleep symptoms whereas Measure 277 includes the assessment along with the severity. This measure also lacks a quality action for positive assessments and does not indicate the use of a standardized tool. Also, the measure does not assess a clinical outcome nor one of the defined MIPS high priority areas.
N/A	278	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Positive Airway Pressure Therapy Prescribed:** Percentage of patients aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy.	American Academy of Sleep Medicine	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is duplicative to currently adopted Measure 279: Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy (finalized in 81 FR 77558 through 77675). Measure 279 is more robust and requires assessment of adherence to the therapy. Measure 278 does not assess a clinical outcome nor one of the defined MIPS high priority areas.
N/A	263	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Preoperative Diagnosis of Breast Cancer:** The percent of patients undergoing breast cancer operations who obtained the diagnosis of breast cancer preoperatively by a minimally invasive biopsy method.	American Society of Breast Surgeons	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying. The average performance for this measure is 99.3 percent based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip. In addition, the measure does not assess a clinical outcome nor one of the defined MIPS high priority areas.
N/A	327	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Pediatric Kidney Disease: Adequacy of Volume Management:** Percentage of calendar months within a 12-month	Renal Physicians Association	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to

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NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
						period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) undergoing maintenance hemodialysis in an outpatient dialysis facility have an assessment of the adequacy of volume management from a nephrologist.		improve clinical outcomes as it does not require a quality action if adequate volume management is not achieved. . In addition, the measure does not assess a clinical outcome nor one of the defined MIPS high priority areas.
N/A	334	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.I.3.h.(2) of this final rule. The average performance for this measure is 1.6 percent (inverse measure where a lower score is better performance) based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip.
N/A	359	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging:** Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institution's computer systems.	American College of Radiology	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is duplicative of the currently adopted Measure 361: Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry (finalized in 81 FR 77558 through 77675). The use of standardized nomenclature within this measure is intended to enable reporting to Dose Index Registries to allow comparison across radiology sites. This measure does not require the submission to a Dose Index Registry as indicated in Measure 361, but merely using standard nomenclature. We will continue to maintain Measure 361 that represents a more robust quality action to submit standardized data elements to a Dose Index Registry.
N/A	363	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive:**	American College of Radiology	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because the quality action does not completely attribute to the radiologist submitting the measure. Often, the CT studies are ordered and completed by referring clinicians without opportunity to

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
						Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external healthcare facilities or entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed.		complete the quality action by the radiologist. This allows their quality performance score to be impacted by other eligible clinicians. In addition, the measure does not require a quality action that links to improved outcomes when the search is completed prior to the study (that is, comparison).
N/A	367	CMS169v7	eCQM Specifications	Process	Effective Clinical Care	**Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use:** Percentage of patients with depression or bipolar disorder with evidence of an initial assessment that includes an appraisal for alcohol or chemical substance use.	Center for Quality Assessment and Improvement in Mental Health	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because the measure does not require a quality action that links to improved outcomes when assessed positive for alcohol or chemical substance use. The measure does not assess a clinical outcome or one of the defined MIPS high priority areas.
N/A	369	CMS158v7	eCQM Specifications	Process	Effective Clinical Care	**Pregnant women that had HBsAg testing:** This measure identifies pregnant women who had an HBsAg (hepatitis B) test during their pregnancy.	OptumInsight	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because the measure steward is no longer maintaining the measure for continued utilization. Furthermore, the measure is evaluating a standard of care as this test would be part of the routine screening for women receiving prenatal care and does not evaluate for care with positive testing results.
N/A	373	CMS65v8	eCQM Specifications	Intermediate Outcome	Effective Clinical Care	**Hypertension: Improvement in Blood Pressure:** Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.	Centers for Medicare & Medicaid Services	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because a similar clinical concept is represented in Measure 236. It is our goal to ensure duplicate measures are not included in the program. In addition, Measure 236 may apply to a larger eligible clinician cohort and offers expanded data submission methods that are not offered by Measure 373.
0465	423	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Perioperative Anti-platelet Therapy for Patients Undergoing Carotid Endarterectomy:** Percentage of patients undergoing carotid endarterectomy (CEA) who are taking an anti-platelet agent within 48 hours prior to	Society for Vascular Surgeons	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because the clinical concept is captured within our proposed measure Ischemic Vascular Disease: Use of Aspirin or Anti-platelet Medication. We refer readers to Table A.7 where this measure is proposed. The

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NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
						surgery and are prescribed this medication at hospital discharge following surgery.		proposed measure captures all ischemic vascular disease patients that should be receiving an aspirin or anti-platelet medication. Whereas, Measure 423 only captures a subset of the patient population undergoing carotid endarterectomy.
N/A	426	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU):** Percentage of patients, regardless of age, who are under the care of an anesthesia practitioner and are admitted to a PACU or other non-ICU location in which a post-anesthetic formal transfer of care protocol or checklist which includes the key transfer of care elements is utilized.	American Society of Anesthesiologists	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.I.3.h.(2) of this final rule. The average performance for this measure is 97.7 percent based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip.
N/A	427	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU):** Percentage of patients, regardless of age, who undergo a procedure under anesthesia and are admitted to an Intensive Care Unit (ICU) directly from the anesthetizing location, who have a documented use of a checklist or protocol for the transfer of care from the responsible anesthesia practitioner to the responsible ICU team or team member.	American Society of Anesthesiologists	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.I.3.h.(2) of this final rule. The average performance for this measure is 97.9 percent based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip.
N/A	447	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Chlamydia Screening and Follow-up:** The percentage of female adolescents 16 years of age who had a chlamydia screening test with proper follow-up during the measurement period.	National Committee for Quality Assurance	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is duplicative of currently adopted Measure 310: Chlamydia Screening for Women (finalized in 81 FR 77558 through 77675). We strive to not duplicate in the program. This measure is designated as a core performance measure by the Core Quality Measures Collaborative (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html). Therefore, we

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
								specifically seek comments regarding the impact of removing this measure.

Comment: A commenter supported CMSs proposed removal of 26 MIPS measures and applauded CMS for beginning to use its "Meaningful Measures" framework to streamline the measures used in the MIPS.

Response: We thank the commenter for their support.

Comment: Several commenters opposed the removal of measure Q048: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years. Removing the Urinary Incontinence measure will result in excluding up to half of women with urinary incontinence from quality measurement, resulting in loss of opportunity to improve outcomes. Commenters did not agree that measure Q048 is duplicative in concept and covers the same patient population as currently adopted measure Q050: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older." Measure Q048 is intended to promote screening for urinary incontinence, recognizing that urinary incontinence is under-reported by patients and under-evaluated by clinicians; measure Q050 is intended to ensure that women who have identified as having urinary incontinence are the evaluated and offered treatment, based on literature showing that patients reporting urinary incontinence are often not evaluated for what is otherwise a treatable condition. The denominator for measure 048 is all women aged 65 years and older, whereas the denominator for measure Q050 is all eligible women already diagnosed with urinary incontinence. Relying on measure Q050 alone for quality measurement related to urinary incontinence will exclude nearly half of women over age 65 that have urinary incontinence but have not been diagnosed. Measures 048 and 050 go hand-in-hand because interventions to increase urinary incontinence screenings (as measured by measure Q048) results in higher numbers of women receiving urinary incontinence treatment (as measured by measure Q050). Having measure Q050 without measure Q048 undermines the purpose of improving outcomes for women with urinary incontinence.

Response: After further consideration, we agree with commenters that the denominator for Q050 is not duplicative of Q048 and would not capture the under diagnosis of urinary continence. Therefore, we will not finalize measure Q048 for removal as proposed.

Comment: One commenter opposed the CMS proposal to retire three of the eight current Pathology measures: Q099 – Breast Cancer Resection Pathology Reporting Measure, Q100 – Colorectal Cancer Resection Pathology Reporting Measure Q251 - Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients. Removal of these measures would leave pathologists with only five QPP measures whereas the CMS requirement is to report on a minimum of six quality measures. The commenter noted that would significantly hinder successful participation by pathologists in the Quality category.

Response: Although we acknowledge that removing these measures limits the number of measures specific to pathology available for reporting, we do believe removing these measures is consistent with our policy to remove measures that have an extremely high performance rate. Based on the 2018 MIPS Benchmark results reflect an average of 99 percent for Q99 and Q251, and 99.5 percent for Q100 which allows limited opportunity to improve clinical outcomes. In the event an eligible clinician reports on less than 6 quality measures, because no other measures in the set are available or applicable to their scope of practice, the quality performance category score will be adjusted accordingly through the measure validation process.

Comment: One commenter supported the removal of measure Q122: Adult Kidney Disease: Blood Pressure Management because it cannot estimate the clinical impact based on the information provided by the measure developers and the measure lost NQF endorsement due to a lack of evidence. This measure does not conform to society guidelines and the measure specifications do not align with clinical recommendations on disease classification. Lastly, the denominator population is burdensome for clinicians to document a care plan for all patients classified as stage 3 and above without evidence to support the benefit of the intervention on clinical outcomes.

Response: We thank the commenter for their support to remove measure Q122: Adult Kidney Disease: Blood Pressure Management.

Comment: One commenter disagreed with the removal of measure Q122: Adult Kidney Disease: Blood Pressure Management The commenter stated removal would threaten patient care and disputes that the measure has not been updated nor is planned to be updated.

Response: We are continuously working with measure stewards to update the blood pressure values and were not updated in the annual revision cycle. We do not agree that the removal of this measure would threaten patient care. This clinical concept would also be captured in measure Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented.

Comment: One commenter opposed the removal of measure Q156: Oncology: Radiation Dose Limits to Normal Tissues stating, not only do oncology professionals continue to find value in this measure from a patient safety standpoint, they disagree with CMS' contention that it is truly topped out.

Response: This measure has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying. This does not allow meaningful benchmarks to be established. Based on the 2018 MIPS Benchmark Results, the average performance for this measure is 97.5 percent which does not allow ample opportunity to impact clinical outcomes.

Comment: One commenter supported the removal of measure Q163: Comprehensive Diabetes Care: Foot Exam measure from the from the CMS Web Interface collection type. Although the measure is included in the CQMC ACO Core Measure Set, the commenter recognized that measure sets used to evaluate different types of

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NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal

clinicians may need to differ to some extent, and did not agree it necessary to use the exact same measures to evaluate clinicians/groups and ACOs. The commenter also noted that this measure is not used in other health plan reporting programs such as MA Star Ratings and the QRS, so its removal from MIPS will not cause misalignment with those programs.

Response: We thank the commenter for their support to remove measure Q163: Comprehensive Diabetes Care: Foot Exam from the CMS Web Interface collection type.

Comment: One commenter supported removal of measure Q163: Comprehensive Diabetes Care: Foot Care because this measure is duplicative with measure Q126: Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy-Neurological Evaluation. Measure Q126 is the preferred and appropriate measure as it targets an at-risk patient population, is clinically significant, and is in alignment with current clinical guidelines.

Response: We thank the commenter for supporting the removal of measure Q163.

Comment: One commenter did not support the removal of measure Q163: Comprehensive Diabetes Care: Foot Exam until NQF completes its pending comparison with it and the Diabetes Mellitus: Diabetic Foot and Ankle Care measure (which the proposed rule suggests it duplicates). NQF found no significant difference in the measures' ability to identify the at-risk population or in the components of clinical assessment specified in them. More than 10,000 clinicians in NCQA's Diabetes Recognition Program report Comprehensive Diabetes Care: Foot Exam. The measure also is in the Core Quality Measures Collaborative ACO/PCMH and Primary Care set, which CMS described as "a major step forward" for quality measure alignment" and a "framework upon which future efforts can be based."

Response: We agree with the commenter's statement indicating that both measures' ability to identify the at-risk population or in the components of clinical assessment specified in them. Both measures aim to promote appropriate foot examination to identify risk factors predictive of ulcers and amputations. However, measure Q126 requires the frequency of the exam to be increased if abnormalities are present. More frequent evaluation of the diabetic foot is recommended depending on risk category. It is through systematic examination and risk assessment, patient education, and timely referral that eligible clinicians may further reduce the unnecessarily high prevalence of lower-extremity morbidity in the diabetes population. We attempt to align with CQMC, but believe this is duplicative of a more robust measure. As MIPS moves forwards, we will continue to explore ways to align measurement across programs.

Comment: A commenter did not support removal of the Q185: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use measure. The commenter noted that updated guidelines on the appropriate follow-up interval for patients with a history of adenomatous polyps are set to be released in the near future. The commenter also noted that it is likely that the measure specifications will be updated at that point, which may alter clinician performance. The commenter recommended that CMS retain the measure in MIPS until it is able to review other stakeholder concerns about measure performance, and that CMS work with the measure developer to update the MIPS measure specifications when new guidelines are released.

Response: We agree that updated guidelines could affect the performance of this measure causing the measure to have a substantive change and therefore may no longer have a benchmark that is considered to be topped out. We note this measure shows a 97.7 percent average performance for Medicare Part B Claims Measure Specifications while the MIPS CQMs Specification (registry) version shows less than 97 percent average performance rate. Based on our extremely topped out measure removal policy, we intend to only remove this measure from the Medicare Part B Claims Measure Specification collection type for the 2019 performance period. We will not finalize the removal of MIPS CQM collection type. We will work with the measure steward to update for the new clinical guidelines once those are released and continue to monitor the performance of the MIPS CQM Measure Specification in the future.

Comment: Several commenters supported the proposed removal of the Q204: Ischemic Vascular Disease: Use of Aspirin or Another Anti-Platelet measure.

Response: We thank the commenters for their support to remove measure Q204: Ischemic Vascular Disease: Use of Aspirin or Another Anti-Platelet measure.

Comment: Several commenters were concerned about the removal of Q204: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet because its specialties have identified this measure as a high-priority measure, and therefore, requested the measure not be removed. Another commenter disagreed with removal of Q204 as the Million Hearts Campaign, Core Quality Measures Collaborative ACO/PCHM and Primary Care set and many other public and private programs use this measure.

Response: We originally proposed a replacement measure that included appropriate denominator exceptions, but ultimately decided it was duplicative of measure Q441: Ischemic Vascular Disease All or None Outcome Measure (Optimal Control). Therefore, to be consistent with our policy to remove measures that are duplicative to other measures and to ensure measures are more meaningful, we have decided to not finalize inclusion of this new IVD measure. In addition, it would introduce a measure that was not aligned with the Million Hearts Campaign, Core Quality Measures Collaborative ACO/PCHM and Primary Care set. We will finalize the proposal to remove Q204. Measure Q204 is duplicative and does not have appropriate denominator exceptions/exclusions to account for patients who are not appropriate for aspirin or antiplatelet therapy (that is, history of gastrointestinal bleeding, intracranial bleeding, bleeding disorder, allergy to aspirin or anti-platelets, or use of non-steroidal anti-inflammatory agents). We encourage the commenters to submit the outcome measure that addresses this concept.

Comment: One commenter expressed concern on the proposed removal of measures Q224: Melanoma: Avoidance of Overutilization of Imaging Studies and Q156: Oncology: Radiation Dose Limits to Normal Tissues without proposing new oncology-related measures to replace them. CMS should also be mindful of the need to ensure an adequate number of applicable measures for oncologists and other specialty groups when proceeding with decisions about measure removal.

Response: We refer the commenter to review the Oncology specialty measure set that provides a narrowed list of measures applicable to the oncology specialty. The specialty measure sets are reviewed annually by stakeholders to include applicable measures. The oncology measure set contains 24 quality measures.

Comment: Two commenters opposed the removal of measure Q276: Sleep Apnea: Assessment of Sleep Symptoms; and the adoption of measure Q277: Severity Assessment at Initial Diagnosis. One commenter noted that Q277 focuses on care provided to patients with a diagnosis of obstructive sleep apnea, and that many

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal

patients with neurologic disorders experience sleep disturbances and disorders other than obstructive sleep apnea. They also noted that removing Q276 would result in limited reporting options for neurologists specializing in sleep care. They stated also that while it may be easier to see the value in calculating the severity of sleep apnea, as required in measure Q277; that in accordance with evidence-based Clinical Practice Guideline for Diagnostic Testing for Obstructive Sleep Apnea, diagnostic testing for obstructive sleep apnea should be performed in conjunction with a comprehensive sleep evaluation and adequate follow-up. One of the commenters noted that patients with untreated obstructive sleep apnea are also at an increased risk of being diagnosed with cardiovascular disease, difficult-to-control blood pressure, coronary artery disease, congestive heart failure, arrhythmias, and stroke. They stated further that sleep medicine professionals need relevant measures to report for participation in the MIPS program, and currently there are only four sleep medicine measures available.

Response: These measures address the same patient population; however, Q276, does not identify a standardized tool to assess sleep symptoms whereas Q277 defines a standard method of assessment. This allows clinicians a baseline to assess if the patient is being treated appropriately. A non-standardized assessment of daytime sleepiness may be circumstantial and may not be a reliable indicator of appropriate treatment. In addition, the measure Q276 does not have a quality action if the patient is experiencing daytime sleepiness. We agree with the commenters' suggestions that sleep apnea should be performed in conjunction with a comprehensive sleep evaluation and adequate follow-up. The Q276 measure does not address the adequate follow-up component to mitigate the risks of cardiovascular disease, difficult-to-control blood pressure, coronary artery disease, congestive heart failure, arrhythmias, and stroke. We encourage the commenters to collaborate with measure developers to submit new measures that address sleep apnea in the Call for Measures process. In the event an eligible clinician reports on less than 6 quality measures, because no other measures in the set are available or applicable to their scope of practice, the quality performance category score will be adjusted accordingly through the measure validation process.

Comment: One commenter opposed removal of Q278 Sleep Apnea: Positive Airway Pressure Prescribed and requested that the measure be categorized as a high priority patient safety measure, given the overwhelming amount of evidence in the medical literature describing the negative effects of untreated sleep disorders. They noted that patients with untreated obstructive sleep apnea are also at an increased risk of being diagnosed with cardiovascular disease, difficult-to-control blood pressure, coronary artery disease, congestive heart failure, arrhythmias, and stroke. They stated further that sleep medicine professionals need relevant measures to report for participation in the MIPS program, and currently there are only four sleep medicine measures available.

Response: We are attempting to reduce reporting burden where measures are duplicative in concept or do not drive quality action by eligible clinician. We believe that this measure is low bar and choose to continue to implement measure Q279 is more robust and requires assessment of adherence to the therapy. Measure Q278 does not assess a clinical outcome nor one of the defined MIPS high priority areas. We encourage the commenters to collaborate with measure developers to submit new measures that address sleep apnea in the Call for Measures process. In the event an eligible clinician reports on less than 6 quality measures, because no other measures in the set are available or applicable to their scope of practice, the quality performance category score will be adjusted accordingly through the measure validation process.

Comment: One commenter opposed removal of measure Q327: Pediatric Kidney Disease: Adequacy of Volume Management. This measure meets several national quality strategy domains – clinical care, care coordination, and patient and caregiver experience and removal of this measure would leave only one MIPS measure for pediatric nephrologists. A second commenter also opposed the removal of measure Q327 because they noted that despite the small number of Medicare pediatric patients, many pediatric nephrologists do not meet the low volume threshold and are still required to participate in the Quality Payment Program. The commenter also noted also that very few measures exist that allow pediatric nephrologists to participate meaningfully. They requested CMS not to eliminate this or any other pediatric kidney disease measures from the Quality Payment Program unless and until they can be replaced with other measures specific to pediatric kidney disease.

Response: Although, we acknowledge that removing this measure limits the number of measures specific to pediatric nephrologists available for reporting, we do believe removing this measure is consistent with our policy to move towards more meaningful measures and decrease burden for eligible clinicians. This is a process measure that does not assess if there the patient had appropriate volume management, but whether the adequacy was assessed. As we move toward more outcome-based measures, we suggest the commenter to collaborate with measure stewards to develop an outcome measure that the patient aligns with the post dialysis weight. In addition, although there are not many specific measures available, there are cross-cutting measures that we believe would be applicable to pediatric nephrologists and could be submitted. This measure is only available by CQM Measure Specification, and therefore, in the event an eligible clinician reports on less than 6 quality measures, because no other measures in the set are available or applicable to their scope of practice, the quality performance category score may be adjusted through the measure validation process as applicable.

Comment: One commenter did not support the choice to remove the Q334: Adult Sinusitis CT scan measure because they noted that CMS did not follow the established process of utilizing a 4-year, step-down period for removing topped out measures. The commenter requested that CMS follow this process so that measure stewards are able to plan accordingly for other measure development before an existing measure is retired.

Response: By removing these extremely topped out measures, we are attempting to reduce reporting burden where there is little room for improvement. Additionally, this allows eligible clinicians to maximize their potential quality performance category score. Based on the 2018 Benchmark File, this measure only supported the creation of deciles 3 to 5, which would limit the score awarded for the measure.

Comment: One commenter opposed removal of measure Q359: Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging measure because they did not agree that it is duplicative of Q361: OPEIR - Reporting to a Dose Index Registry, which they noted is only intended to enable reporting to a dose index registry to allow comparison across radiology sites. They stated that removing this measure may affect some radiologists' ability to meet quality measure requirements.

Response: Standardized nomenclature permits data mining in order to participate in research projects, registries, and quality improvement efforts. This facilitates a first step toward structured reporting to Radiation Dose Index Registries, which would be captured in measure Q361: Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry. Even with the removal of this measure, the Radiology specialty measure set has more than 6 quality measures. In the event an eligible clinician reports on less than 6 quality measures, because no other measures in the set are available or applicable to their scope of practice, the quality

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal

performance category score will be adjusted accordingly through the measure validation process.

Comment: One commenter opposed the removal of measure Q363: Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive. The commenter respectfully suggested that CMS fails to appreciate the process upon which this measure has impact. It is correct that referring clinicians place orders, but radiologists would complete the exams. The measure quality action is that prior to performing the ordered exam, the radiologist would search existing image exchanges across institutions or geographic area for existing prior images for the patient. The potential improved outcome would be a reduction in patient exposure to radiation, as well as a substantial reduction when duplicative imaging procedures are avoided. Additionally, broader access to existing imaging studies, including relevant prior images used for comparative purposes of patient history (of lesions for example) could improve diagnostic specificity and accuracy for radiologists and potentially further minimize recommendations for follow-up studies. In addition, they stated that removing this measure may affect some radiologists' ability to meet quality measure requirements.

Response: While we appreciate the intent to review historical images and reduce radiation, the measure requires a finalized report of a CT study to be denominator eligible. Therefore, it would exclude instances where the duplicative CT was appropriately cancelled as they would no longer be denominator eligible. An eligible clinician can be numerator compliant if a CT was completed and had identified a prior CT exam. Therefore, it does not promote radiation reduction. Even with the removal of this measure, the Radiology specialty measure set has more than 6 quality measures. In the event an eligible clinician reports on less than 6 quality measures, because no other measures in the set are available or applicable to their scope of practice, the quality performance category score will be adjusted accordingly through the measure validation process.

Comment: One commenter opposed removal of measure Q373: Hypertension: Improvement in Blood Pressure measure because of its impact on patient care and low reporting burden. They noted that the data is already documented in the EHR as part of standard workflows. One commenter agreed that measure Q373: Hypertension: Improvement in Blood Pressure provides no incremental benefit over measure Q236. However, the commenter expressed concern that a one-size-fits-all SBP goal of < 140/90 mm Hg may suggest to patients and their healthcare providers that their treatment is adequate if they reach this goal. In the future, as further evidence accumulates for other cohorts of patients, the commenter hoped a more comprehensive set of blood pressure control measures that are tailored to patients' cardiovascular risk will become available for CMS reporting.

Response: We are committed to our goal to remove measures that are duplicative to other measures and to be consistent with ensuring measures are more meaningful. As we indicated in our proposal, this measure is very similar in clinical concept to measure Q236: Controlling High Blood Pressure. We believe measure Q236 may apply to a larger eligible clinician cohort and offers expanded collection types that are not offered by measure Q373. Both measures are available via eCQM Specifications, and therefore, measure Q236 would have a low reporting burden since the data is already documented in the EHR as indicated by the commenter. In addition, we will continue to work with measure stewards to update the current blood pressure measures to align with clinical guidelines as appropriate or evaluate potential new measures to propose for the program.

Comment: One commenter expressed concerns about Appendix Table C and that it is premature to remove measures for which replacement measures are concurrently being proposed, (for example, Falls Screening and Functional Status Assessment for Total Knee Replacement), until vendors have had the necessary time to develop, certify and deploy their respective replacement measures.

Response: We provided a measure preview this year to allow for technical revisions, this also allowed vendors to gather preliminary implementation strategies. Additionally, all measure finalized will be posted on the CMS website prior to the start of the 2019 performance period. We also aim to reduce the number of duplicative measures. If we retain the Functional Status Assessment for Total Knee Replacement for the 2019 performance period, this would be duplicated measure concept of measure Q470: Average Change in Functional Status Following Total Knee Replacement Surgery.

Comment: Two commenters did not support removal of Q386: Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences from this measure set. The commenters appreciated the effort to decrease redundancy between this measure and the Q047 Advance Care Plan measure. While these measures do overlap, the commenters noted that ALS measure specification recognizes the likely earlier age of onset of this devastating diagnosis and the need to have earlier planning conversations around palliative and end of life care by having no minimum age requirement. For this reason, the commenter believed the measure should be retained.

Response: We agree with the commenters concerns about removing measure Q386 and will not finalize this measure for removal. Specifically, we agree that patients with ALS are often younger than those in the denominator for Measure 047, which includes patients age 65 and older. For this reason, we concur with commenters that a separate measure applying to all patients with a diagnosis of ALS is clinically indicated.

Comment: One commenter did not support the removal of measure Q426: Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU) and measure Q427: Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU). Their removal would jeopardize many anesthesiologists' opportunities to report the required six quality measures. The anesthesiology measure set currently includes seven anesthesia-specific measures and a handful of measures that are only reportable using evaluation and management codes–codes that are rarely reported by anesthesiologists. For anesthesiologists working in ambulatory settings and on surgeries lasting less than one hour, the number of applicable measures would be reduced to just one measure. In previous years, CMS correctly identified measures Q426 and Q427 as high-priority measures. The proposed removal of these measures would expose contradictions between CMS' intent to improve communication and care coordination with the removal of measures aimed at ensuring communication between clinicians. When considering Advanced Alternative Payment Models (APMs), and the need for entities to use measures comparable to MIPS, these two measures should be identified by those Advanced APMs as helping to reduce medical errors, adverse medication events, expedite recovery and reduce costs.

Response: Measures Q426: Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU) and Q427: Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU) are being removed as they have limited opportunity to produce clinical outcomes as the performance rates are extremely topped out. By removing these extremely topped out measures, we are attempting to reduce reporting burden where there is little room for improvement. In the event an eligible clinician reports on less than 6 quality measures, because no other measures in the set are

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal

available or applicable to their scope of practice, the quality performance category score will be adjusted accordingly through the measure validation process. We agree that promoting communication between clinician is important, the performance data does not support a gap in communication and drive quality improvement in this area. We encourage the commenter to work with measure developers to create a measure that promotes communication that addresses current gap in the anesthesia specialty.

Comment: Another commenter did not support removal of topped out measures: Q426: Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU) and Q427: Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU). The commenter was concerned about removal of these measures as they relate to CRNAs. Without a concerted effort to expand measure specifications to include non-patient facing CPT codes, the commenter recommended that measures attributed to non-patient facing clinicians be excluded from the removal process to assure that CRNAs do not face additional burden by not having enough applicable measures to participate in MIPS.

Response: Measures Q426: Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU) and Q427: Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU) are being removed as they have limited opportunity to produce clinical outcomes as the performance rates are extremely topped out. By removing these extremely topped out measures, we are attempting to reduce reporting burden where there is little room for improvement. In the event a CRNA reports on less than 6 quality measures, because no other measures in the set are available or applicable to their scope of practice, the quality performance category score will be adjusted accordingly through the measure validation process. With the measure validation process in place, we do not agree with the commenter to maintain all non-patient facing measures.

Comment: Two commenters supported removal of the Q447: Chlamydia Screening and Follow-Up measure from the MIPS program. Although the measure proposed for removal is included in the CQMC OB/GYN Core Measure Set, the measure that CMS proposes to retain in MIPS, Q310: Chlamydia Screening in Women, is also a CQMC measure. The commenters agreed that the measure proposed to be retained provides more comprehensive quality information, as it includes a wider age range compared to the measure that would be remove and is limited to patients identified as sexually active.

Response: We thank the commenters for their support.

Comment: One commenter stated that they support CMS' outline of removal criteria to be considered when removing a measure. However, the commenter also requested that CMS evaluate measures for removal based on the collection type. For example, they noted that several eCQMs proposed for removal due to a duplicative measure being available; however, in most instances, that duplicative measure is not available as an eCQM. This would potentially force practices to maintain relationships and pay for reporting through multiple vendors to maintain their list of measures. Specifically, this affects the proposed removal of eCQMs Q163 (Comprehensive Diabetes Care: Foot Exam), Q204 (Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet), Q318 (Falls: Screening for Future Fall Risk), and Q375 (Functional Status Assessment for Total Knee Replacement: Changes to the measure description). Another commenter expressed similar concerns about removal of Q373: Hypertension: Improvement in Blood Pressure: Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.

Response: In response to this concern, we conducted an analysis of the measures proposed for removal with an eCQM collection type. As a result of this analysis, we concluded that we will not finalize measures Q012, Q318, and Q375 for removal because there is not an eCQM collection type offered in the measures that we proposed as duplicative measures. With regard to updating the removal criteria to consider data collection type overall, we will take this into consideration as we refine future removal criteria.

FINAL ACTION: We are finalizing the removal of these measures as proposed for the 2019 Performance Period and future years with the exception of the following measures: Q012, Q048, Q154, Q155, Q185, Q318, Q375 and Q386. Our decisions to not finalize these measures for removal in this final rule are detailed in our responses above to the public comments for these measures. Note: The new measure "Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls" will not be finalized for inclusion in this final rule because the measure steward believes it is not implementable at this time. Therefore, the three falls measures (Q154, Q155, and Q318) will remain in the program for the 2019 performance period because they are important to evaluate for high-risk of falling.

TABLE Group D: Measures with Substantive Changes Finalized for the 2021 MIPS Payment Year and Future Years

D.1. Medication Reconciliation Post-Discharge

Category	Description
NQF #:	0097
Quality#:	046
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of discharges from any inpatient facility (for example hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years and older of age seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is reported as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age • Submission Criteria 2: 65 years and older • Total Rate: All patients 18 years of age and older
Substantive Change:	**Modified collection type**: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We removed the CMS Web Interface Measure Specifications collection type. This is a process measure, which promotes care coordination when transitioning from an inpatient facility to outpatient care. Removal of this measure from the CMS Web Interface supports our effort to move towards outcome and more meaningful measures within the CMS Web Interface. In addition, since clinicians are required to report all available CMS Web Interface measures, removing this measure from the CMS Web Interface will reduce the burden of the number of measures a clinician is required to report under the CMS Web Interface. This measure is broadly applicable to eligible clinicians participating in the MIPS program using the collection types of Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications. Retaining this measure through the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types allows clinicians to choose this measure as one of the six measures clinicians are generally required to report to meet the quality performance category requirements.

Comment: Commenters indicated that CMS should retain this measure because ensuring clinicians are reconciling patient medications limits the occurrence of adverse drug events for elderly patients with multiple co-morbidities and prescription medications.

Response: This is a process measure that promotes care coordination when transitioning from an inpatient facility to outpatient care. While we agree that medication reconciliation is an important aspect of care coordination and avoiding adverse drug events, we believe a more broadly applicable measure that does not just focus on medication reconciliation post discharge would more effectively promote care coordination. In addition, since clinicians are required to report all available CMS Web Interface measures, removing this measure from the CMS Web Interface will reduce the burden of the number of measures a clinician is required to report under the CMS Web Interface. We do not believe removing this measure from one collection type, CMS Web Interface, will increase the occurrence of adverse drug events because eligible clinicians have the opportunity to report this measure as a Medicare Part B Claims Measure Specification or MIPS CQMs Specification.

Comment: In addition, several commenters expressed general concerns that the measures we proposed to remove from the CMS Web Interface would continue to be used in other programs or that they would remain available to report to MIPS via other reporting mechanisms, creating inconsistency in the available measure set by reporting mechanism. One commenter expressed concerns about removal of the CMS Web Interface and its impact on the Medicare Shared Savings Program and ACO participants that utilize this data collection method for this measure.

Response: We acknowledge that measures proposed for removal from the CMS Web Interface may continue to be required by other programs and available by other collection types. However, removing them from the CMS Web Interface would reduce burden on MIPS groups and ACO participants by removing the requirement that they actively submit the measure performance data through the CMS Web Interface. For MIPS groups, we are removing this measure to reduce burden of reporting the required measure set. However, we are retaining this measure through the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types to allow clinicians an opportunity to report this measure as one of the six measures to meet the quality performance category requirements.

FINAL ACTION: We are finalizing the changes to measure Q046 as proposed for the 2019 Performance Period and future years.

D.2. Pneumococcal Vaccination Status for Older Adults

Category	Description
NQF #:	N/A
Quality#:	111
CMS eCQM ID:	CMS127v7
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We removed the CMS Web Interface Measure Specifications collection type. This measure has lost NQF endorsement and no longer reflects the current guidelines. A new measure is under development to reflect current guidelines and may be proposed in the future. In addition, since clinicians are required to report all available CMS Web Interface measures, removing this measure from the CMS Web Interface will reduce the burden of the number of measures a clinician is required to report under the CMS Web Interface. This measure is broadly applicable to eligible clinicians participating in the MIPS program using the collection types of Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications, and eCQM specifications. Retaining this measure through the Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications, and eCQM specification collection types allows clinicians to choose this measure as one of the six measures clinicians are generally required to report to meet the quality performance category requirements. We encourage stakeholders to submit a replacement measure for future consideration that is in alignment with the most current clinical guidelines.

Comment: Several commenters opposed the removal of the CMS Web Interface Measure Specifications collection type for this measure. The commenter recommended that CMS works toward immediately replacing the measure with another similar (and endorsed) measure which will lead to the capture of comprehensive care of elderly patients. They noted that complete removal and no replacement of this measure will lessen the incentive and urgency for ACOs to administer this life saving vaccination, resulting in fewer patients vaccinated, and leading to worsened outcomes and higher costs.

Response: We agree on the importance of a pneumonia vaccination measure. However, we believe the burden to submit this measure via the CMS Web Interface and the loss of NQF endorsement aligns with our goal to be less burdensome for clinicians and ensure measures are still supported by the current clinical guidelines. Furthermore, we acknowledge that pneumonia vaccination is an important preventive clinical intervention, but measure Q111 does not address current pneumonia vaccination guidelines. We believe maintaining the measure under other collection types to provide an option to select a measure that addresses important population health matter. However, until this measure can be replaced with a measure promoting pneumococcal vaccination, we believe it should not be required to be submitted via the CMS Web Interface. Eligible clinicians submitting Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications are able to select quality measures that are applicable to their specialty that are meaningful to their practice. In the CMS Web Interface, all measures are required; therefore, some eligible clinicians may believe the measure to be burdensome since it does not fully align with the current pneumococcal vaccination schedule.

Comment: A few commenters expressed concern that the measures we proposed to remove from the CMS Web Interface would continue to be used in other programs or that they would remain available to report to MIPS via other reporting mechanisms, creating inconsistency in the available measure set by reporting mechanism.

Response: We acknowledge that measures proposed for removal from the CMS Web Interface may continue to be required by other programs and available by other collection types. However, removing them from the CMS Web Interface would reduce burden on MIPS groups and ACO participants by removing the requirement that they actively submit the measure performance data through the CMS Web Interface. Specific to ACO participants, ACOs can track these additional metrics in order to participate in the Shared Savings Program and potentially earn shared savings. We note, however, that one of the advantages of clinician participation in a Shared Savings Program ACO is that the ACO reports quality on the clinicians' behalf, reducing clinician burden. We believe that this streamlined approach benefits ACOs in reducing program complexity and enables CMS to make meaningful comparisons on a consistent measure set, across ACOs who are eligible to share in any earned savings or may be responsible for any owed losses, based on that performance. For MIPS groups, we are removing this measure to reduce burden of reporting the required measure set. However, we are retaining this measure through the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types to allow clinicians an opportunity to report this measure as one of the six measures to meet the quality performance category requirements.

Comment: One commenter stated that measure Q111: Pneumococcal Vaccination Status for Older Adults is aligned with the CMS Meaningful Measures Framework and is a high-impact measure. The commenter did not agree with CMS' concern that the measure is not aligned with ACIP pneumococcal vaccination recommendations. The commenter requested that CMS retain the current pneumococcal vaccination measure until such time as it can be updated with new measure(s).

Response: We agree that the measure addresses an important population health matter and encourage measure developers to submit an updated measure through the Call for Measures process. Please note that we are retaining this measure in the MIPS program and this substantive change only relates to the removal of the CMS Web Interface data collection method. The removal of the CMS Web Interface was proposed to reduce burden on MIPS groups and ACO participants by removing the requirement that they actively submit the measure performance data through the CMS Web Interface. We maintain the concern that it is not in complete alignment with the ACIP recommendations. The measure specification only requires one dose ever documented, either the PCV13 or PPSV23 vaccine (or both). According to ACIP recommendations, patients should receive both vaccines. The order and timing of the vaccinations depends on certain patient characteristics, and are described in more detail in the ACIP recommendations.

Category	Description
FINAL ACTION: We are finalizing the changes to measure Q111 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure: The CMS eCQM ID changed from "CMS127v6" to "CMS127v7." The NQF# changed from "0043" to "N/A" due to loss of NQF endorsement. These changes were also applied to specialty measure sets in Table Group B where this measure was included.	

D.3. Diabetes: Eye Exam

Category	Description
NQF #:	0055
Quality #:	117
CMS eCQM ID:	CMS131v7
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period
Substantive Change:	**Modified collection type**: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We removed the CMS Web Interface Measure Specifications collection type. This measure evaluates a process in the care for the patient. Removal of this measure from the CMS Web Interface Measure Specifications supports our effort to move towards outcome and meaningful measures. In addition, since clinicians are required to report all available CMS Web Interface measures, removing this measure from the CMS Web Interface will reduce the burden of the number of measures a clinician is required to report under the CMS Web Interface. This measure is broadly applicable to eligible clinicians participating in the MIPS program using the collection types of Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications, and eCQM specifications. Retaining this measure through the Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications, and eCQM specification collection types allows clinicians to choose this measure as one of the six measures clinicians are generally required to report to meet the quality performance category requirements

Comment: One commenter opposed the elimination the CMS Web Interface Measure Specifications collection type for this measure as regular exams are vital to preventing unnecessary vision loss.

Response: We believe this measure would be burdensome to require all eligible clinicians using the CMS Web Interface to submit this measure. All measures included in the CMS Web Interface are required to be submitted even if the measure may not apply to a particular specialty. We are maintaining the measure under other collection types to provide an option to select a measure that addresses important process in diabetes care. Eligible clinicians submitting Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications are able to select quality measures that are applicable to their specialty that are meaningful to their practice. In the CMS Web Interface, all measures are required, therefore some eligible clinicians may believe the measure to be burdensome.

Comment: A few commenters expressed concern that the measures we proposed to remove from the CMS Web Interface would continue to be used in other programs or that they would remain available to report to MIPS via other reporting mechanisms, creating inconsistency in the available measure set by reporting mechanism.

Response: We acknowledge that measures proposed for removal from the CMS Web Interface may continue to be required by other programs and available by other collection types. However, removing them from the CMS Web Interface would reduce burden on MIPS groups and ACO participants by removing the requirement that they actively submit the measure performance data through the CMS Web Interface. Specific to ACO participants, ACOs can track these additional metrics in order to participate in the Shared Savings Program and potentially earn shared savings. We note, however, that one of the advantages of clinician participation in a Shared Savings Program ACO is that the ACO reports quality on the clinicians' behalf, reducing clinician burden. We believe that this streamlined approach benefits ACOs in reducing program complexity and enables CMS to make meaningful comparisons on a consistent measure set, across ACOs who are eligible to share in any earned savings or may be responsible for any owed losses, based on that performance. For MIPS groups, we are removing this measure to reduce burden of reporting the required measure set. However, we are retaining this measure through the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types to allow clinicians an opportunity to report this measure as one of the six measures to meet the quality performance category requirements.

FINAL ACTION: We are finalizing measure Q117: *Diabetes: Eye Exam* as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure: The CMS eCQM ID changed from "CMS131v6" to "CMS131v7." These changes were also applied to specialty measure sets in Table Group B where this measure was included.

D.4. Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan

Category	Description
NQF #:	0421
Quality #:	128
CMS eCQM ID:	CMS69v7
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.
Substantive Change:	**Modified collection type**: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications **Updated the denominator exception logic:** for the eCQM Specifications collection type to allow medical reasons for not obtaining the BMI.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We removed the CMS Web Interface Measure Specifications collection type. This measure evaluates a process in the care for the patient. Removal of this measure from the CMS Web Interface Measure Specifications supports our effort to move towards outcome and meaningful measures. In addition, since clinicians are required to report all available CMS Web Interface measures, removing this measure from the CMS Web Interface will reduce the burden of the number of measures a clinician is required to report under the CMS Web Interface. This measure is broadly applicable to eligible clinicians participating in the MIPS program using the collection types of Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications, and eCQM specifications. Retaining this measure through the Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications, and eCQM specification collection types allows clinicians to choose this measure as one of the six measures clinicians are generally required to report to meet the quality performance category requirements. We updated the denominator exception logic for the eCQM Specifications collection type to allow medical reasons for not obtaining the BMI. The Technical Expert Panel (TEP) convened by the measure steward recommended adding a medical reason as there could be valid medical reasons for not obtaining the BMI. We agree with the TEP to add a medical exception. There are valid medical reasons that may inhibit the eligible clinicians from obtaining a BMI. Specifically, CMS69v6 has denominator exceptions for medical reasons for not providing the follow-up plan. These exceptions are currently expressed as "Intervention, Order not done" and "Medication, Order not done". The updated measure, CMS69v7, adds an exception to remove patients from the denominator who have a medical reason for not having a BMI performed. This exception was added to account for patients for whom it may be physically difficult to conduct a BMI, such as patients who are unable to stand or for whom their weight exceeds scale limits. This update will provide eligible clinicians the opportunity to exclude patients when there is an appropriate medical reason documented.

Comment: One commenter suggested that BMI screening and follow-up is an important metric since weight loss and gain are symptoms of some mental health disorders and patients with serious mental illness face increased risks for obesity and early death from medical co-morbidities as a side-effect of psychotropic medications. One commenter supported the updates to this measure. Another commenter suggested that elimination of this measure would impact the long-term importance of assessing clinician performance related to population health.

Response: We agree that obesity-related care is important; however, we believe that this issue will continue to be addressed under several of the measures that remain in the CMS Web Interface and SSP measure set, for example the 30 day all-cause readmission measure, and the hypertension, statin, diabetes measures.

Comment: A few commenters expressed concern that the measures we proposed to remove from the CMS Web Interface would continue to be used in other programs or that they would remain available to report to MIPS via other reporting mechanisms, creating inconsistency in the available measure set by reporting mechanism.

Response: We acknowledge that measures proposed for removal from the CMS Web Interface may continue to be required by other programs and available by other collection types. However, removing them from the CMS Web Interface would reduce burden on MIPS groups and ACO participants by removing the requirement that they actively submit the measure performance data through the CMS Web Interface. Specific to ACO participants, ACOs can track these additional metrics in order to participate in the Shared Savings Program and potentially earn shared savings. We note, however, that one of the advantages of clinician participation in a Shared Savings Program ACO is that the ACO reports quality on the clinicians' behalf, reducing clinician burden. We believe that this streamlined approach benefits ACOs in reducing program complexity and enables CMS to make meaningful comparisons on a consistent measure set, across ACOs who are eligible to share in any earned savings or may be responsible for any owed losses, based on that performance. For MIPS groups, we are removing this measure to reduce burden of reporting the required measure set. However, we are retaining this measure through the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types to allow clinicians an opportunity to report this measure as one of the six measures to meet the quality performance category requirements.

FINAL ACTION: We are finalizing the changes to measure Q128 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure: The CMS eCQM ID changed from "CMS69v6" to "CMS69v7." These changes were also applied to specialty measure sets in Table Group B where this measure is included.

D.5. Oncology: Medical and Radiation – Plan of Care for Moderate to Severe Pain

Category	Description
NQF #:	0383
Quality #:	144
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having moderate to severe pain with a plan of care to address pain documented on or before the date of the second visit with a clinician
Substantive Change:	**The new numerator is revised to read**: Patients for whom a plan of care to address moderate to severe pain is documented on or before the date of the second visit with a clinician. Updated the denominator to clearly state that population for this measure would be limited to patients who had moderate to severe pain. **The new denominator is revised to read**: All patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy who report having moderate to severe pain or All patients, regardless of age, with a diagnosis of cancer currently receiving radiation therapy.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We modified the numerator to state that the plan of care for pain management should be documented in the first 2 visits (not at any point during the performance period). The current measure requires the plan of care to be documented at any time during the performance period. We modified the denominator to clearly state that the population for this measure would be limited to patients who had moderate to severe pain. Pain severity continues to remain largely unaddressed, especially in those patients who have moderate/severe pain. The edits to this measures numerator would ensure that the oncologist documents a plan of care early, so as to ensure that patients who have moderate to severe pain know what pain management options are available to them earlier on when receiving chemotherapy and radiation, and can become engaged early on in their healthcare decisions. The update to the numerator is based on American Society of Clinical Oncology feedback on the measure by Quality Oncology Practice Initiative registry users who realize that the measure should focus on this to ensure quality of life via pain management is improved in cancer patients.

Comment: One commenter supported the changes to this measure.

Response: We thank the commenter for their support.

FINAL ACTION: We are not finalizing the changes to measure Q144 as proposed for the 2019 Performance Period and future years because, upon reviewing the steward's test results for the proposed numerator and denominator changes, NQF determined that the measure steward's testing data was insufficient. As a result, the NQF has requested that the measure steward retest these changes with sufficient data. Therefore, we will retain the current 2018 numerator and denominator specifications for this measure, as follows:

Numerator: Patient visits that included a documented plan of care to address pain
Denominator: All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain.

Please note that, although the proposed substantive changes are not finalized, the following technical changes were made to this measure for further accuracy based on feedback from the measure steward: The Measure Title was changed from "Medical and Radiation – Plan of Care for Pain" to "Medical and Radiation – Plan of Care for Moderate to Severe Pain." This change was applied to specialty measure sets in Table Group B where this measure is included.

D.6. Rheumatoid Arthritis (RA): Tuberculosis Screening

Category	Description
NQF #:	N/A
Quality #:	176
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD)
Substantive Change:	**The new description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 12 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD). **The new numerator is revised to read**: Patients for whom a TB screening was performed and results interpreted within 12 months prior to receiving a first course of therapy using a biologic DMARD.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We updated to the numerator to require the TB screening 12 months prior to the first biologic treatment rather than 6 months as currently stated. The measure steward believes this measure should be more in line with the specifications found in a similar measure developed by the American College of Rheumatology (ACR) and endorsed by the National Quality Forum (NQF). In creating its version of this measure, the ACR conducted an extensive development and review process. The measure was built by a panel of rheumatology experts, in conjunction with the ACR, based on quality of care guidelines and broad reviews of relevant research. Upon completion, the measure was shared with thousands of rheumatology clinicians across the U.S. for public comment. Following the comment period, the measure was updated appropriately based on the feedback received, then rigorously tested to ensure reliability and validity. The measure, along with the results of the testing, was submitted to the NQF for review and obtained trial endorsement. We typically prefer the use of NQF endorsed measures over measures that lack endorsement. However, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure revision from tuberculosis screening from 6 months to 12 months can be supported by evidence and is an important measure to ensure proper tuberculosis screening for rheumatoid arthritis patients.
We did not receive specific comments regarding these measure changes. **FINAL ACTION:** We are finalizing the changes to measure Q176 as proposed for the 2019 Performance Period and future years.	

D.7. Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity

Category	Description
NQF #:	N/A
Quality #:	177
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease activity within 12 months.
Substantive Change:	**The new numerator is revised to read**: Patients with disease activity assessed by an ACR-endorsed rheumatoid arthritis disease activity measurement tool classified into one of the following categories: remission, low, moderate or high, at least >=50 percent of total number of outpatient RA encounters in the measurement year. **The new definition is revised to read**: Assessment and Classification of Disease Activity – Assesses if physicians are utilizing a standardized, systematic approach for evaluating the level of disease activity for each patient at least for >=50 percent of total number of outpatient RA encounters. The scales/instruments listed are the ACR-endorsed tools that should be used to define activity level and cut-off points: -Clinical Disease Activity Index (CDAI) -Disease Activity Score with 28-joint counts (erythrocyte sedimentation rate or C-reactive protein) (DAS-28) -Patient Activity Scale (PAS) -Patient Activity Score-II (PAS-II) -Routine Assessment of Patient Index Data with 3 measures (RAPID 3) -Simplified Disease Activity Index (SDAI) A result of any kind qualifies for meeting numerator performance.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We updated the numerator to change the requirement to assess disease activity from once a year to "≥ 50 percent of encounters in the measurement year" and to change the use of any standardized tool to only use ACR-endorsed tools. Currently, the measure is only required to be submitted once per performance period. The current measure identifies tools that are available, but allows eligible clinicians to utilize tools not listed within the specification. The changes add a considerable degree of specificity to quality measure 177 by (1) limiting options for disease activity measures to those that have been found to be valid through a rigorous ACR process, and (2) changing the frequency of assessment to include a majority of clinical encounters for RA, since this approach would be consistent with current guidelines regarding treating to a pre-specified target. The ACR developed recommendations for the use of RA disease activity measures in clinical practice. And after thorough evaluation of around 63 available measures, ACR recommends the following 6 measures: CDAI, DAS28 (ESR or CRP), PAS, PAS-II, RAPID-3, and SDAI as ACR-endorsed RA disease activity measures to be used in clinical practice. Many of these tools are available free of charge. The tools were selected to ensure a comprehensive and standardized approach to assess disease activity for rheumatoid arthritis. Given this evidence, the measure steward believes this measure should be updated to be more in line with the specifications found in similar measures developed by ACR and endorsed by NQF. We agree with the revision to promote utilization of the most current guidelines that have been developed by the panel of rheumatology experts. We typically prefer the use of NQF endorsed measures over measures that lack endorsement. Disease activity assessment is imperative to development of an appropriate treatment plan. Revising the numerator to require a more frequent assessment supports development of a more effective treatment plan. We support the use of standardized tools to assess disease activity so the score can be standardized and comparable among eligible clinicians.

Comment: One commenter supported the revisions to measure Q177: Rheumatoid Arthritis (RA) Periodic Assessment of Disease Activity as the changes would limit the measurement tools available to clinicians for assessing disease activity levels only to those that have been found to be valid through the American College of Rheumatology process. The change to increase the frequency of disease activity assessment from only once per year to "at least 50 percent or more of clinical encounters for RA" would be consistent with clinical guidelines for RA disease activity assessment and supported those changes. A narrower list of ACR-endorsed measurement tools will create measurement uniformity for clinicians, can help establish clinical consensus in how disease activity levels should be defined, and promotes consistent outcomes measurement across RA patients.

Response: We agree this would align would the current guideline and provide standardized approach to assess rheumatoid arthritis.

FINAL ACTION: We are finalizing the changes to measure Q177 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Description was updated to "Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity at ≥50 percent of encounters for RA for each patient during the measurement year." These changes were also applied to specialty measure sets in Table Group B where this measure is included.

D.8. Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines

Category	Description
NQF #:	N/A
Quality #:	364
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of final reports for computed tomography (CT) imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (for example, follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors.
Substantive Change:	**Updated the denominator**: To patients 35 years and older. **Updated denominator exclusions**: Added heavy tobacco smokers **Updated denominator exceptions**: To include medical reasons. **Updated numerator**: Includes a recommended interval and modality for follow-up. **The new description is revised to read:** Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up [(for example, type of imaging or biopsy) or for no follow-up, and source of recommendations (for example, guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).
Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We updated the measure description and denominator from 18 years and older to 35 years and older. We also updated the numerator to include a recommended interval and modality for follow-up. The revised measure assesses final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up [(for example, type of imaging or biopsy) or for no follow-up, and source of recommendations (for example, guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians)]. The current measure specification does not allow a denominator exclusion for heavy smokers. A new denominator exclusion is included for heavy tobacco smokers who qualify for lung cancer screening. Furthermore, the current denominator exception does not account for the indication of a modality. A new denominator exception for medical reasons for not including a recommended interval and modality for follow-up. The changes add specificity to this measure and ensure the appropriate patient population is being targeted for this measure by: (1) updating the numerator quality action to specify a recommended interval and modality for follow-up; (2) specifying additional denominator exclusions and exceptions; and (3) changing the intended patient population (to 35 years and older) as supported by an update to clinical guidelines. We agree with the revision to promote utilization of the most current guidelines. It creates a more robust measure that defines the required clinical action to the narrowed patient population. We also agree with the addition specific denominator exceptions and denominator exclusions to promote consistent data among eligible clinicians.

We did not receive specific comments regarding these measure changes.

FINAL ACTION: We are finalizing the changes to measure Q364 as proposed for the 2019 Performance Period and future years.

D.9. Depression Remission at Twelve Months

Category	Description
NQF #:	0710
Quality #:	370
CMS eCQM ID:	CMS159v7
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of patients 18 years of age and or older with major depression or dysthymia who reached remission 12 months (+/- 30 days) after an index visit
Substantive Change:	**The new description is revised to read**: The percentage of adolescent patients 12 to 17 years of age and adult patients18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date. **The new denominator is revised to read:** Adolescent patients 12 to 17 years of age with a diagnosis of major depression or dysthymia and an initial PHQ-9 or PHQ-9M score greater than nine during the index event. The new numerator is revised to read: Adolescent patients aged 12 to 17 years of age who achieved remission at 12 months as demonstrated by a 12-month (+/- 60 days) PHQ-9 or PHQ-9M score of less than five.
Steward:	Minnesota Community Measurement (MNCM)
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We added adolescents to the denominator via stratification and references to the PHQ-9M, which is specific for adolescents. The patient population has been revised to include patients 12 years of age and older, when previously only included patients over the age of 18. The score to determine denominator eligibility was based on the PHQ-9 assessment, this was expanded to include the PHQ-9M to accommodate the expanded age with age appropriate assessment tools. The measure steward worked in collaboration with NCQA, who requested a consideration of incorporating adolescents into the existing depression measures. We agreed with the expansion of the denominator to include the adolescent patient population. Depression assessment is a clinically relevant and important topic to address among adolescents. We appreciated the collaboration among the stakeholders to broaden the measure.

Comment: One commenter noted the benefits and challenges associated with reporting the Depression Remission at 12 Months measure. While its inclusion in MIPS provides a more comprehensive measure set from which clinicians can choose to report, the commenter noted it carries a significant data collection burden. A second commenter stated that measure Q370 has been a challenge for academic medical centers is the depression remission measure. The depression remission measure (MH-1) measures the number of patients with major depression as defined as an initial PHQ-9 score> 9 who demonstrate remission at 12 months as defined as a PHQ-9 score <5. The requirement for PHQ-9 use for evaluating patients combined with a follow-up evaluation is problematic for many large group practices. The measure must be recorded for 248 patients, a very difficult bar for large multi-specialty group practices which refer patients for treatment and follow-up to psychiatrists if they have a PHQ-9. The measure seems to be designed for group practices that do not have this type of referral pattern. This is just one example of practice pattern differences between large academic medical groups and small and or/ rural practices. The commenter requested that the measure be removed, and that CMS determine if there may be other measures related to depression that would be more appropriate to use in the MIPS program.

Response: We believe this measure aligns with our policy to maintain meaningful measures within the program. Mental health issues have become prevalent in the nation and we believe it is critical to maintain measures that support improvement in mental health especially since our proposal is to expand this measure to adolescents. For this reason, we believe the benefit of measuring outcomes, as well as providing a more comprehensive measure set for the eligible clinician to report outweighs the data collection burden. In response to the commenter concern regarding the workflow of a large academic medical centers, the PHQ-9 derived from the psychiatrist could be used to determine remission as long as it is documented within the medical record. This would require communication and care coordination between the referring clinician and psychiatrist.

FINAL ACTION: We are finalizing the changes to measure Q370 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure: The CMS eCQM ID changed from "CMS159v6" to "CMS159v7." These changes were also applied to specialty measure sets in Table Group B where this measure is included.

D.10. Depression Utilization of the PHQ-9 Tool

Category	Description
NQF #:	0712
Quality #:	371
CMS eCQM ID:	CMS160v7
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	The percentage of patients age 18 and older with the diagnosis of major depression or dysthymia who have a completed PHQ-9 during each applicable 4-month period in which there was a qualifying visit.
Substantive Change:	**The new description is revised to read**: The percentage of adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) with a diagnosis of major depression or dysthymia who have a completed PHQ-9 or PHQ-9M tool during the measurement period. **The new denominator is revised to read**: Adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) with a diagnosis of major depression or dysthymia. **The new numerator is revised to read**: Adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) included in the denominator who have at least one PHQ-9 or PHQ-9M tool administered and completed during a 4-month measurement period.
Steward:	Minnesota Community Measurement (MNCM)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We added adolescents to the denominator via stratification and references to the PHQ-9M for both denominator and numerator, which is specific for adolescents. The patient population has been revised to include patients 12 years of age and older, when previously only included patients over the age of 18. The measure steward worked in collaboration with NCQA, who requested a consideration of incorporating adolescents into the existing depression measures. We agreed with the expansion of the denominator to include the adolescent patient population. Depression assessment is a clinically relevant and important topic to address among adolescents. We appreciated the collaboration among the stakeholders to broaden the measure.
We did not receive specific comments regarding these measure changes. **FINAL ACTION:** We are finalizing the changes to measure Q371 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure: The CMS eCQM ID changed from "CMS160v6" to "CMS160v7." These changes were also applied to specialty measure sets in Table Group B where this measure is included.	

D.11. Melanoma Reporting

Category	Description
NQF #:	N/A
Quality #:	397
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness and ulceration and for pT1, mitotic rate.
Substantive Change:	**The new numerator is revised to read**: Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness, ulceration and mitotic rate.
Steward:	College of American Pathologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We updated the numerator to include mitotic rate for all pT categories. The current measure specification only requires a statement the mitotic rate for pT1. The American Joint Committee on Cancer's Melanoma Expert Panel strongly recommends that mitotic rate be assessed and recorded for all primary melanomas, although it is not used for T1 staging in the eighth edition. The mitotic rate will likely be an important parameter for inclusion in the future development of prognostic models applicable to individual patients. Although it is not included in the T1 subcategory criteria, mitotic activity in T1 melanomas also has been associated with an increased risk of sentinel lymph node metastasis. We agreed with the addition of mitotic rate assessment for all primary melanomas. This creates valuable clinical information to the eligible clinician in order to create an effective treatment plan specific to the melanoma.
We did not receive specific comments regarding these measure changes. **FINAL ACTI**ON: We are finalizing the changes to measure Q397 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Description was updated to **"**Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness, ulceration and mitotic rate." These changes were also applied to specialty measure sets in Table Group B where this measure is included. .	

D.12. Psoriasis: Clinical Response to Systemic Medications

Category	Description
NQF #:	N/A
Quality #:	410
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of psoriasis vulgaris patients receiving oral systemic or biologic therapy who meet minimal physician-or patient-reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.
Substantive Change:	**The new description is revised to read**: Percentage of psoriasis vulgaris patients receiving systemic medication who meet minimal physician-or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment **The new denominator is revised to read**: All patients with a diagnosis of psoriasis vulgaris and treated with a systemic medication. **The new numerator is revised to read**: Patients who have a documented physician global assessment (PGA; 5-point OR 6-point scale), body surface area (BSA), psoriasis area and severity index (PASI) and/or dermatology life quality index (DLQI) that meet any one of the below specified benchmarks.
Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We updated the measure title, description and denominator to expand the measure to include systemic medications that are administered both orally and subcutaneously. The measure still includes biologics rather than only oral and biologic medications. The patient population includes those diagnosed with psoriasis vulgaris receiving systemic medications that are administered both orally and subcutaneously or biologic therapy who meet minimal physician-or patient- reported disease activity levels. In addition, the numerator is being expanded to include the 5-point PGA scale as an additional benchmark. The current numerator allow the use of PGA; 6-point scale), body surface area (BSA), psoriasis area and severity index (PASI) and/or dermatology life quality index (DLQI) to assess clinical response. The measure steward believes the update to allow all systemic medications is relevant as they have deemed them to all apply to the measure. Based on recent literature, there is a strong correlation in how the 5-point scale is used like the 6-point PGA scale, resulting in comparative results. This scale is requested to be added to allow clinicians a shorter scale to choose from which would be more user-friendly in a clinical setting. We agreed with the expansion of the denominator to include all systemic medications, not limited to oral systemic or biologic therapy. Including systemic medications administered subcutaneously provides an additional opportunity to assess effective outcomes this treatment option. We agreed with the 5-point PGA scale to allow an additional tools to assess psoriasis outcomes.

Comment: Several commenters supported the measure expansion for Q410: Psoriasis: Clinical Response to Systemic Medications to systemic drugs that are administered both orally and subcutaneously. Psoriasis had been an underrepresented clinical category within the MIPS measure set in recent years, and the expansion of this measure creates additional opportunities to demonstrate the effectiveness of new treatment options.

Response: We thank the commenters for their support of measure Q410: Psoriasis: Clinical Response to Systemic Medications.

FINAL ACTION: We are finalizing the changes to measure Q410 as proposed for the 2019 Performance Period and future years. We are finalizing this measure as a MIPS CQMs Specification only. This measure will not be available as a Medicare Part B Claims Measure Specification as it is not analytically feasible for this collection type. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Title was changed from "Psoriasis: Clinical Response to Oral Systemic or Biologic Medications" to "Psoriasis: Clinical Response to Systemic Medications." These changes were applied to specialty measure sets in Table Group B where this measure is included.

D.13. Depression Remission at Six Months

Category	Description
NQF #:	0711
Quality #:	411
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of patients 18 years of age or older with major depression or dysthymia who reached remission 6 months (+/- 30 days) after an index visit.
Substantive Change:	**The new description is revised to read**: The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 6 months (+/- 60 days) after an index event date. **The new denominator is revised to read:** Submission Criteria 1: Adolescent patients 12 to 17 years of age with a diagnosis of major depression or dysthymia and an initial PHQ-9 or PHQ-9M score greater than nine during the index event. Submission Criteria 2: Adult patients 18 years of age or older with a diagnosis of major depression or dysthymia and an initial PHQ-9 or PHQ-9M score greater than nine during the index event.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We added adolescents to denominator via stratification and references to the PHQ-9M which is specific for adolescents. The patient population has been revised to include patients 12 years of age and older, when previously only included patients over the age of 18. The score to determine denominator eligibility was based on the PHQ-9 assessment, this was expanded to include the PHQ-9M to accommodate the expanded age with age appropriate assessment tools. The measure steward worked in collaboration with NCQA, who requested a consideration of incorporating adolescents into the existing depression measures. We agreed with the expansion of the denominator to include the adolescent patient population. Depression assessment is a clinically relevant and important topic to address among adolescents. We appreciated the collaboration among the stakeholders to broaden the measure.
We did not receive specific comments regarding these measure changes. **FINAL ACTION:** We are finalizing the changes to measure Q411 as proposed for the 2019 Performance Period and future years.	

D.14. Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older

Category	Description
NQF #:	N/A
Quality #:	415
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 18 years and older who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT
Substantive Change:	Updated the measure description and denominator to remove the requirement of a patient presenting to the emergency department within 24 hours of a minor blunt head trauma, as well as remove the requirement to document a GCS of 15. **The new description is revised to read:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care clinician who have an indication for a head CT. **The new denominator is revised to read**: All emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider **Updated the numerator**: To indicate the GCS score less than 15 is an appropriate indication for a head CT. The new definition within the numerator is revised to include a GSC score less than 15.
Steward:	American College of Emergency Physicians (ACEP)
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We updated to the measure description and denominator to remove the requirement of a patient presenting to the emergency department within 24 hours of a minor blunt head trauma, as well as remove the requirement to document a GCS of 15. We updated the numerator to indicate the GCS score less than 15 is an appropriate indication for a head CT. The new description is revised to read: Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT. Based on feedback from the measure steward, this measure is appropriate for all minor blunt head traumas, regardless of when they occurred in relation to presentation to the ED. Additionally, in order to better align the measure with the evidence base and guidelines supporting the measure, the measure steward determined that the GCS of <15 data element would be more accurately included as an appropriate indication for ordering a head CT, so this has been relocated to the numerator definition. We agreed with the recommendation and accept the revision as this promotes utilization of the most current guidelines to determine imaging requirements based on the documented GCS.
We did not receive specific comments regarding these measure changes. **FINAL ACTION:** We are finalizing the changes to measure Q415 as proposed for the 2019 Performance Period and future years.	

D.15. Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years

Category	Description
NQF #:	N/A
Quality #:	416
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 2 through 17 years who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury
Substantive Change:	**Updated denominator**: To remove the requirement of a patient presenting to the emergency department within 24 hours of a minor blunt head trauma, as well as remove the requirement to document a GCS of 15. **The measure description is revised to read**: Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury. **Updated the numerator**: To indicate the GCS score less than 15 is an appropriate indication for a head CT.
Steward:	American College of Emergency Physicians
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We updated the measure description and denominator to remove the requirement of a patient presenting to the emergency department within 24 hours of a minor blunt head trauma, as well as remove the requirement to document a GCS of 15. We updated the numerator to indicate the GCS score less than 15 is an appropriate indication for a head CT. Based on feedback from the measure steward, this measure is appropriate for all minor blunt head traumas, regardless of when they occurred in relation to presentation to the ED. Additionally, in order to better align the measure with the evidence base and guidelines supporting the measure, ACEP physician leaders determined that the GCS of <15 data element would be more accurately included as an appropriate indication for ordering a head CT, so this has been relocated to the numerator definition. We agreed with the revision as this promotes utilization of the most current guidelines to determine imaging requirement based on the documented GCS.
We did not receive specific comments regarding these measure changes. **FINAL ACTION:** We are finalizing the changes to measure Q416 as proposed for the 2019 Performance Period and future years.	

D.16. Functional Status Change for Patients with Knee Impairments

Category	Description
NQF #:	0422
Quality #:	217
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report measure of change in functional status for patients 14 year+ with knee impairments. The change in functional status (FS) assessed using FOTO's (knee) PROM (patient-reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Substantive Change:	Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. **The new denominator is revised to expand to**: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We expanded the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agreed with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

Comment: Two commenters supported the substantive change proposed for measure Q217: Functional Status Change for Patients with Knee Impairments measure by allowing coding for chiropractic clinicians but emphasized that unless chiropractors are reimbursed for CPT code 98943 which covers extraspinal, one or more regions (currently NOT covered by Medicare), the current three codes will not apply to this measure.

Response: This measure can only be submitted utilizing the MIPS CQMs Specifications, which allows all payer data to be submitted, not just Medicare. Therefore, chiropractors utilizing CPT code 98943 can include those patients in the denominator for this measure. Specific Medicare reimbursement for this code would not preclude the eligible clinician from submitting this measure.

FINAL ACTION: We are finalizing changes to measure Q217 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Description was updated to "A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the Knee FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey)." The Measure Type was changed from "Outcome" to "Patient Reported Outcome." These changes were applied to specialty measure sets in Table Group B where this measure is included. (Please note that these technical changes were erroneously characterized as substantive changes in the proposed rule.)

D.17. Functional Status Change for Patients with Hip Impairments

Category	Description
NQF #:	0423
Quality #:	218
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report measure of change in functional status (FS) for patients 14 years+ with hip impairments. The change in functional status (FS) assessed using FOTO's (hip) PROM (patient- reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Substantive Change:	Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. **The new denominator is revised to expand to**: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We expanded the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agreed with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

Comment: Two commenters supported the substantive change proposed for measure Q218: Functional Status Change for Patients with Hip Impairments measure by allowing coding for chiropractic clinicians but emphasized that unless chiropractors are reimbursed for CPT code 98943 which covers extraspinal, one or more regions (currently NOT covered by Medicare), the current three codes will not apply to this measure.

Response: This measure can only be submitted utilizing the MIPS CQMs Specifications, which allows all payer data to be submitted not just Medicare. Therefore, chiropractors utilizing CPT code 98943 can include those patients in the denominator for this measure. Specific Medicare reimbursement for this code would not preclude the eligible clinician from submitting this measure.

FINAL ACTION: We are finalizing the changes to measure Q218 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Description was updated to "A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the Hip FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey)." The Measure Type was changed from "Outcome" to "Patient Reported Outcome." These changes were applied to specialty measure sets in Table Group B where this measure is included. (Please note that these technical changes were erroneously characterized as substantive changes in the proposed rule.)

D.18. Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments

Category	Description
NQF #:	0424
Quality #:	219
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report measure of change in functional status (FS) for patients 14 years+ with foot and ankle impairments. The change in functional status (FS) assessed using FOTO's (foot and ankle) PROM (patient reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Substantive Change:	Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. **The new denominator is revised to expand to**: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We expanded the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agree with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

Comment: Two commenters supported the substantive change proposed for the Q219: Functional Status Change for Patients with Foot or Ankle Impairments measure by allowing coding for chiropractic clinicians but emphasized that unless chiropractors are reimbursed for CPT code 98943 which covers extraspinal, one or more regions (currently NOT covered by Medicare), the current three codes will not apply to this measure.

Response: This measure can only be submitted utilizing the MIPS CQMs Specifications, which allows all payer data to be submitted not just Medicare. Therefore, chiropractors utilizing CPT code 98943 can include those patients in the denominator for this measure. Specific Medicare reimbursement for this code would not preclude the eligible clinician from submitting this measure.

FINAL ACTION: We are finalizing the changes to measure Q219 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Title was changed from "Functional Status Change for Patients with Foot or Ankle Impairments" to "Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments". The Measure Description was updated to "A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) assessed using the Foot/Ankle FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey)." The Measure Type was changed from "Outcome" to "Patient Reported Outcome." These changes were also applied to specialty measure sets in Table Group B where this measure is included. (Please note that these technical changes were erroneously characterized as substantive changes in the proposed rule.)

D.19. Functional Status Change for Patients with Low Back Impairments

Category	Description
NQF #:	0425
Quality #:	220
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report outcome measure of change in functional status for patients 14 years+ with lumbar impairments. The change in functional status (FS) assessed using FOTO (lumbar) PROM (patient reported outcome measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality
Substantive Change:	Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. **The new denominator is revised to expand to**: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We expanded the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agreed with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

Comment: Two commenters supported the substantive change proposed for the Q220: Functional Status Change for Patients with Lumbar Impairments measure by allowing coding for chiropractic clinicians but emphasized that unless chiropractors are reimbursed for CPT code 98943 which covers extraspinal, one or more regions (currently NOT covered by Medicare), the current three codes will not apply to this measure.

Response: This measure can only be submitted utilizing the MIPS CQMs Specifications, which allows all payer data to be submitted not just Medicare. Therefore, chiropractors utilizing CPT code 98943 can include those patients in the denominator for this measure. Specific Medicare reimbursement for this code would not preclude the eligible clinician from submitting this measure.

FINAL ACTION: We are finalizing the changes to measure Q220 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Title was changed from "Functional Status Change for Patients with Lumbar Impairments" to "Functional Status Change for Patients with Low Back Impairments". The Measure Description was updated to "A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the Low Back FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey)." The Measure Type was changed from "Outcome" to "Patient Reported Outcome." These changes were also applied to specialty measure sets in Table Group B where this measure is included. (Please note that these technical changes were erroneously characterized as substantive changes in the proposed rule.)

D.20. Functional Status Change for Patients with Shoulder Impairments

Category	Description
NQF #:	0426
Quality #:	221
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report outcome measure of change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in functional status (FS) assessed using FOTO's (shoulder) PROM (patient reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Substantive Change:	**The new description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.).The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey). Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. **The new denominator is revised to expand to**: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We expanded the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agreed with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

Comment: Two commenters supported the substantive change proposed for measure Q221: Functional Status Change for Patients with Shoulder Impairments measure by allowing coding for chiropractic clinicians but emphasized that unless chiropractors are reimbursed for CPT code 98943 which covers extraspinal, one or more regions (currently NOT covered by Medicare), the current three codes will not apply to this measure.

Response: This measure can only be submitted utilizing the MIPS CQMs Specifications, which allows all payer data to be submitted not just Medicare. Therefore, chiropractors utilizing CPT code 98943 can include those patients in the denominator for this measure. Specific Medicare reimbursement for this code would not preclude the eligible clinician from submitting this measure.

FINAL ACTION: We are finalizing the changes to measure Q221 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Description was updated to "A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.).The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey)." The Measure Type was updated from "Outcome" to "Patient Reported Outcome". These changes were also applied to specialty measure sets in Table Group B where this measure is included. (Please note that these technical changes were erroneously characterized as substantive changes in the proposed rule.)

D.21. Functional Status Change for Patients with Elbow, Wrist or Hand Impairments

Category	Description
NQF #:	0427
Quality #:	222
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report outcome measure of functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS assessed using FOTO (elbow, wrist and hand) PROM (patient reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Substantive Change:	Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. **The new denominator is revised to expand to**: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We expanded the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agreed with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

Comment: Two commenters supported the substantive change proposed for measure Q222: Functional Status Change for Patients with Elbow, Wrist or Hand Impairments measure by allowing coding for chiropractic clinicians but emphasized that unless chiropractors are reimbursed for CPT code 98943 which covers extraspinal, one or more regions (currently NOT covered by Medicare), the current three codes will not apply to this measure.

Response: This measure can only be submitted utilizing the MIPS CQMs Specifications, which allows all payer data to be submitted not just Medicare. Therefore, chiropractors utilizing CPT code 98943 can include those patients in the denominator for this measure. Specific Medicare reimbursement for this code would not preclude the eligible clinician from submitting this measure.

FINAL ACTION: We are finalizing the changes to measure Q222 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Description was updated to "A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS is assessed using the Elbow/Wrist/Hand FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.) The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey)." The Measure Type was updated from "Outcome" to "Patient Reported Outcome". These changes were also applied to specialty measure sets in Table Group B where this measure is included. (Please note that these technical changes were erroneously characterized as substantive changes in the proposed rule.)

D.22. Functional Status Change for Patients with General Orthopedic Impairments

Category	Description
NQF #:	0428
Quality #:	223
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report outcome measure of functional status (FS) for patients 14 years+ with general orthopedic impairments (neck, cranium, mandible, thoracic spine, ribs or other general orthopedic impairment). The change in FS assessed using FOTO (general orthopedic) PROM (patient reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality
Substantive Change:	Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. **The new denominator is revised to expand to**: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We expanded the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agreed with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

Comment: Two commenters supported the substantive change proposed for measure Q223: Functional Status Change for Patients with Other General Orthopedic Impairments measure by allowing coding for chiropractic clinicians but emphasized that unless chiropractors are reimbursed for CPT code 98943 which covers extraspinal, one or more regions (currently NOT covered by Medicare), the current three codes will not apply to this measure.

Response: This measure can only be submitted utilizing the MIPS CQMs Specifications, which allows all payer data to be submitted not just Medicare. Therefore, chiropractors utilizing CPT code 98943 can include those patients in the denominator for this measure. Specific Medicare reimbursement for this code would not preclude the eligible clinician from submitting this measure.

FINAL ACTION: We are finalizing the changes to measure Q223 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Description was updated to "A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients aged 14 years+ with general orthopedic impairments (neck, cranium, mandible, thoracic spine, ribs or other general orthopedic impairment). The change in FS is assessed using the General Orthopedic FS PROM (patient reported outcome measure) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey)." The Measure Type was updated from "Outcome" to "Patient Reported Outcome". These changes were also applied to specialty measure sets in Table Group B where this measure is included. (Please note that these technical changes were erroneously characterized as substantive changes in the proposed rule.)

D.23. Overuse of Imaging for the Evaluation of Primary Headache

Category	Description
NQF #:	N/A
Quality #:	419
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with a diagnosis of primary headache disorder whom advanced brain imaging was not ordered
Substantive Change:	Updated the measure analytics to be an inverse measure and remove the assessment of the appropriate use for Computed Tomography Angiography (CTA) and Magnetic Resonance Angiography (MRA). **The new description is revised to read**: Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present **The new numerator is revised to:** Patients for whom imaging of the head (Computed Tomography (CT) or Magnetic Resonance Imaging (MRI)) is obtained for the evaluation of primary headache when clinical indications are not present.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We adjusted the measure analytics to produce inverse performance data and update the numerator to reflect new clinical evidence regarding the diagnostic imaging modalities (removing CTA and MRA). Updating inverse measure analytics for this measure will appropriately represent the data produced by an overuse measure. The measure development workgroup, procured by AAN, reviewed available evidence and found that there are different indications for imaging with CTA and MRA compared to CT and MRI. The indications for clinical management of primary headache, (which are listed in the measure) are only appropriate for CT and MRI. The updated clinical guidelines included in the measure support this as well.

Comment: One commenter supported changes to measure Q419: Overuse Of Imaging For Patients With Primary Headache so that it would focus only on CT and MRI scans ordered (omitting CTA and MRA imaging to create consistency with the indication for clinical management of primary headache), and will also capture inverse performance data. However, the commenter underscored that unmet needs continue to exist related to quality measures for migraine and primary headache disorder, and that CMS is missing an opportunity to consider the costly impact of medication overuse that can result from inadequate response to existing treatments for migraine and primary headache disorder. The commenter requested that CMS, along with the MAP, NQF, and other stakeholders consider new and/existing measures that addresses the rate of acute medication overuse among patients suffering from migraine. The Institute for Clinical Systems Improvement (ICSI) has developed the measure, "Percentage of patients with migraine headache with a prescription for opiates or barbiturates for the treatment of migraine" to address overuse of opioids and narcotics for the treatment of migraine headache.

Response: We encourage the commenter to collaborate with measure developers to submit measures to the Call for Measures process that have been fully tested and address migraine and headache disorder.

FINAL ACTION: We are finalizing the changes to measure Q419 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: Measure Title was updated from "Overuse of Imaging For Patients With Primary Headache" to "Overuse of Imaging for the Evaluation of Primary Headache". Measure Type was updated from "Efficiency" to "Process". These changes were also applied to specialty measure sets in Table Group B where this measure is included.

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

Note: The following table summarizes public comments received that are general to individual MIPS measures but not specific to newly proposed measures, specialty measure sets, measures proposed for removal, or measures with substantive changes.

Q005: Heart Failure: Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction

Specialty Sets: Cardiology, Family Medicine, Internal Medicine

Comment: One commenter supported measure Q005: Heart Failure: Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction because there is good evidence that ACE inhibitors and ARBs improve the health of people with heart failure and LVEF < 40%, and the measure aligns with current guidelines and represents high-value care for patients with chronic heart failure.

Response: We thank the commenter for the support of measure Q005: Heart Failure: Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction.

Q006: **Coronary Artery Disease: Antiplatelet Therapy**

Specialty Sets: Cardiology, Family Medicine, Internal Medicine, Skilled Nursing Facility

Comment: One commenter supported measure Q006: Coronary Artery Disease: Antiplatelet Therapy. The evidence base would benefit from re-evaluation as data surfaces on the benefits and risks of aspirin therapy in patients who are already prescribed warfarin therapy as supported by several societies. It may also be difficult for clinicians to capture over the counter aspirin use unless explicitly stated by the patient.

Response: We do not see the over the counter aspirin use to be a major impact to performance. In addition, medication lists should include all known prescriptions, over-the counters, herbals, and vitamin/mineral/dietary (nutritional) supplements with the medications' name, dosages, frequency and route of administration.

Q007: **Coronary Artery Disease: Beta-Blocker Therapy--Prior Myocardial Infarction or Left Ventricular Systolic Dysfunction (LVEF < 40%)**

Specialty Sets: Cardiology, Family Medicine, Internal Medicine, Skilled Nursing Facility

Comment: One commenter supported measure Q007: Coronary Artery Disease: Beta-Blocker Therapy--Prior Myocardial Infarction or Left Ventricular Systolic Dysfunction (LVEF < 40%). However, the commenter cited that skepticism exists surrounding consistency across operating systems to include all billing codes for appropriate exclusion criteria. Furthermore, while the measure is based on clinical recommendations of a number of societies, there is some question surrounding the need for continued beta-blocker therapy for 3 years in low-risk patients in the contemporary era of revascularization. Lastly, it is unnecessarily burdensome for clinicians to look at all LVEF assessments in a complete patient history, and developers should consider revising the specifications to limit the look-back window and exclude patients with a normal LVEF without history of LVSD.

Response: The measure is based on the ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guidelines and we will continue to monitor and collaborate with the measure steward if updated guidelines are published. We disagree that inconsistent billing coding would not allow appropriate exclusion submission. As an eCQM, it has been fully tested to appropriately identify exclusions within an EHR. As a MIPS CQMs, data is not limited to billing coding to determine exclusions. Documentation of prior LVEF <40% is required to determine denominator eligibility is supported by clinical guidelines. Beta-blockers have been shown to reduce risk of death are recommended indefinitely for patients with CAD and LV systolic dysfunction.

Q008: **Heart Failure: Beta-blocker therapy for Left Ventricular Systolic Dysfunction**

Specialty Sets: Cardiology, Family Medicine, Internal Medicine, Skilled Nursing Facility

Comment: One commenter supported measure Q008: Heart Failure: Beta-blocker therapy for Left Ventricular Systolic Dysfunction because the balance of evidence shows that long-term treatment with beta-blockers can lessen the symptoms of heart failure, improve the clinical status of patients, and enhance the patient's overall sense of well- being. The measure aligns with current guidelines and represents high-value care for patients with chronic heart failure.

Response: We thank the commenter for the support of measure Q008: Heart Failure: Beta-blocker therapy for Left Ventricular Systolic Dysfunction.

Q009: Antidepressant Medication Management

Specialty Sets: Family Medicine, Internal Medicine, Mental/Behavioral Health

Comment: One commenter did not support measure Q009: Antidepressant Medication Management. Reasons cited included: the time frame used in the measure contradicts recommendations from evidence-based guidelines; measure specifications do not consider alternative interventions for depression management such as psychotherapy, electroconvulsive therapy (ECT), or the combination of somatic and psychotherapy; the measure excludes patient choice to switch to another modality of effective therapy due to side effects (where measure specifications should include exclusion criteria for lack of patient adherence due to the side effects of medication with documentation of alternative therapy); the requirement for acute phase treatment should be deleted; and the measure intends to evaluate quality outcomes at the health plan level, but the measure as included in MIPS intends to assess performance at the individual clinician level where clinicians are unaware of information (for example, medication refill data) related to effective management of medication adherence.

Response: We consulted with the measure steward and they will take your suggestions regarding adjustment of timeframes, alternative interventions, inclusion of patient choice, and assessing outcome evaluation levels under consideration for future updates to this measure.

Q039: Screening for Osteoporosis for Women 65-85 Years of Age

Specialty Sets: Family Medicine, Internal Medicine, Preventive Medicine, Rheumatology, Geriatrics

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

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Comment: One commenter supported measure Q039: Screening for Osteoporosis for Women 65-85 Years of Age. The commenter noted that implementation could promote overuse of screening if patients receive care from multiple clinicians and/or have poor record continuity, and in women who are at lower risk for osteoporosis based on reasonably identifiable factors (for example, BMI, ethnicity). The commenter suggested that developers should consider updating the denominator specifications to include exclusion criteria for patients who have already been assessed with the FRAX tool and for patients receiving hospice and palliative care where the intervention

Response: We do not agree that it would promote overuse of screening as it requires documentation of one historical screening. Eligible clinicians are expected to coordinate their care with eligible clinicians. We will provide feedback to the measure steward to include the FRAX tool exclusion to be fully vetted through the annual revision process. In response to the commenter's request to include a hospice exclusion, this is included within the measure specification.

Q046: Medication Reconciliation Post-Discharge

Specialty Sets: Orthopedic Surgery, Nephrology, General Surgery, Geriatrics

Comment: One commenter did not support measure Q046: Medication Reconciliation Post-Discharge although it can help to eliminate medication errors that may occur during transitions of care and will not promote over- or underuse and timely reconciliation of discharge medication lists. The commenter expressed the following concerns: 2013 PQRS participation results do not necessarily represent performance on a national level; the measure has insufficient evidence to support this as an accountability measure and it is a "check the box measure;" a more standardized approach is needed for medication adherence, the numerator specifications exclude clinicians who are capable of reconciling medication lists which could limit the success of this measure from a health plan/integrated delivery system perspective; and clinicians may encounter interoperability barriers to data access.

Response: This measure promotes appropriate medication management, communication and care coordination between caregivers. Although the impact of medication reconciliation alone on patient outcomes is not well studied, there is expert agreement that potential benefits outweigh the harm. We applaud the clinicians that adhere to this practice, but believe this concept improves communication and patient safety. This is considered a process measure and we are looking to move towards outcome-based measures. In addition, we encourage the commenter to work with measures' developers to submit new measures through the Call for Measures process. We disagree with the commenter citing barriers based on clinicians utilizing different EHRs. The measure stewards allow multiple methods of medication reconciliation as defined in the numerator. The measure steward has standardized the clinicians that are able to complete the quality action. A prescribing practitioner, clinical pharmacists or registered nurse should conduct medication reconciliation. We will provide your recommendation to the measure steward to include pharmacy technicians in future iterations of the measure specification.

Q047: Advance Care Plan

Specialty Sets: Cardiology, Gastroenterology, Family Medicine, Internal Medicine, Obstetrics/Gynecology, Orthopedic Surgery, Otolaryngology, Physical Medicine, Preventive Medicine, Neurology, Nephrology, General Surgery, Vascular Surgery, Thoracic Surgery
Urology, Oncology, Rheumatology, Geriatrics, Skilled Nursing Facility

Comment: One commenter did not support measure Q047: Advance Care Plan, and cited it could prevent overuse of unnecessary end of life care interventions. The commenter noted the measure is burdensome for clinicians to annually document an advance care plan for all patients aged 65 years and older and also objects to the 12-month measurement period included in the denominator specifications. There is no evidence to guide optimal frequency and at what age to begin planning, and it may be inappropriate for clinicians to perform this intervention during an initial office visit. Lastly, the denominator population could be revised to established patient visits only.

Response: We disagree with concern this measure may be burdensome to document an advance care plan annually. The eligible clinician is not required to create a new advance care plan but confirms annually that the plan in the medical record is still appropriate or starts a new discussion. We will provide your suggestion to the measure steward regarding the narrowing of the patient population to established patient only. The measure steward does state the measure is appropriate for use in all healthcare settings (for example, inpatient, nursing home, and ambulatory) except the emergency department. For each of these settings, there should be documentation in the medical record(s) that advance care planning was at least discussed or documented. Eligible clinicians are still able to be numerator compliant if the advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan. We maintain the notion that Q047 is a good measure that promotes initiation of communication. With the inclusion of new patient visit coding, this would likely affect all eligible clinicians submitting the measure, therefore data would be comparable.

Q050: Urinary Incontinence: Plan of care for Urinary Incontinence in Women Aged 65 Years and Older

Specialty Sets: Family Medicine, Internal Medicine, Obstetrics/Gynecology, Urology, Geriatrics

Comment: One commenter supported measure Q050: Urinary Incontinence: Plan of care for Urinary Incontinence in Women Aged 65 Years and Older because a performance gap exists, treatments exist to create meaningful improvements in clinical outcomes/quality of life and the benefits of reducing the patient disease burden outweigh the clinician measurement burden. Although, they stated that developers cite weak evidence to support the benefit of care plan development on clinical outcomes in women with urinary incontinence. Additionally, developers should consider updating denominator specifications to include exclusion criteria for patients who refuse care plan services. Lastly, this measure is meant for the system level and individual clinicians may encounter interoperability barriers retrieving this data.

Response: There is some high quality evidence for use pelvic floor muscle training in the treatment of older women with UI and pharmacologic treatment if training is unsuccessful. In response to the request to add a denominator exception for patient refusal of a care plan, the measure steward does not allow patient refusals for this measure. We understand the commenter's concern; however, all eligible clinicians submitting measure Q050, regardless of data method, will not have the ability to submit a patient refusal and therefore are comparable when calculating the performance of the measure.

Q107: Adult Major Depressive Disorder: Suicide Risk Assessment

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

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Specialty Sets: Family Medicine, Emergency Medicine, Mental/Behavioral Health

Comment: One commenter supported measure Q107: Adult Major Depressive Disorder: Suicide Risk Assessment but noted several recommendations that could improve the measure quality. These included: the measure is close to being topped out and developers should include current, national performance data in the updated measure report; the numerator is not clearly specified, such as what constitutes a "recurrent" episode because as currently stated, the measure could apply to all follow-up visits with the mention of even well-controlled depression; this is a "check the box measure" with little potential to shift quality; and the measure poses significant burden.

Response: We will work with the measure developer to provide additional context in future years. We suggest the commenter to review the full measure specification for guidance on defining a recurrent episode. It clarifies an episode of major depressive disorder (MDD) would be considered to be recurrent if a patient has not had an MDD-related encounter in the past 105 days. If there is a gap of 105 or more days between visits for major depressive disorder (MDD) that would imply a recurrent episode. The 105-day look-back period is an operational provision and not a clinical recommendation, or definition of relapse, remission, or recurrence.

Q109: Osteoarthritis: Function and Pain Assessment

Specialty Sets: Family Medicine, Orthopedic Surgery, Physical Medicine

Comment: One commenter did not support measure Q109: Osteoarthritis: Function and Pain Assessment, citing insufficient evidence to support an appropriate assessment time interval and the denominator specifications are unclear. The measure should specify utilization of a validated, standardized assessment tool that demonstrates improvements in quality outcomes. It is burdensome for clinicians to perform this assessment at every visit where OA is not the primary patient complaint. The commenter stated this measure is not an appropriate accountability measure for general internists. Additionally, clinicians may encounter interoperability barriers to data access and embedding data into the information system.

Response: It is important to remember that absence of hard evidence supporting function and pain assessment is not evidence that it is not effective. It allows eligible clinicians to adjust their treatment plans at the patient level. In response to the request to specify the validated tools, we direct the commenters to review the measure specification as it provides an extensive list of assessment tools. The submission frequency has been updated for the 2019 performance period to once per performance period. This measure is not required and encourage eligible clinicians to select quality measures that are applicable to their specialty.

Q110: Preventive Care and Screening: Influenza Immunization

Specialty Sets: Family Medicine, Internal Medicine, Obstetrics/Gynecology, Otolaryngology, Pediatrics, Preventive Medicine, Nephrology, Oncology, Infectious Disease, Rheumatology, Geriatrics, Skilled Nursing Facility

Comment: One commenter supported measure Q110: Preventive Care and Screening: Influenza Immunization because the measure aligns with current CDC Advisory Committee recommendations. However, the commenter noted that electronic health record (EHR) information blocking could prevent the transmission of immunization information between competing electronic systems.

Response: We continue to align with the Centers for Disease Control and Prevention recommendations for routine annual influenza vaccinations for all persons aged greater than or equal to 6 months. We continue to promote interoperability through Certified Electronic Health Record technology and the prevention of Information blocking. We encourage the reporting of immunizations to the appropriate Registries through Promoting Interoperability performance category and Registry reporting measures.

Comment: One commenter supported having measure Q110: Preventive Care and Screening: Influenza Immunization available in multiple specialty sets.

Response: We thank the commenter for their support of this measure.

Q111: Pneumococcal Vaccination Status for Older Adults

Specialty Sets: Family Medicine, Internal Medicine, Obstetrics/Gynecology, Otolaryngology, Nephrology, Oncology, Infectious Disease, Rheumatology, Geriatrics

Comment: One commenter did not support measure Q111: Pneumococcal Vaccination Status for Older Adults. While this measure represents an important clinical concept, implementation could promote treatment overuse if patients seek medical care from multiple clinicians and/or have poor medical record continuity. In addition, the developer should update the numerator specifications to align with current clinical recommendations on pneumococcal vaccination.

Response: The Centers for Disease Control and Prevention continues to recommend the pneumococcal vaccine in adults 65 years and older due to the high incidence of pneumococcal-related deaths and costs associated with this condition. We recommend attempts to locate missing records in a reasonable timeframe so that the initial vaccine not be postponed. We will provide the numerator language feedback to the measure steward. There is a numerator note included within the specification to provide submission guidance. We are exploring options to replace this measure in future performance periods that more closely aligns with the guidelines. However, until this measure can be replaced with a measure promoting pneumococcal vaccination, we believe this measure still promotes pneumococcal vaccination and addresses an important population health matter. As stated within the measure specification: The measure allows administration or documentation of PCV13 or PPSV23 vaccine (or both) to be numerator compliant. According to ACIP recommendations, patients should receive both vaccines. The order and timing of the vaccinations depends on certain patient characteristics, and are described in more detail in the ACIP recommendations.

Comment: One commenter supported having measure Q111: Pneumococcal Vaccination Status for Older Adults available in multiple specialty sets.

Response: We thank the commenter for their support of this measure.

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

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Q112: Breast Cancer Screening

Specialty Sets: Family Medicine, Obstetrics/Gynecology, Preventive Medicine

Comment: One commenter supported measure Q112: Breast Cancer Screening due to current evidence and that most health systems that have networks in place to address this issue. However, the commenter expressed concern that this measure could promote screening overuse and that a stronger measure may include exclusion criteria for system and patient related issues (for example, availability of mammography screening tools, patient preference, and limited life expectancy). Also, this measure may be less impactful than other cancer screening measures (for example, MIPS 113: Colorectal Cancer Screening).

Response: The measure's intent is to promote preventive breast cancer screening, not to address the overuse of screening. If data supports an overuse of breast screening, we encourage the development of an appropriate use of breast cancer screening measure to be submitted to the annual Call for Measures. The measure steward does incorporate denominator exclusion to exclude patients with bilateral mastectomy, receiving hospice services or residing in an Institutional Special Needs Plans (SNP) or long-term care facility. The intent of the exclusion for individuals age 65 and older residing in long-term care facilities, including nursing homes, is to exclude individuals who may have limited life expectancy and increased frailty where the benefit of the process may not exceed the risks. The numerator allows for patient preference and more accessible screening methods by including screening, diagnostic, film, digital or digital breast tomosynthesis mammography to be considered numerator compliant.

Q113: Colorectal Cancer Screening

Specialty Sets: Family Medicine, Preventive Medicine

Comment: One commenter supported measure Q113: Colorectal Cancer Screening but expressed that the developer should update the measure specifications to align with current clinical recommendations on colorectal cancer screening. Specifically, numerator specifications should include the option for clinicians to document emerging cancer screening tests (for example, stool FIT-DNA, CT colonography). Additionally, measure specifications do not include appropriate exclusion criteria and could promote overuse of screening in patients where the benefits do not outweigh the risk of harms, and this risk adjustment could be addressed by measure developers. A better measure would include exclusion criteria for patients diagnosed with dementia, patients with limited life expectancy, patients with advanced comorbidities, and patient refusal.

Response: The specification defines the screening to include any of following: Fecal occult blood test (FOBT), Flexible sigmoidoscopy, Colonoscopy Computed tomography (CT) colonography, Fecal immunochemical DNA test (FIT-DNA). The measure's intent is to promote preventive colorectal cancer screening, not to address the overuse of screening. We suggest the commenter review measure Q439: Age Appropriate Screening Colonoscopy which addresses the appropriate use with consideration to the benefits and risks. The measure excludes patients with a diagnosis or past history of total colectomy or colorectal cancer, receiving hospice services, and patient aged 65 or older in Institutional Special Needs Plans or residing in long-term care. The intent of the exclusion for individuals age 65 and older residing in long-term care facilities, including nursing homes, is to exclude individuals who may have limited life expectancy and increased frailty where the benefit of the process may not exceed the risks. The measure steward does not include a patient refusal as it is the eligible clinician's responsibility to educate their patients to see the value of preventive colorectal screening. In addition, all eligible clinicians submitting measure Q113, regardless of data submission method, will not have the ability to submit a patient refusal and therefore are comparable when calculating the performance of the measure.

Q116: Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis

Specialty Sets: Family Medicine, Internal Medicine, Preventive Medicine, Urgent Care

Comment: One commenter supported measure Q116: Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis because implementation could lead to measurable and meaningful improvements in clinical outcomes and prevent overuse of inappropriate antibiotic therapy in patients diagnosed with acute bronchitis. However, the commenter noted the potential for clinicians to manipulate the measure through inaccurate coding of disease classification (that is, ICD10).

Response: Eligible clinicians should not change their billing or documentation to manipulate eligibility or determination of appropriate treatment. Any claims submitted to the CMS are subject to an audit, inclusive of any performance data submitted to the quality program.

Q126: Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy –Neurological Evaluation

Specialty Sets: Family Medicine, Internal Medicine, Preventive Medicine, Podiatry

Comment: One commenter did not support measure Q126: Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy –Neurological Evaluation. Issues cited included: the measure developer cites a 44 percent performance gap based on data from the 2012 PQRS reporting year which may inaccurately represent nationwide performance levels; there is insufficient evidence to support a dedicated monofilament examination or the need to repeat the exam once the patient produces negative examination results. The numerator should specify the utilization of neurological assessment tools that are equally as effective as the mono filament in diagnosing neurological deficits in diabetic patients; and there is a lack of high-quality evidence to suggest that regular, comprehensive full lower extremity neurological examinations in the primary care setting improves outcomes for asymptomatic patients. While this measure represents good clinical care, quality improvement programs should not implement this measure to assess the performance quality of individual clinicians. The commenter cited that measure specifications had appropriate exclusion criteria.

Response: We disagree with the commenter's performance data as it was based on 2012 PQRS performance data. The 2018 MIPS Benchmark Results reflect an average 58.7 percent compliance rate. This measure is consistent with the recommendation from the Diabetics Foot Disorders: A Clinical Practice Guideline. The measure does not require the test to be repeated once the patient produces a negative result. Neurological examination is required at least once within the 12 months prior to eligible encounter. This aligns with the guidelines for a normal risk profile. We encourage eligible clinicians to perform neurological examination more frequently based on the risk. In response to the lack of evidence to support primary care to evaluate footwear, this is not a required measure

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and encourage eligible clinicians to select measures that are clinically appropriate and align with their clinical workflow.

Q127: Diabetic Foot & Ankle Care, Ulcer Prevention – Evaluation of Footwear

Specialty Sets: Podiatry

Comment: One commenter did not support measure Q127: Diabetic Foot & Ankle Care, Ulcer Prevention – Evaluation of Footwear, citing a lack of high-quality evidence on improved patient outcomes. This measure is topped with a 93 percent compliance rate although the measure may appropriately evaluate quality performance of podiatrists.

Response: We disagree with the commenter's performance data. The 2018 MIPS Benchmark Results reflect an average 55 percent performance rate. The measure is applicable to all eligible clinicians, not just podiatry that was the basis of the commenter's performance data. In response to the lack of evidence to support primary care to evaluate footwear, this is not a required measure and encourage eligible clinicians to select measures that are clinically appropriate and align with their clinical workflow.

Q130: Documentation of Current Medications in the Medical Record

Specialty Sets: Cardiology, Gastroenterology, Dermatology, Family Medicine, Internal Medicine, Obstetrics/ Gynecology, Ophthalmology, Orthopedic Surgery, Otolaryngology, Physical Medicine, Preventive Medicine, Neurology, Mental/Behavioral Health, Nephrology, General Surgery, Vascular Surgery, Thoracic Surgery, Urology, Oncology, Infectious Disease, Neurosurgical, Rheumatology, Physical Therapy/Occupational Therapy, Geriatrics, Urgent Care

Comment: One commenter did not support measure Q130: Documentation of Current Medications in the Medical Record due to lack of high-quality evidence, it is burdensome for clinicians to document complete medication lists at every patient visit, and it is a "check the box" measure. A more appropriate measure may encourage documentation of medication lists according to clinical necessity and incentivize a standardized, methodological approach to reconciliation, according to clinician practice level (for example, physician, nurse, medical assistant) that leads to improvements in the medication management process. Furthermore, practice variables can impede the physician's ability to document complete accurate medication lists.

Response: This measure promotes patient safety to avoid adverse drug events (ADE). Documentation of current medications in the medical record facilitates the process of medication review and reconciliation by the eligible clinicians, which are necessary for reducing ADEs and promoting medication safety. This is considered a process measure and we are looking to move towards outcome-based measures. In addition, the commenter suggested substantive revisions that would require a new measure to be developed. We will continue to explore opportunities to revise this measure, but we encourage the commenter to work with measures' developers to submit new measures through the Call for Measures process. The quality action requires eligible clinicians to attest to documenting, updating or reviewing a patient's current medications using all immediate resources available on the date of encounter. We would expect if eligible clinicians identify unnecessary medications, they would collaborate with their patient to make appropriate adjustments of their medications. While we move towards outcome-based measure, we maintain Q130 initiates a clinical process that would impact patient safety.

Q131: Pain Assessment and Follow-Up

Specialty Sets: Orthopedic Surgery, Physical Medicine, Urology, Rheumatology, Physical Therapy/Occupational Therapy, Geriatrics, Urgent Care

Comment: One commenter did not support measure Q131: Pain Assessment and Follow-Up due to specification flaws that included: (1) performance rates are close to 100 percent; (2) the measure distracts from measurement of change in functional status; (3) implementation of this measure could unintentionally promote overuse of opioid therapy; (4) outdated evidence is cited to form the basis of the measure; (5) specifications do not address the importance of including a functional assessment during the patient visit; 96) specifications do not exclude patients who have known diversions to opioid therapy (for example, substance abuse and alcohol abuse disorders) and this could fuel the opioid epidemic; (7) it is burdensome for clinicians to document pain assessment and follow-up plan at every visit regardless of the patient's primary complaint; (8) referral to a pain management specialist is not practical in every area of the country; and (9) the measure language around "eliminating" pain is unreasonable.

Response: We continue to move towards high priority measures which include outcome-based measures and opioid measures. The quality action does not require an opioid prescription. We disagree with the commenter's performance data, based on the 2018 MIPS Benchmark Results this measure has an average 68.2 percent (MIPS CQMs Specifications) and 87.2 percent (Medicare Part B Claims Measure Specifications) performance rate. The measure does not require a pain management specialist nor an opioid prescription. A follow-up plan may consist of planned follow-up appointment or a referral, a notification to other care clinicians as applicable OR indicate the initial treatment plan is still in effect. These plans may include pharmacologic, interventional therapies, behavioral, physical medicine and/or educational interventions. We do not agree this measure to be burdensome as the tools to assess pain may include the Numeric Rating Scale where documentation of a fraction would meet the screening requirement. We agree with the addition of functional assessment but may add burden which was a concern raised by the commenter. In response to the measure language surround "eliminating pain," we refer the commenter to the measure specification as this is not included within the measure language.

Q134: Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan

Specialty Sets: Family Medicine, Internal Medicine, Orthopedic Surgery, Pediatrics, Preventive Medicine, Neurology, Mental/Behavioral Health

Comment: One commenter did not support measure Q134: Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan although it aligns with USPSTF recommendations on screening for clinical depression. The commenter suggested the denominator specifications exclude patients who are currently under the care of a mental health specialist for comorbid illness or severe cognitive impairment. Developers should consider revising the denominator specifications to reflect patients seen in the calendar year instead of all patients. Measure specifications do not define an appropriate screening frequency. It is not clear whether this measure applies to all patients in a clinicians' panel or only those seen during the calendar year in a face-to-face visit.

Response: In response to the concerns surrounding the denominator, the measure does not include patients within an active diagnosis of depression or has a

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diagnosed bipolar disorder within that patient population. In addition, the measure also allows denominator exceptions for situations where the patient's functional capacity or motivation to improve may impact the accuracy of results of standardized depression assessment tools. Patients are denominator eligible when they meet the denominator criteria within the performance period. For all MIPS quality measures at this time, eligibility is not based on the eligible clinicians' panel but requires an eligible encounter within the performance period as defined by the denominator criteria which allows both face-to-face and telehealth visits.

Comment: One commenter provided extensive information on how the PREV 12 Depression Screening (Q134) using the Web Interface methodology is being operationalized in its facility. The commenter provided specific related to the PHQ scores in its decision-making. The commenter's practice has decided on 4, but a score of 3 is also accepted in the literature and could be a reasonable cutoff for the PHQ-2. As a result, the commenter asked that CMS consider revisiting how this measure is operationalized to allow the use of evidence-based cutoffs for when further documentation is required. The commenter was also concerned that the measure numerator poses a discrepancy by still requiring depression screening and review to occur in a visit setting. The commenter has adopted a care coordination program where the primary health care provider oversees a multi-disciplinary team to address complex health conditions in a non-visit modality. A Registered Nurse care coordinator may perform the depression screening, review, and arrange for follow up during a non-visit interaction performed at regular intervals. If no active concerns are present, the patient may not be seen again before the end of the measurement period for the health care provider to review the screening at an eligible visit. This results in a measure failure, despite the patient receiving quality team-based care individualized to the patient's situation. Another situation where a patient may receive quality team-based care yet result in the patient not meeting numerator conditions is at the Annual Medicare Wellness visit. Depression Screening is a component of the Medicare Annual Wellness Visit, and one of the MIPS Web Interface required metrics in addition to being used for collection methods such as the EHR collection method. However, the PREV-12 Depression Screening specifications state: The depression screening must be reviewed and addressed in the office of the health care provider filing the code, on the date of the encounter. Our Annual Wellness Visits are typically scheduled within a month of the patient's annual visit with the health care provider; therefore, the only way to meet both requirements is to have the patient complete the depression screening questionnaire twice. The commenter noted this is redundant and takes time away from other components of patient care. The commenter requested that CMS either accept the depression screening performed at the Annual Wellness Visit as meeting the PREV-12 requirements, or eliminate depression screening from the Annual Wellness Visit, or preferably simplify the numerator to allow the latest depression screening and review to occur any time during the measurement period and not tie it to a particular visit.

Response: In regards to the determination of a positive screen, whether or not a PHQ-9 (or other standardized screening tool) screening score is considered positive would be determined by the eligible professional administering and reviewing the standardized tool results. The measure steward does not define "positive" so it is at the discretion of the eligible clinician based on their knowledge of the patient to determine if the result is considered positive or negative. For the purpose of submitting PREV-12 information, the measure requires medical record documentation of positive or negative for the depression screen result per the measure steward. There are only two instances when specific documentation of positive or negative is not required. One instance is when the PHQ result is 0 in which case the result can be assumed to be negative. The other instance is when there is documentation of a depression screen using a normalized and standardized screening tool and at the same encounter there is documentation of a recommended follow up, in which case it can be assumed the result of the screen was positive. The Web Interface allows for telehealth for PREV-12, so it is not necessary to tie the review of the screening results to a specific encounter. As long as the most recent screening during the measurement period is used, the screening occurred during the measurement period, there is documentation of positive or negative, the results have been reviewed by the clinician, and if positive a recommended follow up, the measure has been met.

Based on the commenter's scenario, this workflow would not cause the eligible clinician to fail the quality action. We encourage the commenter to work with the measure subject matter experts through the Quality Payment Program Service Center to address the concerns.

Q154, Q155, and Q318

Specialty Sets:
Q154: Family Medicine, Internal Medicine, Orthopedic Surgery, Otolaryngology, , Neurology, Podiatry, Physical Medicine, Preventive Medicine
Q155: Family Medicine, Internal Medicine, Neurology, Orthopedic Surgery, Otolaryngology, Physical Medicine, Preventive Medicine, Podiatry
Q318-Orthopedic Surgery, Nephrology

Comment: One commenter did not support measures Q154, 155, and 318 (NQF measure Q0101): Falls: Screening, Risk-Assessment, and Plan of care to Prevent Future Falls as it is unclear whether they will lead to meaningful improvements in clinical outcomes. The commenter suggested that developers consider revising the denominator specifications to include only those patients who are at high-risk of falling. Clinicians should individualize the plan of care and the care plan should be less prescriptive to account for individual patient requirements. Data collection burden associated with the multiple measure components is high and data elements seem unlikely to capture how well the service was performed. The measure relies heavily on CPT-II codes which are not widely used or captured in electronic health records (EHRs). Also, developers should consider updating the specifications to reflect the most current clinical recommendations of the USPSTF. Additionally, the evidence-base for what clearly defines best practice is complex. Lastly, while the numerator is clearly defined, it is complicated with variable validity and the components of the risk assessment model are not clearly defined.

Response: Please note these measures were being proposed for removal from the MIPS program in 2019 and we proposed a new combined Falls measure (Q477 based on specifications in NQF 0101) that will include strata components for Future Falls Risk, Falls Risk Assessment, and Falls Risk Plan of Care. As discussed already, the proposed new Q477 Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls measure will not be finalized for inclusion as the measure steward believes it is not implementable at this time. Therefore, these three measures will remain in the program for the 2019 performance period as it is important to evaluate for high-risk of falling. We appreciate the feedback regarding these measures and encourage the commenter to discuss their suggestions with the measure steward for their consideration in updates for these measures. A comprehensive falls assessment is multifactorial and should be performed by a health care professional with appropriate skills and experience.

Q180: Rheumatoid Arthritis: Glucocorticoid Management

Specialty Sets: Orthopedic Surgery, Rheumatology

Comment: One commenter did not support measure Q180: Rheumatoid Arthritis: Glucocorticoid Management, citing that they did not receive adequate

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information from the developer to evaluate the validity of this measure. The commenter noted the numerator and the denominator are poorly specified. The measure specifications do not include appropriate exclusions for patients prescribed prednisone therapy for a symptomatic flare. A cleaner measure may specify "patients with rheumatoid arthritis who are on glucocorticoids" in the denominator statement. Additionally, clinical guidelines demonstrate the importance of assessing glucocorticoid use, but only in patients who have specifically been prescribed glucocorticoid therapy.

Response: We will work with the measure steward to consider the suggested denominator exception. Limiting the denominator to those patients with RA who are on a glucocorticoid would limit the clinician's ability to report on the measure and may not capture those RA patients who are started on a glucocorticoid during the performance period.

Q181: Elder Maltreatment Screen and Follow-Up

Specialty Sets: Family Medicine, Internal Medicine, Neurology, Mental/Behavioral Health, Geriatrics, Skilled Nursing Facility

Comment: One commenter did not support measure Q181: Elder Maltreatment Screen and Follow-Up, citing that implementation could promote overuse of unnecessary, elder services referrals and potentially fracture relationships between clinicians and their patients. The commenter stated the measure does not align with USPSTF recommendations on abuse of elderly and vulnerable adults. The commenter also stated that developers should consider revising the numerator specifications to clearly define "high risk" as some way other than age (for example, cognitive impairment, functional impairment). Moreover, the numerator details specify an overly prescriptive screening process. It may be clinically inappropriate to screen all patients over the age of 65 for elder abuse. Developers should consider revising the measure to specifically encourage screening in patients who are dependent on a caregiver or who are otherwise at risk for abuse. It is unnecessarily burdensome for physicians to document maltreatment screening for all patients aged 65 years and older at every visit. Finally, the measure requires clinicians to assess for maltreatment using a screening tool even when abuse may be readily apparent.

Response: Though the USPSTF does not support elder maltreatment screening, we respectfully disagree. It is important to remember that absence of hard evidence supporting screening is not evidence that it is not effective. There have been many qualitative reports that do support the benefits of screening. Expert consensus and public policy for mandatory reporting support the value of screening this vulnerable population. It is unclear how a definition of high risk would benefit the numerator. Limiting the denominator to patients who are dependent on a caregiver or who are otherwise at risk for abuse would be subjective and may not identify all instances of elder maltreatment. This measure advocates for a vulnerable patient population and do not agree that limiting the measure to a high-risk patient population would be appropriate. The measure does not limit to high risk patients but requires elder maltreatment screening for all patients over the age of 65 years.

Q205: HIV/AIDS: Sexually Transmitted Diseases – Screening for Chlamydia, Gonorrhea, and Syphilis

Specialty Sets: Pediatrics, Infectious Disease

Comment: One commenter did not support measure Q205: HIV/AIDS: Sexually Transmitted Diseases – Screening for Chlamydia, Gonorrhea, and Syphilis even though developers cite a significant performance gap based on data from the 2011 PQRS reporting year and that implementation will likely lead to meaningful improvements in clinical outcomes. The measure does align with the USPSTF and CDC recommendations on the prevention and treatment of opportunistic infections in HIV-infected adults, yet the commenter stated the implementation of the measure could promote overuse of screening in asymptomatic patients and in situations where clinicians encounter interoperability barriers to data retrieval. While specifications include an evidence-based time interval, they are flawed in a number of respects. The numerator and denominator envision one test since HIV diagnosis, although new infections and reinfections may occur repeatedly; gonorrhea screening may encompass several loci of infection, which should be listed; and the measure does not include an appropriate exclusion for patients who are not sexually active or otherwise unlikely to become infected. Also, the numerator specifies an indefinite look-back window. Developers should consider revising the specifications to include an evidence-based look-back window.

Response: We disagree this measure will lead to screening overuse. The denominator is limited to a high-risk patient population and we promote interoperability and is the responsibility of the care team to provide care coordination. We do agree that the subsequent screening may be appropriate to detect new or recurrent infections. We will provide this suggestion to the measure steward for possible inclusion during the annual revision cycle. In response to the request for appropriate exclusion for patients who are not sexually active or otherwise unlikely to become infected, the measure does allow for patient refusal as a denominator exception. While we agree with the suggestion to add subsequent screening for reinfection, it does not invalidate the measure. It may be more appropriate to include an annual risk assessment. The cost of screening and the variability of prevalence of these infections, decisions about routine screening for these infections should be based on epidemiologic factors (including prevalence of infection in the community or the population being served), availability of tests, and cost

Q217: Functional Status Change for Patients with Knee Impairments
Q218: Functional Status Change for Patients with Hip Impairments
Q219: Functional Status Change for Patients with Foot or Ankle Impairments
Q220: Functional Status Change for Patients with Lumbar Impairments
Q221: Functional Status Change for Patients with Shoulder Impairments
Q222: Functional Status Change for Patients with Elbow, Wrist or Hand Impairments
Q223: Functional Status Change for Patients with General Orthopedic Impairments

Specialty Sets: Physical Therapy/Occupational Therapy

Comment: One commenter stated that the issue with FOTO (Focus on Therapeutic Outcomes) measures is the measure may require payment to use the measure. Eligible clinicians may not have 100 patients in the specific joint being measured to meet the measure requirements. As a result, the clinician needs to get an exemption because he or she may not have 100 patients eligible, such as for the hip measure Q218. Also, the measure for functional outcome (general) becomes mutually exclusive to these individual FOTO measures.

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Response: As indicated within the measure specification's Copyright, the functional status measures are available in both short form (static/paper-pencil) and computer adaptive test formats, together with a scoring table and risk adjustment specifications, free of charge for the purposes of individual clinical practice, that is, patient-level measurement, including but not limited to for the purposes of participation in MIPS. We acknowledge that meeting this minimum threshold can be challenging for some eligible clinicians but for scoring purposes you would only need 20 eligible patients to meet the minimum reliability threshold for each of the measures which may be more feasible to achieve. The functional outcome (general) measure is ensuring that all visits regardless of impairment has functional outcomes assessed and although these would be covered in the functional status change measures it also measures other impairments.

Q226: Preventive Care and Screening: Tobacco use: Screening & Cessation Intervention

Specialty Sets: Cardiology, Gastroenterology, Dermatology, Family Medicine, Internal Medicine, Obstetrics/Gynecology, Ophthalmology, Orthopedic Surgery, Otolaryngology, Physical Medicine, Preventive Medicine, Neurology, Mental/Behavioral Health, General Surgery, Vascular Surgery, Thoracic Surgery, Urology, Oncology, Neurosurgical, Podiatry, Rheumatology, Urgent Care

Comment: One commenter supported measure Q226: Preventive Care and Screening: Tobacco use: Screening & Cessation Intervention because reduction of tobacco use slows the progression of respiratory disease, tobacco use is a modifiable risk factor, and the measure aligns with clinical recommendations.

Response: We thank the commenter for the support of measure Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.

Q236: Controlling High Blood Pressure

Specialty Sets: Obstetrics/Gynecology, Vascular Surgery, Thoracic Surgery, Rheumatology

Comment: One commenter did not support measure Q236: Controlling High Blood Pressure although it may result in measurable and meaningful improvements in clinical outcomes and there is a known performance gap in the area of blood pressure control. The commenter stated that the specifications for the measure under consideration for NQF-endorsement align with several societies, the MIPS measure specifications do not stratify patients into well-defined risk groups (that is, comorbid disease diagnosis) and guidelines from its own society. Furthermore, the numerator specifications define office measurements as the preferred monitoring method, while home monitoring is the preferred method to assess for adequately controlled BP. The commenter suggested that developers update the numerator specifications to include an average of several measurement results to increase accuracy and reduce the potential for overtreatment. Finally, the measure was created to assess system-level performance and may not be an appropriate accountability measure for individual clinicians who do not have access to all BP measurement results. The commenter supported CMS adoption of this measure if approved by NQF.

Response: We agree with updating the numerator to reflect the updated blood pressure values and have been discussing the revision with the measure steward. We do not agree with taking an average blood pressure as the performance is determined by the most recent blood pressure value. It does allow for multiple blood pressure readings during an eligible visit, using the lowest systolic and the lowest diastolic reading as the most recent blood pressure reading. We agree with the measure steward to exclude home readings due to the variability and may not be an accurate representation of blood pressure measurements. In addition, performance can be determined by blood pressure taken by any clinician within the clinician office. This would include blood pressure readings from other eligible clinicians participating in the patient care (that is consultation notes). We maintain the opinion this is a good measure since the new guidelines have not been widely accepted and will allow time for eligible clinicians to adopt the updated blood pressure values. This measure also encourages management of a prevalent condition.

Comment: Several commenters indicated that for measure Q236: Controlling High Blood Pressure that it should be revised to reflect recent national consensus about appropriate blood pressure measurements. A national consensus has developed that blood pressure should vary by age and diagnosis. The MIPS measure requires a strict policy of controlling to less than 140/90 for hypertensive patients, regardless of age, and 120/80 for screening purposes. These levels are not consistent with current medical evidence or opinion such as those noted in the Eighth Joint National Committee. There should be a mechanism for removal of a measure that is no longer consistent with clinical guidelines or current practice and adding the measure back to the program when re-specified.

Response: We appreciate the recommendation to update the guidelines and agree the measure should be updated in future revision cycles. However, we maintain the opinion this is a good measure since the new guidelines have not been widely accepted and will allow time for eligible clinicians to adopt the updated blood pressure values. This measure also encourages management of a prevalent condition and is limited to patients with an existing hypertension diagnosis. Additionally, the intent of the measure is not to screen patients for hypertension.

Q238: Use of High-Risk Medications in the Elderly

Specialty Sets: Cardiology, Family Medicine, Internal Medicine, Rheumatology, Geriatrics

Comment: One commenter did not support measure Q238: Use of High-Risk Medications in the Elderly, citing that controversial criteria was used to form the basis of the measure, which is based on expert opinion as opposed to high-quality evidence. The commenter noted issues with the measure specifications as follows: the denominator may inaccurately define "elderly adults" as > 65 years of age and developers should consider increasing the denominator threshold to > 80 years of age; the denominator specifications do not stratify patients into well-defined risk groups; the measure specifies medications that are not presumed to be high risk in all elderly adults (for example, acetaminophen); and the specifications do not include exclusion criteria for patient preference. Lastly, individual clinicians may encounter interoperability barriers to patient information access.

Response: We disagree with interoperability barrier, but suggest all eligible clinician maintain a current medication list, especially for patient received high-risk medications. We will provide the commenter's recommendation to risk-stratify and increase the age criteria from 65 to 80 years of age to be vetted through a technical expert panel and possible inclusion in subsequent revision cycles. One study of the prevalence of potentially inappropriate medication use in older adults found that 40 percent of individuals 65 and older filled at least one prescription for a potentially inappropriate medication and 13 percent filled two or more (Fick et al. 2008). While some adverse drug events are not preventable, studies estimate that between 30 and 80 percent of adverse drug events in the elderly are preventable (MacKinnon and Hepler 2003). The measure is based on recommendations from the American Geriatrics Society Beers Criteria for

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Potentially Inappropriate Medication Use in Older Adults. The criteria were developed through key clinical expert consensus processes by Beers in 1997, Zahn in 2001 and an updated process by Fick in 2003, 2012 and 2015.

Q243: Cardiac Rehabilitation: Patient Referral from an Outpatient Setting

Specialty Sets: Cardiology, Family Medicine, Internal Medicine

Comment: One commenter supported measure Q243: Cardiac Rehabilitation: Patient Referral from an Outpatient Setting. However, the commenter advised developers to address the following concerns during the update process to improve the measure quality: the measure is nearly capped out; implementation of this measure could unfairly penalize clinicians who practice in rural areas and who care for medically complex patient populations, so risk or socioeconomic adjustment is advised; the measure is an inappropriate accountability measure for general internists who do not report data in the PINNACLE registry; the measure may not apply well to clinicians practicing in rural settings where patients have limited access to rehabilitative services; and patients who are faced with significant travel burdens are less likely to adhere to prescribed services.

Response: We encourage the commenters to work with measures' developers to submit new measures through the Call for Measures process that would address the appropriate diagnosis and testing of COPD as we currently do not have a benchmark established for this measure. In addition, the performance data supplied was derived from a single qualified registry. We disagree that this measure may unfairly penalize clinicians who practice in rural areas and who care for medically complex patient populations. The numerator includes denominator exceptions for both system and medical reasons for not referring to an outpatient cardiac rehabilitation program. The measure does not hold general internists inappropriately accountable for referrals, as this is not a required measure. Eligible clinicians are able to choose the measures that are clinically appropriate for their specialty.

Q268: Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy

Specialty Sets: Neurology

Comment: One commenter did not support measure Q268: Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy although it addresses a clinical condition that is high- impact and the measure developers cite a significant gap in care. The commenter stated that evidence cited to form the basis of the measure where the interventions could potentially result in harmful patient outcomes. Problems were cited with measure specifications. The denominator specifications should include exclusion criteria for surgically sterile women, women without a history of recent seizure, and women who are not currently prescribed pharmacotherapy; the numerator definition of counseling seems overly inclusive and not necessary in all cases. Requiring six dimensions for counseling could be overly prescriptive and developers should consider revising the specifications to allow for selection of appropriate therapy that is most relevant to individual patients (that is, change the definition to include "or" rather than "and"); Developers should consider revising the denominator specifications to include women aged 45 years and older who are of childbearing potential. The commenter stated that while the many of the specifications are flawed, the developers do include validity and reliability data in the measure.

Response: To address the comment regarding denominator exclusion, we encourage the commenter to review the 2019 measure specification as the measure steward has revised the measure to exclude menopausal or surgically sterile patients. We disagree on the exclusion for patients without a recent seizure, and women who are not currently prescribed pharmacotherapy. Impacts to fertility and pregnancy risks are not limited patients receiving pharmacologic therapy. The measure steward indicates counseling should include discussion about folic acid supplementation, contraception, and potential anti-seizure medications effect on pregnancy, safe pregnancies, and breastfeeding. While we agree this definition covers an inclusive list of counseling areas, it does allow eligible clinicians to exercise their clinical judgment if medical reasons exist for not completing counseling women of childbearing potential with epilepsy. We agree with the expansion of the denominator criteria to include women who are 45 years and older who are of childbearing potential. We have requested the measure steward to consider expanding the age criteria during the annual revision cycle of the quality measures. We still believe the measure addresses an important clinical topic; the narrow denominator does not invalidate the measure.

Q271: IBD: Preventive Care: Corticosteroid Related Iatrogenic Injury--Bone Loss Assessment

Specialty Sets: Gastroenterology

Comment: One commenter did not support measure Q271: IBD: Preventive Care: Corticosteroid Related Iatrogenic Injury--Bone Loss Assessment, citing that measure developers do not cite high-quality evidence to form the basis of the measure and using dexa-scans to assess for risk of bone loss does not necessarily prevent hip fractures in patients prescribed corticosteroid therapy for IBD. Furthermore, implementation could promote overuse of dexa scans and underuse of corticosteroid therapy. Numerator specifications encourage clinicians to screen patients who receive 10 mg/day of prednisone for 60 days, while evidence demonstrates that hip fractures are significantly higher in patients treated with medium steroid doses (2.5-7mg/day) over a duration of time. As written, the numerator could miss patients who are at risk for fracture. Also, it is unclear whether the measure encourages clinicians to screen patients who are currently prescribed prophylactic bisphosphonate therapy for risk of bone loss, which may not be clinically necessary. Lastly, developers should consider revising the numerator specifications to include an evidence-based look-back window for review of medication history as that is less burdensome. Another commenter also expressed concerns related to the numerator of this measure reflecting the risk of bone loss associated with oral corticosteroids, at any time over the patient's life, exceeding 5 mg/day for 3 or more consecutive months.

Response: The intent of the measure is to screen patients who are at risk of fracture. This knowledge can assist eligible clinicians in creation of their treatment plan. We disagree that the measure would lead to overuse of dexa-scans. Individuals who received an assessment for bone loss during the year prior and current year are considered adequately screened. Corticosteroid use is the variable most strongly associated with osteoporosis (level A evidence). However, it is difficult to distinguish corticosteroid use from disease activity in terms of causal impact on bone density, because the two are closely linked. However, there is strong evidence that those on long-term steroids of greater than 3 months have a significant increase risk of fracture (Papaioannou A. et al. All Patients with Inflammatory Bowel Disease Should Have Bone Density Assessment: Pro. Inflammatory Bowel Diseases. 2001.7(2):158-162). In response to lowering the threshold from 10 mg/day to 2.5-7 mg/day, this would expand the denominator requiring additional screening. We will provide both of the commenter's concerns regarding dexa overuse and the request to expand the denominator to the measure steward to identify the appropriate population, but based on the

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provided response, we maintain the notion this is an appropriate measure.

Q281: Dementia: Cognitive Assessment

Specialty Sets: Neurology, Mental/Behavioral Health, Geriatrics

Comment: One commenter did not support measure Q281: Dementia: Cognitive Assessment, citing a lack of high-quality evidence on the assessment of cognitive status on clinical outcomes or assessment intervals, and it is unclear how clinicians should manage assessment results. The numerator specifications include cognition assessment tools that will not necessarily benefit clinical outcomes and adherence to a formal assessment protocol is burdensome on clinicians. A more meaningful measure may encourage assessments that are likely to lead to meaningful improvements in clinical outcomes. Furthermore, the numerator specifications include proprietary cognition assessment tools (for example, Mini-Mental State Examination) that are not readily accessible to clinicians who practice in primary care settings.

Response: The measure is supported by the Guidelines for the Management of Cognitive and Behavioral Problems in Dementia. Initial and ongoing assessments of cognition are fundamental to the proper management of patients with dementia. These assessments serve as the basis for identifying treatment goals, developing a treatment plan, monitoring the effects of treatment, and modifying treatment as appropriate. While there is not a set interval for assessment, the guidelines state that assessments and visits will be based on the severity or complexity of the patient's status. For this measure, the cognitive assessment should be completed at least once per performance period but does not penalized clinicians for additional cognitive assessments completed throughout the performance period. We thank the commenter for the suggestion create more meaningful improvements to clinical outcomes and encourage the commenter to work with measures' developers to submit new measures through the Call for Measures process. We do not agree with the concern that the numerator has proprietary cognition tools as the measure also includes non-proprietary options for eligible clinician use.

Q283: Dementia: Associated Behavioral and Psychiatric Symptoms Screening and Management

Specialty Sets: Neurology, Mental/Behavioral Health, Geriatrics

Comment: One commenter did not support measure Q283: Dementia: Associated Behavioral and Psychiatric Symptoms Screening and Management, citing a lack of high-quality evidence examining the impact of assessment on clinical outcomes or on appropriate assessment intervals, and implementation may result in overuse of pharmacologic therapy. Non-pharmacologic treatment modalities exist to manage neuropsychiatric symptoms, but implementation requires caregiver involvement. The commenter stated that numerator details do not clearly specify a structured process for documentation of neuropsychiatric symptom assessment and the measure developers do not describe any reliability or validity data in the measure report.

Response: The measure is supported by the Guidelines for the Management of Cognitive and Behavioral Problems in Dementia. Neuropsychiatric symptoms may go unrecognized and untreated by eligible clinician do not actively screen their patients with specific attention to discrete symptom domains. We disagree with the unintended consequences identified by the commenter. The measure does not promote the use of pharmacologic interventions. The Clinical Recommendation Statements within the specification state, "new trials and studies better define adverse effects, but they do not strengthen the evidence for efficacy of antipsychotic drugs in treating psychosis or agitation. Rather, they demonstrate minimal or no efficacy with strong placebo effects, as well as variations in response with trial duration. These findings strengthen the support for using nonpharmacological interventions and environmental measures to attempt to reduce psychosis and agitation prior to initiation of medications." In addition, the specification provides examples of reliable and valid instruments to document neuropsychiatric symptom assessment.

Q286: Dementia: Counseling Regarding Safety Concerns

Specialty Sets: Neurology, Mental/Behavioral Health, Geriatrics

Comment: One commenter did not support measure Q286: Dementia: Counseling Regarding Safety Concerns although it can lead to improved safety outcomes and the measure specifications are appropriate. The commenter stated there is no evidence to support the impact of this intervention on clinical outcomes, the level or intensity of counseling required to change behavior, or the interval at which this intervention should be performed. This measure is also burdensome on clinicians and there is a lack of high quality evidence to support the intervention as an accountability measure.

Response: The measure is supported by the American Psychiatric Association practice guideline for the treatment of patients with Alzheimer's disease and other dementias. Screening for safety concerns has been identified as a major unmet need of persons with dementia. Though the guidelines do not identify the impact of the intervention, it is important to remember that absence of hard evidence supporting screening is not evidence that it is not effective.

Q288: Dementia: Caregiver Education and Support for Patients with Dementia

Specialty Sets: Neurology, Mental/Behavioral Health, Geriatrics

Comment: One commenter did not support measure Q288: Dementia: Caregiver Education and Support for Patients with Dementia because it may be inappropriate for clinicians to advise caregivers on medical concerns without performing appropriate clinical assessments and there is no evidence to support the impact of this intervention on clinical outcomes, the level or intensity of counseling required to change behavior, or the interval at which this intervention should be performed. Developers do not present any validity or reliability data within the measure report. Lastly, this measure is burdensome on clinicians and there is a lack of high- quality evidence to support the intervention as an accountability measure.

Response: The measure is supported by the Optimal management of Alzheimer's disease patients: Clinical guidelines and family advice. The American Medical Association (AMA) has developed a standard Caregiver Health Self-Assessment Questionnaire to help caregivers analyze their own behavior and health risks and, with the eligible clinician's assistance, make decisions that will benefit both the caregiver and the patient. This questionnaire is available on the AMA website. Based on the results of the assessment, the eligible clinician would be required to provide education and resources based on their clinical expertise. These components have been defined within the measure specification. Though the guidelines do not define the level of counseling or impact of the

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intervention, it is important to remember that absence of hard evidence supporting screening is not evidence that it is not effective.

Q305: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment

Specialty Sets: Family Medicine, Internal Medicine, Pediatrics

Comment: One commenter did not support measure Q305: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment because the specifications are flawed and the measure is not appropriately specified to evaluate performance at the level of the individual clinician. Developers should consider dividing the numerator statement to form two discrete measures: (1) initiation of alcohol and other drug dependence treatment; and (2) engagement of alcohol and other drug dependence treatment. Also, it is unclear what constitutes a "new episode of drug or alcohol dependency." The commenter did not support including this measure in accountability programs designed to assess performance of individual clinicians. It is unclear whether individual clinicians will be able to control the outcomes of this measure, and individual clinicians will likely face interoperability challenges to data collection.

Response: We will forward the commenter's recommendation to divide the numerator into two separate measures, but we believe the measure is appropriately specified into one measure. We refer the commenter to the measure specification for the definition of episode: The new episode of alcohol and other drug dependence should be the first episode of the measurement period that is not preceded in the 60 days prior by another episode of alcohol or other drug dependence. This measure is attributed to eligible clinicians who provide care to patients diagnosed with alcohol, opioid, or other drug abuse or dependency. It is important to intensify the monitoring for substance use during periods when the patient is at a high risk of relapsing, including during the early stages of treatment, times of transition to less intensive levels of care, and the first year after active treatment has ceased.

Q309: Cervical Cancer Screening

Specialty Sets: Family Medicine, Internal Medicine, Obstetrics/Gynecology

Comment: One commenter supported measure Q309: Cervical Cancer Screening because the current evidence supports screening in women 21-64 years of age, and this measure is based on the most recent USPSTF recommendations on cervical cancer screening.

Response: We thank the commenter for the support of measure Q309: Cervical Cancer Screening.

Q310: Chlamydia Screening in Women

Specialty Sets: Obstetrics/Gynecology, Pediatrics

Comment: One commenter supported measure Q310: Chlamydia Screening in Women because it aligns with USPSTF and CDC recommendations, is supported by evidence and denominator criteria is clearly specified.

Response: We will continue to align with USPSTF and CDC recommendations on Chlamydia screening.

Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Specialty Sets: Cardiology,
Gastroenterology, Dermatology, Family Medicine, Internal Medicine, Emergency Medicine, Obstetrics/Gynecology, Orthopedic Surgery, Otolaryngology, Physical Medicine, Preventive Medicine, Neurology, Mental/Behavioral Health, Nephrology, General Surgery, Vascular Surgery, Thoracic Surgery, Urology, Oncology, Rheumatology, Urgent Care, Skilled Nursing Facility

Comment: Two commenters provided feedback for measure Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented, citing that the measure developers should update the measure specifications to align with current Joint National Committee-8 (JNC-8), USPSTF, and American College of Physicians (ACP) clinical recommendations on blood pressure screening and management. Additionally, the denominator specifications should include exclusion criteria for patients with medical contraindications to treatment (for example, frail, elderly adults, patients with life limiting diagnoses). Another commenter expressed concerns about the numerator criteria for measure Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented. Specifically, the commenter stated that most doctors believe it goes against their medical training to recommend evaluation/referral to a primary care physician and/or lifestyle changes to someone who has a blood pressure reading of 122/82.

Response: We agree with aligning with the most current blood pressure guidelines. We disagree with the recommendation to exclude elderly, frail, or patients with life limiting diagnosis citing contraindications for treatment. In response to the commenters concerns regarding the numbers, for the 2019 performance period, this blood pressure value falls into the "Pre-Hypertensive BP Reading" classification. The recommendation may consist of a blood pressure rescreen within 1 year and promoting of physical activity, alcohol reduction, weight reduction or changes in diet which have limited contraindications to recommend. We may update the level of blood pressure reading in the future based on new blood pressure guidelines. We maintain the opinion this is a good measure since the new guidelines have not been widely accepted and will allow time for eligible clinicians to adopt the updated blood pressure values. This measure also encourages management of a prevalent condition.

Q321: CAHPS Clinician & Group Surveys (CG-CAHPS)-Adult, Child

Specialty Sets: Family Medicine, Internal Medicine

Comment: One commenter did not support measure Q321: CAHPS Clinician & Group Surveys (CG-CAHPS)-Adult, Child, citing that implementation could promote overuse of unnecessary treatments where the potential benefits do not outweigh the risk of harms (for example, opiate prescriptions, imaging studies). The commenter stated that developers do not present any evidence to form the basis of the measure and that validity of the survey process and the impact of survey results on improving patient outcomes is in question. Individual clinicians should not be held accountable to organizational factors beyond their control (for example, appointment wait times, and friendliness of staff).

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Response: We disagree that the CAHPS survey promotes the overuse of unnecessary treatments, but rather addresses the quality and appropriate access to healthcare services. While the survey does ask patients the level of friendliness of the staff, improving the patient experience throughout the course of treatment aligns with program goals.

Q322: Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients

Specialty Sets: Cardiology

Comment: One commenter did not support measure Q322: Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients. While this measure promotes appropriate use of cardiac stress imaging in low-risk surgery patients and cites clinical recommendations on perioperative evaluation of patients undergoing non-cardiac surgery to form the basis of the measure, developers do not cite a performance gap. Additionally, the denominator population is not specified for individual clinician use and clinicians may misinterpret the measure as currently written. The commenter recommended that developers consider revising the numerator to include cardiac stress images performed within 30 days preceding low-risk, non-cardiac surgery and the denominator specifications to include asymptomatic patients undergoing low-risk surgery.

Response: We continue to evaluate methods to display performance data. We have previously published Experience Reports to provide a detailed summary and continue to create meaningful benchmarks based on the submitted data. Performance data is evaluated annually to ensure the measure addresses a gap in care. The measure mimics the NQF #0670: Cardiac stress imaging not meeting appropriate use criteria: Preoperative evaluation in low risk surgery patients with minor updates regarding the timing of imaging assessment. The National Quality Forum indicated the level of analysis is based on the clinician, group/practice and facility data. We will provide the numerator language feedback to the measure steward. There is a numerator note included within the specification to provide submission guidance. We appreciate the revision suggestion to clarify the numerator, but the measure still addresses appropriate use of healthcare resources.

Q324: Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients

Specialty Sets: Cardiology

Comment: One commenter did not support measure Q324: Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients. The commenter stated that the numerator is not specified for individual clinician use, the measure does not specify a standardized approach to risk assessment, and it relies on the individual clinician's ability to appropriately document level of risk. Clinicians attest to the accuracy of their estimation by submission, but a stronger measure may specify a more systematic approach to risk assessment. Developers should consider revising the numerator specifications to include "healthy, low-risk patients."

Response: The measure directs clinicians should consider the maximum number of available patient factors used to estimate risk based on Framingham (ATP III criteria), typically age, gender, diabetes, smoking status, and use of blood pressure medication, and integrate age appropriate estimates for missing elements, such as LDL or standard blood pressure. The measure mimics the NQF #0672: Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients with language updates. The National Quality Forum indicated the level of analysis is based on the clinician, group/practice and facility data. We will provide the numerator language feedback to the measure steward. We appreciate the revision suggestion to clarify the numerator, but the measure still addresses appropriate use of healthcare resources.

Q325: Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions

Specialty Sets: Mental/Behavioral Health

Comment: One commenter did not support measure Q325: Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions, citing a lack of high quality evidence examining the impact of disease communication on meaningful clinical outcomes. Additionally, the measure specifications do not include appropriate exclusion criteria for patients with mild or stable depression. It is also burdensome for clinicians to retrieve specialists' reports for all patient visits, especially if the primary care clinician did not refer the patient to care.

Response: The cited guidelines recommend with substantial clinical confidence, patients with major depressive disorder will be evaluated by or receive treatment from other eligible clinicians in addition to the psychiatrist or behavioral health provider. If more than one eligible clinician is involved in providing the care, all treating clinicians should have sufficient ongoing contact with the patient and with each other to ensure that care is coordinated, relevant information is available to guide treatment decisions, and treatments are synchronized. In response to the concern of the diagnosis criteria, the diagnosis codes indicate major depressive disorder and need to be active at the date of the encounter. We disagree commenters concern that the measure is burdensome for eligible clinicians to retrieve specialists' reports. The intent of the measure is to promote care coordination by requiring the eligible clinician treating MDD to provide relevant information to the clinician treating the comorbid condition.

Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy

Specialty Sets: Cardiology, Family Medicine, Internal Medicine, Skilled Nursing Facility

Comment: One commenter supported measure Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy but stated that inclusion of broad exclusion criteria may discourage clinicians from prescribing therapy in patients where the benefits outweigh the risk of harms. The commenter suggested this issue be addressed by developers by explicitly defining denominator exclusion criteria to prevent underuse of anticoagulation therapy in clinically appropriate cases, and that denominator specifications should be updated to include the CHADs2VASc risk stratification tool.

Response: The denominator exclusion removes patients that have mitral stenosis, prosthetic heart valves, or transient or reversible cause of atrial fibrillation. Any documentation meeting the defined criteria would remove the patient from the measure and would not be evaluated for anticoagulation therapy. The 2018

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

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measure specification was updated in during the previous measure revision cycle to utilize the CHADs2VASc risk stratification tool.

Q331: Adult Sinusitis: Appropriate Choice of Antibiotic Prescribed for Acute Sinusitis (Overuse)

Specialty Sets: Family Medicine, Internal Medicine, Emergency Medicine, Otolaryngology, Urgent Care,

Comment: One commenter did not support measure Q331: Adult Sinusitis: Appropriate Choice of Antibiotic Prescribed for Acute Sinusitis (Overuse). They cited that numerator specifications do not define an appropriate performance rate and a 0 percent performance rate will promote underuse of antibiotic therapy in appropriate treatment cases. Furthermore, the numerator specifications define "acute sinusitis" according to typical bacterial infection symptoms and it is appropriate to prescribe antibiotics to treat a bacterial infection. The commenter suggested that developers should consider revising denominator specifications to define "acute sinusitis" according to viral symptoms to prevent overuse of antibiotic therapy in viral sinusitis infections, and to align the measure with current clinical recommendations. The commenter supported inclusion of appropriate exclusion criteria, but cites that inclusion of broad exclusion criteria may provide opportunity for measure manipulation by reporting clinicians.

Response: The Centers for Disease Control and Prevention identifies that 98 percent of rhino sinusitis cases are viral. Treatment of these cases with antibiotics may increase patient harm and lead to antibiotic resistance. The numerator note adds clarification for inverse measures, which indicates as the performance rate trends towards 0 percent, quality increases. In response to manipulation of data, any claims submitted to the CMS are subject to an audit, inclusive of any performance data submitted to the quality program. The measure is specific to viral sinusitis, we do not agree that it promotes underuse of antibiotic therapy in the appropriate cases. The clinical recommendation within the measure specification includes diagnosis of acute bacterial rhino sinusitis when symptoms persist for at least 10 days or worsening of symptoms after initial improvement. The measure includes a denominator exception for a documented reason for antibiotic regimen prescribed within 10 days of symptom onset, which is appropriate for this inverse measure.

Q332: Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin with or without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use)

Specialty Sets: Family Medicine, Internal Medicine, Emergency Medicine, Otolaryngology, Urgent Care

Comment: One commenter did not support measure Q332: Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin with or without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use) as numerator specifications do not align with specialty society recommendations. The commenter suggested that developers update the measure specifications to encourage prescription of amoxicillin-clavulanate as first-line therapy in patients diagnosed with bacterial sinusitis. In addition, the measure specifications do not include exclusion criteria for patients who do not tolerate amoxicillin. About 30-40 percent of patients are bacterial resistant to amoxicillin therapy alone.

Response: The measure specification does include a denominator exception for a documented reason for not prescribing amoxicillin. The IDSA identifies their clinical recommendation of use of Amoxicillin-clavulanate rather than amoxicillin alone weighted as low strength and weak quality of evidence. The Centers for Disease Control and Prevention continue to recommend Amoxicillin or amoxicillin/clavulanate as the recommended first-line therapy in confirmed cases of bacteria sinusitis.

Q333: Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse)

Specialty Sets: Family Medicine, Internal Medicine, Emergency Medicine, Otolaryngology, Urgent Care

Comment: One commenter supported measure Q333: Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse) because it is clinically important to promote appropriate use of CT scans in patients diagnosed with acute sinusitis. However, the commenter stated that developers do not clearly define denominator exclusion criteria and as such, implementation could promote underuse of CT scans in clinically appropriate cases. Developers should consider revising exclusion criteria based on current guidelines.

Response: The measure includes a denominator exception for documented reasons of a CT scan ordered at the time of diagnosis which is appropriate for this inverse measure and would allow for use of CT scan for appropriate cases. We refer the commenter to the clinical recommendation statements within the measure specification that indicate that clinicians should not obtain radiographic imaging for patients presenting with uncomplicated acute rhino sinusitis (ARS) to distinguish ABRS from VRS, unless a complication or alternative diagnosis is suspected. Radiographic imaging of the paranasal sinuses is unnecessary for diagnosis in patients who already meet clinical diagnostic criteria for ABRS. Sinus involvement is common in documented viral URIs, making it impossible to distinguish ABRS from VRS based solely on imaging studies. This measure is intended to avoid costly diagnostic tests that do not improve diagnostic accuracy yet expose the patient to unnecessary radiation.

Q342: Pain Brought under Control within 48 Hours

Specialty Sets: Family Medicine, Internal Medicine

Comment: One commenter did not support measure Q342: Pain Brought under Control within 48 Hours as it is unclear whether implementation will produce reliable, meaningful results, and there is insufficient evidence to support the 48 hour time interval. Additionally, the specifications include an assessment tool is that is not well validated. Measure developers should consider modifying the specifications to include a more appropriate assessment tool (for example, Numeric Pain Rating Scale). The commenter stated this is an inappropriate internal medicine accountability measure.

Response: The measure is intended to evaluate the effectiveness and timeliness of initial pain management after the start of palliative care services vs. immediate pain control. It strives to incorporate the patient's pain goals relative to perception of comfort rather than aiming for a specific numeric pain intensity rating. This is not a required measure and encourage eligible clinicians to select clinically appropriate measures.

Q357: Surgical Site Infection (SSI)

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

Note: The following table summarizes public comments received that are general to individual MIPS measures but not specific to newly proposed measures, specialty measure sets, measures proposed for removal, or measures with substantive changes.

Specialty Sets: Otolaryngology, General Surgery, Vascular Surgery

Comment: One commenter noted the Q357: Surgical Site Infection (SSI) measure lacks rigor, and the chance for misclassification of surgeons is high. The commenter stated that standardized risk adjustment methodologies are critical when comparing clinical outcomes across different registries/cohorts, yet surgical MIPS measures do not account for risk factors. For example, the commenter tested the SSI measure collected through the ACS Surgeon Specific Registry (SSR). The commenter compared the unadjusted SSI measure rates to the risk-adjusted SSI rates and found that approximately 50 percent of cases were misclassified when risk adjustment was not performed. Yet, CMS does not require the risk adjustment of the SSI measure.

Response: This measure is constructed so that risk adjustment is performed by the parsimonious dataset and aims to allow efficient data collection resources and data submission. In the prior PQRS program, risk-adjustment methodology was provided to vendors if they wanted to provide their clients with this comparison to other eligible clinicians. We do understand the concern of disparities and discussing mitigation strategies to not hold eligible clinicians to different standards for the outcomes of their patients with risk factors or degree of invasiveness. We do not want to mask potential disparities or minimize incentives to improve the outcomes for different patient populations and procedures. However, at this time, we do not require measures to be risk-adjusted. We believe this is still a valid measure to maintain within the program as the denominator is restricted. We will provide this feedback to the measure steward but encourage the commenter to collaborate with the measure steward as well.

Q370: Depression Remission at Twelve Months

Specialty Sets: Family Medicine, Internal Medicine, Mental/Behavioral Health, Geriatrics

Comment: One commenter did not support measure Q370: Depression Remission at Twelve Months, citing that the measure does not account for individual starting points for each patient and there is a lack of high-quality evidence to support the 12-month (+/- 30 days) time interval. The threshold of reaching a specific PHQ-9 score (<5) is arbitrary and does not take into account the individual starting points for each patient. The measure may unfairly penalize clinicians caring for severely depressed patients for their inability to satisfy the measure requirements and as such, this measure may encourage clinicians to overtreat patients for major depressive disorder. Many patients are unable to achieve a PHQ-9 score of <5 and the PHQ-9 is not necessarily the best tool to track patient remission. The commenter suggested that developers consider revising the denominator specifications to include additional depression remission tracking tools and that measure specifications exclude patients with dementia or severe cognitive impairments and patients permanently residing in nursing homes. Lastly, the commenter would be amenable to using this measure as a tracking mechanism but opposed any linkage to performance and payment.

Response: This measure is not intended to assess the depression response, but the remission. Full remission is defined as a 2-month period devoid of major depressive signs and symptoms (American Psychiatric Association, 2013). If using a PHQ-9 tool, remission translates to PHQ-9 score of less than 5 (Kroenke, 2001). We agree that depression response and remission take time. In the STAR*D study, longer times than expected were needed to reach response or remission. In fact, one-third of those who ultimately responded did so after 6 weeks. Of those who achieved remission by Quick Inventory of Depressive Symptomatology (QIDS), 50 percent did so only at or after 6 weeks of treatment (Trivedi, 2006). If the eligible clinician is seeing improvement, this measure encourages the continuation of treatment to reach remission. This can take up to 3 months. Relapse is common within the first 6 months following remission from an acute depressive episode; as many as 20-85 percent of patients may relapse (American Psychiatric Association, 2010). For that reason, we agree with the remission outcome be assessed at multiple points in time.

Q371: Utilization of the PHQ-9 Tool

Specialty Sets: Family Medicine, Internal Medicine, Mental/Behavioral Health

Comment: One commenter did not support measure Q371: Utilization of the PHQ-9 Tool although it is clinically important and could lead to the development of an accurate outcome measure by determining well validated levels of depression severity. The commenter stated there is insufficient evidence to support the 4-month time interval specified in the denominator and the 4-month measurement period is unclear as to whether it's one measurement within a 4-month period, or every 4 months for patients with an on-going disease diagnosis. Evidence supports utilization of the PHQ-9 tool, but many clinicians utilize additional remission screening tools that are equally as effective as the PHQ-9. The measure intends to assess performance at the system level. While this measure may appropriately assess the performance of mental health practitioners (for example, psychiatrist), it may be an inappropriate accountability measure for primary care clinicians who may encounter interoperability barriers to satisfy the measure requirements (for example, subspecialist reports).

Response: We have proposed substantive changes to this measure that address the commenter's concerns. The measure has been revised to assess both adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) with a diagnosis of major depression or dysthymia who have a completed PHQ-9 or PHQ-9M tool during the performance period. Regarding the interoperability barriers for primary care clinicians, this is not a required measure and encourage eligible clinicians to select measures that are clinically appropriate and align with their clinical workflow.

Q374: Closing the Referral Loop: Receipt of the Specialist Report

Specialty Sets: Cardiology, Gastroenterology, Dermatology, Family Medicine, Internal Medicine, Obstetrics/Gynecology, Ophthalmology, Orthopedic Surgery, Otolaryngology, Physical Medicine, Preventive Medicine, Neurology, Mental/Behavioral Health, Vascular Surgery, General Surgery, Thoracic Surgery, Urology, Oncology, Rheumatology

Comment: Two commenters provided feedback on measure Q374: Closing the Referral Loop: Receipt of the Specialist Report because it could lead to an unintended consequence of encouraging unnecessary care. One commenter provided a number of suggestions for measure developers: the specifications are not well defined and should include an evidence-based time interval and some element of risk-adjustment; there is not enough evidence cited to form the basis of the measure; the outcome is based on the level of integration of the participating information system rather than on how well the individual clinician tracks the referral; the data trail for submission may vary by submitter type; it is not necessary for clinicians to close all referral loops; and the patient may not see the specialist within the measurement period causing the referring clinician to fail the measure. Lastly, this measure may become less relevant due to the use of electronic health records (EHRs), and there is less evidence that this measure will improve care if it is implemented at the individual clinician level. One

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

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commenter recommended that CMS work with measure developers to change Q374: Closing the Referral Loop: Receipt of Specialist Report from patient-based to episode-based because reports are associated with a specific encounter and it would reduce the timing complexity.

Response: We disagree that the measure encourages unnecessary care but promotes communication between eligible clinicians. We will evaluate the request to determine an appropriate timeframe but need to consider the variance between specialties and testing. As indicated within the comment, depending on the urgency to complete the referral within a given timeframe, the patient may not see the specialist. We agree the variance of timeframes may be mitigated by risk-adjustment but may overcomplicate the measure. We disagree that performance is based on the level of integration of information systems. Referral tracking methods should be developed within individual practices or networks. In response to the request to move towards episode-based reporting, the measure is specified at the patient-level and limited to the first referral of the measurement period to minimize reporting burden on clinicians. However, we received similar feedback from stakeholders during our periodic reassessment of the measure, and we are currently testing an episode-based revision to this measure. We will consider implementing the revised measure in future program years if it continues to meet our standards for feasibility, reliability, and validity. This measure promotes communication and care coordination no matter the method of referral tracking. We maintain the notion that Q374 is still a valid measure to promote care coordination based on the responses above.

Q377: Functional Status Assessment for Patients with CHF

Specialty Sets: Family Medicine, Internal Medicine

Comment: One commenter did not support measure Q377: Functional Status Assessment for Patients with CHF as it is unclear whether implementation of this measure will lead to meaningful improvements in quality outcomes and the measure developers do not cite a performance gap. Also, incentivizing clinicians to perform routine assessments in asymptomatic patients may result in underuse of more meaningful clinical interventions. The commenter supported valid, reliable patient reported outcome measures (PROMs), there says this measure has insufficient evidence to support the benefit of this intervention on quality outcomes. Implementation of evidence-based PROMs using validated instruments to assess clinical performance is likely the first step towards collecting PROM data. As currently specified, congestive heart failure is not clearly defined, and developers should consider revising the specifications to clearly differentiate between preserved ejection fraction and systolic dysfunction because this intervention will more likely lead to quality improvements in the latter population .

Response: We consulted with the measure steward and they will give consideration to providing further clarity on the definition of congestive heart failure included in the measure in the future.

Q387: Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users

Specialty Sets: Family Medicine, Internal Medicine, Infectious Disease

Comment: One commenter supported measure Q387: Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users. The commenter agreed that the implementation will likely lead to measurable and meaningful improvements in clinical outcomes and it aligns with USPSTF recommendations and other society recommendations. The commenter advised developers to address the following concerns during the update process: the benefit of diagnosing active injection drug users on injection habits is unclear and implementation is unlikely to largely benefit population health outcomes because most clinicians treat a low patient denominator for the measure; denominator specifications may not capture patients who deny injection drug use status and denominator specifications could be revised to be more inclusive of all patients at risk for HCV (for example, baby-boomer populations); and clinicians may encounter barriers to data access as information systems may not automatically identify the denominator population unless end users create a specific code to capture injection drug use.

Response: We will continue to monitor the level of impact to this patient population and will collaborate with the measure steward to potentially expand the patient population. However, we refer the commenter to measure Q400 One-Time Screening for Hepatitis C Virus for Patients at Risk that would include the requested patient population. We do not agree that data access will create any type of barrier. The data abstraction is not limited to a specific code or discrete data. As long as the medical record can substantiate the quality action, it would meet the intent of the measure.

Q390: Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options

Specialty Sets: Gastroenterology

Comment: One commenter did not support measure Q390: Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options because it ceases to be relevant in an era of superior pharmacologic treatment advancements. Newer treatments have minimal side effects, and therefore, decisions about tolerability are no longer applicable. Furthermore, measure developers do not cite any evidence to form the basis of the measure and do not include measurement validity or reliability data in the measure report. Additionally, the numerator specifications are unclear. Developers should consider revising the specifications to define explicit "shared decision making" documentation requirements. Lastly, patients who receive government funded insurance may encounter accessibility barriers to treatment options. It may inappropriate to base treatment options on shared- decision making alone because payers play a significant role in the therapy selection process.

Response: To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment. This would include the superior pharmacologic treatment with consideration to financial burden. We do understand the concern of socioeconomic disparities and discussing mitigation strategies to not hold eligible clinicians to different standards for the outcomes of their patients with social risk factors. We do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations.

Q398: Optimal Asthma Control

Specialty Sets: Family Medicine, Internal Medicine, Otolaryngology, Pediatrics

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Comment: One commenter did not support measure Q398: Optimal Asthma Control, citing that implementation of the measure will likely prevent overuse of emergency department services to treat acute disease exacerbations. The commenter noted that measure developers did not cite enough evidence to form the basis of the measure, that measure specifications are difficult to navigate, and that the measure is not currently risk-adjusted for disease severity and socioeconomic status. Lastly, the commenter stated that the Asthma Control Test (ACT) is a best practice but it is a proprietary assessment tool.

Response: We will work with the measure steward to incorporate the citation within the specification. We have been trying to reduce the burden of reporting but disagree with the commenter indicating 6 components are required. It is only requiring 3 components: well-controlled, risk of exacerbation, and emergency visits. The measure is stratified by age to accommodate the age-specific assessment tools. The measure is not risk-adjusted at this time to address socioeconomic status but do not believe this should deter eligible clinician from making every effort to accommodate patients' financial situations. Eligible clinicians could provide sample controller medication to improve asthma control. We do understand the concern of socioeconomic disparities and discussing mitigation strategies to not hold eligible clinicians to different standards for the outcomes of their patients with social risk factors. We do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. The ACT may be proprietary, but the measure allows for additional asthma control tools to be utilized (Asthma Control Questionnaire or Asthma Therapy Assessment Questionnaire). We continue to evaluate methods to display performance data. We have previously published Experience Reports to provide a detailed summary and continue to create meaningful benchmarks based on the submitted data. We have explored alternative asthma measures that promote controller medication therapy over quick reliever medication, but unable to implement at the clinician level at this time. We agree that the goal is to achieve 100 percent adherence and will continue to collaborate with the measure steward to raise the Percentage Days Covered (PDC) to drive quality improvement. The measure is not risk-adjusted at this time to address socioeconomic status but do not believe this should deter adherence and all efforts should be made to accommodate patients' financial situations. As indicated within the comment, eligible clinicians could provide sample medication to improve patient adherence and alleviate financial burden. Medications dispensed as samples would be included within the PDC assessment. While this may pose difficulty in abstracting by pharmacy data, the medical record should capture this provision. Within the 2018 measure specification, there is a table that defines appropriate asthma controller medications. Based on the provided response, we maintain the notion this is an appropriate measure.

Q400: One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk

Specialty Sets: Family Medicine, Internal Medicine, Nephrology, Infectious Medicine

Comment: One commenter supported measure Q400: One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk**.** They agreed that a performance gap does exist, it is important to screen for HCV in patients at risk because it is a treatable disease, the measure aligns with CDC and USPSTF recommendations on screening for HCV in patients at risk and the measure specifications include appropriate exclusion criteria. However, the commenter stated that while the measure is clearly specified, clinicians may encounter interoperability barriers to patient information retrieval. One recommendation for the measure developers is to re-assess the benefit of screening all patients included in the denominator population during the measure update, particularly patients born in the years 1945-1965.

Response: We will forward the commenters suggestion to restrict the screening for patients born in the years 1945-1965. One-time HCV testing is recommended for persons born between 1945 and 1965 without prior ascertainment of risk (Rating: Class I, Level B) (AASLD/IDSA, 2017). However, the same commenter requested this population be added to measure Q387: Annual Hepatitis C Virus Screening for Patients who are Active Injection Drug Users. We will collaborate with all stakeholders to vet the appropriate patient population. The measure is currently appropriate for each separate patient populations. One requires an annual screening for high-risk active injection drug use, while the broader denominator requires a one-time screening which is appropriate for historical risk factors (born from 1945-1965, history of blood transfusion prior to 1992, hemodialysis, or history of drug use).

Q401: Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis

Specialty Sets: Gastroenterology, Family Medicine, Internal Medicine

Comment: One commenter did not support measure Q401: Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis because the screening benefits do not outweigh the substantial risks of harms related to radiation exposure and treatment of incidental findings. Developers cite weak evidence to form the basis of the measure, and a recent evidence review demonstrates insufficient evidence for screening for hepatocellular carcinoma among patients with cirrhosis.

Response: We will continue to monitor the clinical guidelines that suggest the benefits do not outweigh the risks. In regards to the comment, to weighing the risk versus benefits, the measure allows for a denominator exception for patient and medical reasons for not completing the screening.

Q402: Tobacco Use and Help with Quitting among Adolescents

Specialty Sets: Cardiology, Gastroenterology, Dermatology, Family Medicine, Internal Medicine, Obstetrics/Gynecology, Orthopedic Surgery, Otolaryngology, Pediatrics, Physical Medicine, Preventive Medicine, Neurology, Mental/Behavioral Health, General Surgery, Vascular Surgery, Thoracic Surgery, Oncology, Rheumatology, Urgent Care

Comment: One commenter supported measure Q402: Tobacco Use and Help with Quitting among Adolescents because, tobacco use is a modifiable risk factor and clinical evidence supports patient counseling. The commenter stated the denominator population is unclear, and the developer should consider separating the measure into two distinct measures: (1) tobacco use screening measure; and (2) tobacco cessation measure for patients who screened positive on measure 1.

Response: We do not agree in separating the measure into two distinct measures. We will provide your recommendation to the measure steward to stratifying the measure so to provide separate performance rates to identify areas where a gap exists.

Q408: Opioid Therapy Follow-Up and Evaluation

Specialty Sets: Family Medicine, Internal Medicine, Orthopedic Surgery, Physical Medicine, Neurology, Geriatrics

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

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Comment: One commenter did not support measure Q408: Opioid Therapy Follow-Up and Evaluation as it is a "check the box measure." A more appropriate measure may incentivize a standardized, methodological approach to evaluation that is likely to improve the opioid therapy management process and result in improved clinical outcomes. There is insufficient evidence to support the 6 weeks and 3 months durations included in the denominator and numerator specifications. The commenter suggested that developers revise the specifications to include an evidence based-definition of chronic opioid therapy. Furthermore, it is unclear whether clinicians who prescribe therapy for less than 3 months should require patient follow-up earlier than 3 months' time. The measure would benefit from reliability and validity testing prior to inclusion in quality payment programs**.**

Response: We agree with the commenter's suggestion to revise the quality action to require follow up or mitigation plan if patient is not responding or misusing the opioid. We have collaborated with the measure steward to provide a definition of follow-up evaluation included in the 2019 measure specification. We will provide the commenter's recommendation to the measure steward to align the denominator with the definition of chronic opioid therapy. However, we believe frequent patient education and follow-up regarding opioid use is necessary and aligns with our program goals to address the opioid epidemic.

Q411: Depression Remission at Six Months

Specialty Sets: Mental/Behavioral Health

Comment: One commenter did not support measure Q411: Depression Remission at Six Months, citing a lack of high-quality evidence to support the 6-month (+/- 30 days) time interval included in the numerator specifications and the threshold of reaching a specific PHQ-9 score (<5) is arbitrary, does not take into account the individual starting points for each patient, and is difficult for patients to achieve. The measure may also penalize clinicians caring for severely depressed patients for their inability to satisfy measure requirements and as such, this measure may encourage clinicians to over treat patients for major depressive disorder. The commenter recommended that developers: should consider revising the specifications to include risk adjustment to account for individual starting points for each patient; that PHQ-9 is not necessarily the best tool to track patient remission; that denominator specifications could be revised to include additional depression remission tracking tools; and that measure specifications exclude patients with dementia or severe cognitive impairments and patients permanently residing in nursing homes.

Response: This measure is not intended to assess the depression response, but the remission. Full remission is defined as a 2-month period devoid of major depressive signs and symptoms (American Psychiatric Association, 2013). If using a PHQ-9 tool, remission translates to PHQ-9 score of less than 5 (Kroenke, 2001). We agree that depression response and remission take time. In the STAR*D study, longer times than expected were needed to reach response or remission. In fact, one-third of those who ultimately responded did so after 6 weeks. Of those who achieved remission by Quick Inventory of Depressive Symptomatology (QIDS), 50 percent did so only at or after 6 weeks of treatment (Trivedi, 2006). If the eligible clinician is seeing improvement, this measure encourages the continuation of treatment to reach remission. This can take up to 3 months. Relapse is common within the first 6 months following remission from an acute depressive episode; as many as 20-85 percent of patients may relapse (American Psychiatric Association, 2010).

Q412: Documentation of Signed Opioid Treatment Agreement

Specialty Sets: Family Medicine, Internal Medicine, Orthopedic Surgery, Physical Medicine, Neurology, Geriatrics

Comment: One commenter supported measure Q412: Documentation of Signed Opioid Treatment Agreement because it protects clinicians from the repercussions of patients who violate the opioid agreement. Also, considering the magnitude and urgency of the opioid epidemic, quality programs should adopt this measure unless data is otherwise available to describe the negative consequences of this measure. The commenter suggested that developers update the measure specifications to include appropriate exclusion criteria for patients receiving active cancer treatment, and patients receiving palliative and end-of-life care.

Response: We agree with the commenter's suggestion to exclude patients who are undergoing active cancer treatment and who are receiving palliative and end-of-life care. We have previously collaborated with the measure steward to add a hospice exclusion for the 2019 performance period. We encourage the commenter to review the measure specification when published.

Q414: Evaluation or Interview for Risk of Opioid Misuse

Specialty Sets: Family Medicine, Internal Medicine, Orthopedic Surgery, Physical Medicine, Neurology, Geriatrics

Comment: One commenter supported measure Q414: Evaluation or Interview for Risk of Opioid Misuse because implementation will likely lead to measurable and meaningful improvements in patient outcomes and prevent the misuse and abuse of opioid prescription therapy. However, the commenter stated that evidence exists to suggest that opioid addiction develops in less than 6 weeks duration of prescribed therapy, so the measure could unfairly penalize clinicians who do not initiate opioid therapy. Measure developers should consider updating the denominator specifications to include an evidence-based therapy duration. Also, the opioid measures would benefit from additional testing to determine which interventions are most impactful in preventing opioid misuse and abuse, exclusion criteria could include patients receiving active cancer treatment, palliative care, and end-of-life care.

Response: We agree with the commenter's suggestion to exclude patients undergoing active cancer treatment, receiving palliative and end-of-life care. We have collaborated with the measure steward to add a hospice exclusion for the 2019 performance period. We encourage the commenter to review the measure specification when published. In addition, we will provide the commenter's recommendation to the measure steward to align the denominator with the definition of chronic opioid therapy. The revision of chronic opioid therapy does not make this an invalid measure as it promotes risk assessment for a large opioid epidemic.

Q418: Osteoporosis Management in Women who had a Fracture

Specialty Sets: Family Medicine, Internal Medicine, Obstetrics/Gynecology, Orthopedic Surgery

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

Note: The following table summarizes public comments received that are general to individual MIPS measures but not specific to newly proposed measures, specialty measure sets, measures proposed for removal, or measures with substantive changes.

Comment: One commenter supported measure Q418: Osteoporosis Management in Women who had a Fracture because a performance gap exists, the specifications align with current recommendations to screen for osteoporosis in women aged 65 years and older, and specifications include appropriate exclusion criteria for women with fracture related to traumatic injury. The commenter stated that implementation may promote overuse of bone mineral density testing, and developers should consider tapering the fracture definition to only include women with vertebral and hip fractures.

Response: We do not agree that it would promote overuse of screening as it allows a 2-year timeframe for completing the bone mineral density test. In addition, an eligible clinician can meet the intent of the measure by pharmacotherapy. Eligible clinicians are expected to coordinate their care with eligible clinicians. We will provide feedback to the measure steward regarding the narrowing of eligible ICD10 codes and possibly incorporated in a future annual revision process. In response to the commenter's request to include a hospice exclusion, this is included within the measure specification.

Comment: For measure Q418: Osteoporosis Management in Women Who Had a Fracture, one commenter stated that there is a disconnect between this quality measure and the communication and care transition quality measure application to the clinician treating the fracture. The commenter urged CMS to align measure Q418 with clinical guidelines recommending that patients with a history of hip or vertebral fracture receive (or are offered) pharmacotherapy to treat osteoporosis.

Response: This measure promotes further evaluation or pharmacotherapy to treat osteoporosis for patients experiencing a fracture. U.S. Food and Drug Administration approved pharmacologic options for osteoporosis prevention and/or treatment of postmenopausal osteoporosis include, in alphabetical order: bisphosphonates (alendronate, alendronate-cholecalciferol, ibandronate, risedronate, zoledronic acid, calcitonin, teriparatide, denosumab, and raloxifine.

Q419: Overuse of Imaging for Patients with Primary Headache and a Normal Neurological Evaluation

Specialty Sets: Neurology

Comment: One commenter supported measure Q419: Overuse of Imaging for Patients with Primary Headache and a Normal Neurological Evaluation. However, the commenter stated that measure developers cite outdated evidence to form the basis of the measure. Additionally, quality reporting programs should be aware of the potential for clinicians to manipulate the measure to work in their favor by documenting an exception to the rule (for example, "change in the type of headache"). To avoid potential measure gaming, developers should consider revising the specifications to clearly define appropriate exceptions to eligibility.

Response: In response to the outdate guidelines concern, we encourage the commenter to review the substantively updated measure specification that reflect the most recent guidelines. Eligible clinicians should not change their billing or documentation to manipulate eligibility or performance. Any claims submitted to the CMS are subject to an audit, inclusive of any performance data submitted to the quality program.

Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling

Specialty Sets: Cardiology, Gastroenterology, Family Medicine, Internal Medicine, Obstetrics/Gynecology, Otolaryngology, Physical, Medicine, Preventive Medicine, Mental/Behavioral Health, Urology, Oncology, Urgent Care

Comment: One commenter supported measure Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling because it is clinically important to screen for unhealthy alcohol use. They agreed that the measure aligns with the United States Preventive Services Task Force (USPSTF) recommendations on screening and behavioral health counseling interventions in primary care, and the measure does not pose undue burden on clinicians. The commenter suggested the developers revise the numerator specifications to clearly define "brief counseling.

Response: We direct the commenter to the measure specification that defines brief counseling: Brief counseling for unhealthy alcohol use refers to one or more counseling sessions, a minimum of 5-15 minutes, which may include: feedback on alcohol use and harms; identification of high risk situations for drinking and coping strategies; increased motivation and the development of a personal plan to reduce drinking.

Q435: Quality of Life Assessment for Patients with Primary Headache Disorders

Specialty Sets: Neurology

Comment: One commenter did not support measure Q435: Quality of Life Assessment for Patients with Primary Headache Disorders because it cannot estimate the measure impact on improved clinical outcomes. The commenter stated that following on the measure specifications: denominator specifications include exclusion criteria for patients without insurance to cover assessment costs, reinforcing uncertainty surrounding the intervention's ability to improve quality outcomes; the numerator specifies an assessment tool that is specific to migraine headaches; and as currently specified, clinicians are required to perform quality of life assessments on all patients with primary headache disorders, regardless of clinical relevance to the patient's primary complaints. Developers should consider revising the specifications to include a principle diagnosis of primary headache and more meaningful, evidence-based interventions.

Response: We disagree with the commenter's assessment of the measure and refer the commenter to review the MIPS quality measure. It does not have an exclusion for patients without insurance to cover assessment costs. The measure does provide a list of quality of life tools applicable to this specific patient population: Migraine Disability Assessment (MIDAS) and PedMIDAS (proprietary); Headache Impact Test-6 (HIT-6)(proprietary); Migraine Specific Quality of Life Tool (MSQ); Neck Disability Index (NDI)-used for cervicogenic headaches; McGill Questionnaire. This measure may be submitted by eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding. The eligible clinician would only submit the measure if there was a qualifying encounter(s).

Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Specialty Sets: Cardiology, Family Medicine, Internal Medicine, Preventive Medicine

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

Note: The following table summarizes public comments received that are general to individual MIPS measures but not specific to newly proposed measures, specialty measure sets, measures proposed for removal, or measures with substantive changes.

Comment: One commenter supported measure Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease based on an increase in the performance gap due to new guidelines, available evidence and that measure specifications include appropriate exclusion criteria for patient intolerance. The commenter noted that implementation of statin therapy alone does not guarantee meaningful improvements in clinical outcomes. A more meaningful measure may examine patient adherence to prescribed statin therapy. Additionally, a high percentage of patients prescribed statin therapy for the management of cardiovascular disease exacerbations (for example, acute MI) discontinue therapy without consulting their clinician. However, the measure may unfairly penalize clinicians for lack of control over non-adherent patients.

Response: We will evaluate the commenter's request for adding an adherence component, but the commenter also cited concerns that this may not attribute to the eligible clinician due to lack of control of non-adherent patients. Based on the commenter's feedback to add adherence but caution adherence would out of the eligible clinician's control, we maintain the notion this is a good measure,

Q441: Ischemic Vascular Disease: All or None Outcome Measure

Specialty Sets: Cardiology, Family Medicine, Internal Medicine, Vascular Surgery

Comment: One commenter did not support measure Q441: Ischemic Vascular Disease: All or None Outcome Measure, citing that it did not receive adequate information from the developer for review and that it rated the measure based on the specifications provided on the MIPS website. The commenter stated the measure because it disregards patient preferences, specifications do not consider factors beyond the clinician's control, and it does not align committee recommendations for hypertension management.

Response: We agree with updating the numerator to reflect the updated blood pressure values and have been discussing the revision with the measure steward. We maintain the opinion this is a good measure since the new guidelines have been controversial and encourages comprehensive management of a prevalent condition.

Q442: Persistence of Beta-Blocker Treatment after a Heart Attack

Specialty Sets: Cardiology, Family Medicine, Internal Medicine

Comment: One commenter supported measure Q442: Persistence of Beta-Blocker Treatment after a Heart Attack, citing high-quality evidence from the most recent recommendations of various organizations. The commenter noted this measure is close to being topped out.

Response: We encourage the commenter to review the most current MIPS performance data when available.

Q443: Non-Recommended Cervical Cancer Screening in Adolescent Females

Specialty Sets: Family Medicine, Internal Medicine, Obstetrics/Gynecology

Comment: One commenter supported measure Q443: Non-Recommended Cervical Cancer Screening in Adolescent Females because implementation will likely promote appropriate use of cervical cancer screening in adolescents, the measure is well specified, and specifications include appropriate exclusion criteria for women diagnosed with HIV. The measure also aligns with USPSTF recommendations on cervical cancer screening. However, the commenter noted that earlier screening is not as effective and that the evidence base would benefit from re-evaluation as data surfaces on the benefits and risks of screening in women < 20 years old. Because the performance gap is not cited in the measure report, it is difficult to estimate the potential impact of the measure on quality outcomes.

Response: We continue to evaluate methods to display performance data. We have previously published Experience Reports to provide a detailed summary and continue to create meaningful benchmarks based on the submitted data. The measure aligns with United States Preventive Services Task Force recommendations on cervical cancer screening in addition to the ACOG and ASCCP guidelines. We will continue to monitor for updated cervical cancer screening guidelines and collaborate with the measure steward to align with any updated guidelines.

Q444: Medication Management for People with Asthma

Specialty Sets: Family Medicine, Internal Medicine, Pediatrics

Comment: One commenter supported measure Q444: Medication Management for People with Asthma because implementation may promote patient adherence to prescribed controller medication therapy. However, the commenter indicated the following concerns: the performance gap is not cited; there is no evidence cited to support the Percentage of Days Covered (PDC) threshold; the measure is not measure is not risk-adjusted for disease severity or socioeconomic status and implementation; the measure numerator should clearly specify an appropriate asthma controller medication list; the measure could unfairly penalize clinicians who encounter interoperability barriers to data retrieval; the measure uses pharmacy data to track medication adherence where lower socioeconomic patients may encounter cost barriers and adherence issues; and lastly, the measure assesses quality at the system level where individual clinicians may encounter interoperability barriers to data retrieval.

Response: We continue to evaluate methods to display performance data. We have previously published Experience Reports to provide a detailed summary and continue to create meaningful benchmarks based on the submitted data. We have explored alternative asthma measures that promote controller medication therapy over quick reliever medication, but unable to implement at the clinician level at this time. We agree that the goal is to achieve 100 percent adherence and will continue to collaborate with the measure steward to raise the Percentage Days Covered (PDC) to drive quality improvement. The measure is not risk-adjusted at this time to address socioeconomic status but do not believe this should deter adherence and all efforts should be made to accommodate patients' financial situations. We do understand the concern of socioeconomic disparities and discussing mitigation strategies to not hold eligible clinicians to different standards for the outcomes of their patients with social risk factors. We do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. As indicated within the comment, eligible clinicians could provide sample medication to improve patient adherence

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

Note: The following table summarizes public comments received that are general to individual MIPS measures but not specific to newly proposed measures, specialty measure sets, measures proposed for removal, or measures with substantive changes.

and alleviate financial burden. Medications dispensed as samples would be included within the PDC assessment. While this may pose difficulty in abstracting by pharmacy data, the medical record should capture this provision. Within the 2018 measure specification there is a table that defines appropriate asthma controller medications. Based on the provided response, we maintain the notion this is an appropriate measure.

Specialty Measure Sets: Cardiology, General Surgery, Skilled Nursing Facility

Comment: One commenter encouraged CMS to add the following immunization quality measures into a new Endocrinology specialty measure sets:

- ***Cardiology*** - Q474: Zoster (Shingles) Vaccination; Q110: Preventive Care and Screening: Influenza Immunization and Q111: Pneumonia Vaccination Status for Older Adults
- ***General Surgery*** - Q110: Preventive Care and Screening: Influenza Immunization and Q111: Pneumonia Vaccination Status for Older Adults
- ***Skilled Nursing Facility*** -. Q111: Pneumonia Vaccination Status for Older Adults
- ***Endocrinology*** - Q474: Zoster (Shingles) Vaccination; Preventive Care and Screening: Influenza Immunization and Q111: Pneumonia Vaccination Status for Older Adults

Response: We thank the commenter for the recommendation to create an Endocrinology specialty measure set and to add these measures to existing specialty measure sets for Cardiology, General Surgery, and Skilled Nursing Facility. Prior to rulemaking we solicit feedback from stakeholders with regards to measures that should be added or removed to existing specialty sets or the development of new specialty sets. Specific measure to create an Endocrinology specialty measure set were not suggested as part of the feedback received from specialty stakeholders for the 2019 performance period. We ask the commenter to submit their feedback during this solicitation process for future consideration in rulemaking. This allows stakeholder to provide feedback to the specialty set proposed prior to the finalization of the specialty set. We do not agree with the recommendation to include Q110, Q111, and Q474 to the Cardiology and General Surgery specialty sets as the patient would likely be referred to the PCP to receive immunizations. While we agree that Q111 may apply to Skilled Nursing Facilities, the denominator coding does not support this request.

Specialty Measure Set: Allergy/Immunology (A/I)

Comment: One commenter expressed concerns with the Allergy/Immunology (A/I) Specialty Measure Set, which they noted includes measures that are not pertinent to our Allergy/Immunology Specialty. Given A/I specialists do not diagnose, treat or manage HIV/AIDS, measures related to this disease do not belong in the A/I Specialty Measure Set. Therefore, the commenter requested that CMS remove the following measures: Measure 160: HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis; Measure 338: HIV Viral Load Suppression; Measure 340: HIV Medical Visit Frequency.

In addition, the commenter noted that A/I specialists do diagnose, treat and frequently manage sinusitis and asthma, therefore, they requested that CMS return the following measures to the A/I Specialty Measure Set: Measure 331: Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis, Measure 332: Adult Sinusitis: Appropriate Choice of Antibiotic.

Response: Prior to rulemaking we solicit feedback from stakeholders with regards to measures that should be added or removed to existing specialty sets or the development of new specialty sets. The suggestion to remove the measures from the Allergy/Immunology specialty measure set was not provided as part of the feedback received from specialty stakeholders for the 2019 performance period. We ask the commenter to submit their feedback during this solicitation process for future consideration in rulemaking.

Specialty Measure Set: Dentistry

Comment: One commenter supported the inclusion of measure Q379: Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists, but stated the measure specifications do not reflect the best clinical evidence. Existing clinical recommendations recommend that topical fluoride be applied more frequently than once per year and as often as every 3 months for children at elevated risk for dental caries. The commenter recommended that this measure be amended to reflect increased risk for tooth decay in line with the existing pediatric measure set developed by the Dental Quality Alliance (DQA). The commenter also supported the inclusion of measure Q378: Children Who Have Dental Decay or Cavities, as it represents the type of outcome measures that oral health care has long been lacking. However, there has been no visible progress in developing or testing this measure for use by Medicaid programs. The commenter requested that CMS transfer the measure stewardship for measures Q378 and Q379 to the DQA, which was as established at the request of CMS to serve as a multi-stakeholder organization focused on oral health quality measurement and improvement Furthermore, the commenter noted that two additional measures have been developed by the DQA through support from the Office of National Coordinator for Health Information Technology (ONC) and tested for validity, reliability, feasibility and usability for use at the clinicians level and rely on standard data elements in electronic health records and are specified precisely using the Measure Authoring Tool based on the Quality Data Model and value sets.

Response: We thank the commenter for feedback that this outcome measure is not risk adjusted for clinical or sociodemographic factors. We support the goal of identifying and reducing disparities in health and healthcare. We will explore risk adjustment for this measure and the potential impact on clinician burden in the next update period. Thank you for bringing up the current evidence-based clinical recommendations and the need to incorporate within this measure. We will review these recommendations in the next update period. With regard to the DQA and measure stewardship, we seek collaborative partnerships and engagement with stakeholders in the development and continued maintenance of important, feasible, reliable, valid, and useful measures and appreciates the opportunity to engage the current measure steward and other stakeholders. Thank you for your comments on the need for additional measures for dental professionals and your recommendations to improve the current program dental measures. We will take your suggestions under consideration as we continue to review and update program measures. We provide opportunities for introducing new measures into programs through an annual call for measures and encourage the commenter to submit measures and measure concepts at the next Call for Measures solicitation.

General Comments

Comment: One commenter supported the inclusion of a number of dementia and cognitive impairment measures in MIPS. The commenter urged CMS to develop quality measures related to mild cognitive impairment and its detection for future years. The commenter further urged CMS to include the cognitive impairment quality measures currently under development by the measure steward when they are finalized. The commenter also stated that cognitive impairment detection is the only aspect of the Annual Wellness Visit that is not fully reinforced with clinicians through MIPS quality measures. The existing

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

Note: The following table summarizes public comments received that are general to individual MIPS measures but not specific to newly proposed measures, specialty measure sets, measures proposed for removal, or measures with substantive changes.

dementia-related quality measures apply solely to patients who have already been diagnosed with dementia, and do not reflect overall incorporation of the required cognitive impairment component in the AWV. The Quality Payment Program, therefore, perpetuates ADRD under diagnosis and impedes appropriate interventions for patients and their families.

Response: We encourage the comment to collaborate with measure developers to submit measures to the Call for Measures process for future implementation.

Comment: One commenter urged CMS to adopt the following malnutrition eCQMs adopted by the National Quality Forum 14: NQF #3087/MUC16-294: Completion of a Malnutrition Screening within 24 hours of Admission; NQF #3088/MUC16-296: Completion of a Nutrition Assessment for Patients Identified as At Risk for Malnutrition within 24 hours of a Malnutrition Screening; NQF #3089/MUC16-372: Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment; NQF #3090/MUC16-344: Appropriate Documentation of a Malnutrition Diagnosis. A second commenter indicated that given the demonstrated gap, it is critical that CMS act quickly to use its statutory authority through direction of the national quality strategy and focus on malnutrition care in the hospital. Malnutrition should be a priority area for CMS, as malnutrition care aligns with the main principles of the Meaningful Measures Initiative.

Response: We encourage the commenter to collaborate with the measure steward of the mentioned measures and submit to the Call for Measures process under the MIPS program. The referenced measures were submitted to the Hospital Inpatient Quality Reporting program, but not for MIPS consideration.

Comment: One commenter was disappointed that adult immunization quality measures were not included in a few key specialty areas who care for chronically ill patients at-risk of serious complications from vaccine preventable illness. The Advisory Committee on Immunization Practices (ACIP) includes age-based, as well as condition-specific recommendations for adult vaccination. For pregnant women, ACIP recommends a Tdap vaccination. We are pleased that efforts to develop a composite Tdap/influenza measure for pregnant women has completed testing and is now under review by the National Committee for Quality Assurance (NCQA). The commenter noted they look forward to further dialogue with CMS on this topic as it moves forward. In addition, patients living with chronic conditions such as heart disease and diabetes are at a significantly higher risk of complications and death from influenza and pneumonia. The CDC has reported that in 2013 only 21.2 percent of adults in this group had received a pneumococcal vaccination, and this number has remained unchanged for at least a decade. Individuals with diabetes are at increased risk for hepatitis B infection. As such, the ACIP recommends hepatitis B vaccination for all patients with diabetes age 6011 and under, as well as other at-risk patients, such as those living with HIV/AIDS and chronic kidney disease.

Response: We appreciate the support for the pneumococcal quality measures. We agree this is an important public health issue. We continue to explore opportunities to implement a composite adult vaccination measure for future implementation. We encourage the commenter to work with measure developers to submit the immunization measures to the Call for Measures process. We did add adult immunization measures to the existing Oncology and Internal Medicine specialty measure set, as well as new specialty measure set.

Comment: A few commenters supported the proposal to remove six measures from CMS Web Interface reporting criteria.

Response: We thank the commenters for their support. Note: Because measure Q318 is not finalized for removal from the MIPS program in this final rule, there are now five measures that will be finalized in this final rule with the change to remove the CMS Web Interface data collection type.

Comment: Concerning the quality category proposed to be weighted at 45 percent in Year 3 continuing to represent the performance category with the greatest contribution to a clinician's final score in MIPS, commenters noted that this performance category still represents the greatest challenge for chiropractic clinicians due to the limited CPT codes the provider is reimbursed by CMS. These codes are currently limited to two clinical quality measures, specifically #131 & #182. These measures have a high risk of being removed based on the proposed rule for topped out measures in Year 3, leaving the chiropractic clinician forced to bill his/her Medicare patients out of pocket expenses to report other quality measures.

Response: We encourage stakeholders to submit feedback on specific MIPS quality measures where they believe codes should be added to reflect a specialty practice not currently reflected in a given measure. We would take that feedback into consideration, and if we agree with the recommendation, could communicate such recommendations to the measure stewards for their consideration. MIPS eligible clinicians should report on quality measures that are meaningful to their practice and within the scope of the care they provide. We note that chiropractor clinician codes have been added to the following measures for the 2019 performance period: Quality ID# 217: Functional Status Change for Patients with Knee Impairments; Quality ID# 218: Functional Status Change for Patients with Hip Impairments; Quality ID# 219: Functional Status Change for Patients with Foot or Ankle Impairments; Quality ID#220: Functional Status Change for Patients with Lumbar Impairments; Quality ID#221: Functional Status Change for Patients with Shoulder Impairments; Quality ID#222: Functional Status Change for Patients with Elbow, Wrist or Hand Impairments; and Quality ID#223: Functional Status Change for Patients with Other General Orthopaedic Impairments. We remind all clinicians that they should bill Medicare only for services that are reasonable and necessary. We encourage MIPS eligible clinicians to review the list of MIPS quality measures and QCDR measures available for quality reporting in order to report on measures that are meaningful to their scope of practice. We believe it is important to gradually remove topped out measures from the program as they demonstrate high, unvarying performance with no gaps for quality improvement.

APPENDIX 2: Improvement Activities

NOTE: For previously finalized improvement activities, we refer readers to the finalized Improvement Activities Inventory in Table F in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175) and in Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77818). Unless modified or removed in the CY 2019 Physician Fee Schedule final rule, previously finalized improvement activities continue to apply for the MIPS CY 2019 performance period and future years.

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53569) for previously adopted criteria for nominating new improvement activities. We refer readers to section III.I.3.h.(4)(d)(i) of this final rule, where we are finalizing our proposals to add one new criterion and remove a previously adopted criterion. In addition, we refer readers to section III.I.3.h.(4)(d)(i) of this final rule where we clarify: (1) considerations for selecting improvement activities for the CY 2019 performance period and future years; and (2) the weighting of improvement activities. In the CY 2019 PFS proposed rule (83 FR 36359), for CY 2019 performance period and future years we proposed: six (6) new improvement activities; the modification of five (5) existing activities; and the removal of one (1) existing activity. These are discussed in greater detail below.

TABLE A: New Improvement Activities for the MIPS CY 2019 Performance Period and Future Years

Proposed Improvement Activity	
Proposed Activity ID:	**IA_AHE_7**
Proposed Subcategory:	Achieving Health Equity
Proposed Activity Title:	Comprehensive Eye Exams
Proposed Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must promote the importance of a comprehensive eye exam, which may be accomplished by providing literature and/or facilitating a conversation about this topic using resources such as the "Think About Your Eyes" campaign[84] and/or referring patients to resources providing no-cost eye exams, such as the American Academy of Ophthalmology's EyeCare America[85] and the American Optometric Association's VISION USA.[86] This activity is intended for: (1) non-ophthalmologists/optometrist who refer patients to an ophthalmologist/optometrist; (2) ophthalmologists/optometrists caring for underserved patients at no cost; or (3) any clinician providing literature and/or resources on this topic. This activity must be targeted at underserved and/or high- risk populations that would benefit from engagement regarding their eye health with the aim of improving their access to comprehensive eye exams.
Proposed Weighting:	Medium
Rationale:	This activity fills a gap as the Inventory does not currently contain an activity related to ophthalmology. Furthermore, we believe promoting and educating patients about the importance of a comprehensive eye exam can improve access to this service and, in turn, improve health status particularly for traditionally underserved populations or to those who are otherwise unable to access these important services. For these reasons, we believe this activity meets the inclusion criteria of an activity that could lead to improvement in practice to reduce health care disparities. We proposed the weighting of this activity as medium because this activity may be accomplished by providing literature and/or facilitating a conversation with a patient during a regular visit. This task may be incorporated into a patient's regular visit with a relatively low investment of time or resources
Comments:	Several commenters supported the inclusion of this improvement activity. Commenters stated that the activity will have positive clinical impacts on patients. In addition, routine eye exams can identify both ocular conditions as well as other health problems, including serious conditions like brain tumors, thyroid disease, and pituitary tumors. Another commenter supported improvement activities that specifically promote health equity, the goal of this improvement activity. One commenter recommended this improvement activity not be finalized due to concern that comprehensive eye exams are not appropriate for most healthy populations and should only be targeted to those at risk. The commenter stated the improvement activity may lead to increases in unnecessary expenditures for public programs and low income patients.
Response:	We believe this improvement activity will have a positive impact on patient care and promote health equity. Regarding the commenter's concern that this improvement activity may lead to the provision of comprehensive eye exams for those who are not at risk, as stated in the description, "this activity must be targeted at underserved and/or high-risk populations that would benefit from engagement regarding their eye health with the aim of improving their access to comprehensive eye exams." Therefore, we believe that the improvement activity is appropriately targeted at populations with the highest risk for conditions that

[84]The Think About Your Eyes resource at http://thinkaboutyoureyes.com.
[85] The American Academy of Ophthalmology's EyeCare America resource at https://www.aao.org/eyecare-america.
[86] The American Optometric Association's VISION USA resource at http://www.aoafoundation.org/vision-usa/.

	can be detected through a comprehensive eye exam. Additionally, since comprehensive eye exams are relatively low cost interventions and early detection of conditions that can be identified through an eye exam may reduce more costly treatment later, we believe this improvement activity will not unnecessarily increase expenditures for public programs and the target population.
Final Action:	After consideration of the public comments received, we are finalizing this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_AHE_7**
Subcategory:	Achieving Health Equity
Activity Title:	Comprehensive Eye Exams
Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must promote the importance of a comprehensive eye exam, which may be accomplished by providing literature and/or facilitating a conversation about this topic using resources such as the "Think About Your Eyes" campaign[87] and/or referring patients to resources providing no-cost eye exams, such as the American Academy of Ophthalmology's EyeCare America[88] and the American Optometric Association's VISION USA.[89] This activity is intended for: (1) non-ophthalmologists/optometrist who refer patients to an ophthalmologist/optometrist; (2) ophthalmologists/optometrists caring for underserved patients at no cost; or (3) any clinician providing literature and/or resources on this topic. This activity must be targeted at underserved and/or high- risk populations that would benefit from engagement regarding their eye health with the aim of improving their access to comprehensive eye exams.
Weighting:	Medium
Proposed Improvement Activity	
Proposed Activity ID:	**IA_BE_24**
Proposed Subcategory:	Beneficiary Engagement
Proposed Activity Title:	Financial Navigation Program
Proposed Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must attest that their practice provides financial counseling to patients or their caregiver about costs of care and an exploration of different payment options. The MIPS eligible clinician may accomplish this by working with other members of their practice (for example, financial counselor or patient navigator) as part of a team-based care approach in which members of the patient care team collaborate to support patient- centered goals. For example, a financial counselor could provide patients with resources with further information or support options, or facilitate a conversation with a patient or caregiver that could address concerns. This activity may occur during diagnosis stage, before treatment, during treatment, and/or during survivorship planning, as appropriate.
Proposed Weighting:	Medium
Rationale:	We believe there is the possibility for improved outcomes when financial navigation programs are in place, such as reducing patient anxiety about costs and improved access to care for underserved populations. For these reasons, we believe this activity meets the inclusion criteria of an activity that could lead to improvement in practice to reduce health care disparities. We proposed the weighting of this activity as medium because the activity may be accomplished by providing literature and/or facilitating a conversation with a patient during a regular visit. This task may be incorporated into a patient's regular visit with a relatively low investment of time or resources.

[87] The Think About Your Eyes resource at http://thinkaboutyoureyes.com.
[88] The American Academy of Ophthalmology's EyeCare America resource at https://www.aao.org/eyecare-america.
[89] The American Optometric Association's VISION USA resource at http://www.aoafoundation.org/vision-usa/.

Comments:	Several commenters supported the inclusion of this improvement activity. One commenter noted that this improvement activity may be challenging for clinicians, especially those in smaller practices who have difficulty accessing cost of care data and should therefore be weighted as high. Another commenter provided support for the inclusion of this improvement activity as proposed because this improvement activity is likely to have a large impact on patients with serious illnesses who are at high risk for medical debt and its related problems, and recommended we remain flexible in the members of the patient care team that can provide financial navigation services.
Response:	As explained in section III.I.3.h.(4)(d)(i)(C) of this final rule, the weighting of "medium" is in accordance with our policy, as high weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being and/or is of high intensity, requiring significant investment of time and resources. We do not believe accessing cost of care data requires a significant investment of time and resources, even for smaller practices, and therefore, we do not believe a high weighting is warranted. We appreciate the supportive comment that this improvement activity will have an impact on patients with serious illnesses who are at risk for medical debt. Regarding the comment that we remain flexible in the members of the patient care team that can provide financial navigation services, the activity description states that the MIPS eligible clinician may meet this improvement activity by working with other members of the patient care team, including financial counselors or patient navigators and we intend to continue this flexibility.
Final Action:	After consideration of the public comments received, we are finalizing this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_BE_24**
Subcategory:	Beneficiary Engagement
Activity Title:	Financial Navigation Program
Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must attest that their practice provides financial counseling to patients or their caregiver about costs of care and an exploration of different payment options. The MIPS eligible clinician may accomplish this by working with other members of their practice (for example, financial counselor or patient navigator) as part of a team-based care approach in which members of the patient care team collaborate to support patient-centered goals. For example, a financial counselor could provide patients with resources with further information or support options, or facilitate a conversation with a patient or caregiver that could address concerns. This activity may occur during diagnosis stage, before treatment, during treatment, and/or during survivorship planning, as appropriate.
Weighting:	Medium
Proposed Improvement Activity	
Proposed Activity ID:	**IA_BMH_10**
Proposed Subcategory:	Behavioral and Mental Health
Proposed Activity Title:	Completion of Collaborative Care Management Training Program
Proposed Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must complete a collaborative care management training program, such as the American Psychological Association (APA) Collaborative Care Model training program available as part of the Centers for Medicare & Medicaid Services (CMS) Transforming Clinical Practice Initiative (TCPI),[90] available to the

[90] Centers for Medicare & Medicaid Services (CMS) Transforming Clinical Practice Initiative (TCPI) information at https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/.

	public,[91] in order to implement a collaborative care management approach that provides comprehensive training in the integration of behavioral health into the primary care practice.
Proposed Weighting:	Medium
Rationale:	Collaborative care management approaches to integrating behavioral health into primary care practice have been associated with significant improvements in mental health symptom acuity and adherence to treatment in the short- to mid-term.[77] [78] [79] In addition, this activity meets the inclusion criteria of an activity that is likely to lead to improved beneficiary health outcomes. We proposed the weighting of this activity as medium because participation in a training program consists of online reading, attending webinars, or other one-time or short-term activities, which, though beneficial, do not require substantial time or effort by clinicians.
Comments:	Several commenters provided general support for the new improvement activities. A few commenters supported the inclusion of this improvement activity.
Response:	We appreciate the comments of support for this improvement activity.
Final Action:	After consideration of the public comments received, we are finalizing this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_BMH_10**
Subcategory:	Behavioral and Mental Health
Activity Title:	Completion of Collaborative Care Management Training Program
Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must complete a collaborative care management training program, such as the American Psychological Association (APA) Collaborative Care Model training program available as part of the Centers for Medicare & Medicaid Services (CMS) Transforming Clinical Practice Initiative (TCPI),[92] available to the public,[93] in order to implement a collaborative care management approach that provides comprehensive training in the integration of behavioral health into the primary care practice.
Weighting:	Medium
Proposed Improvement Activity	
Proposed Activity ID:	**IA_CC_18**
Proposed Subcategory:	Care Coordination
Proposed Activity Title:	Relationship-Centered Communication
Proposed Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must participate in a minimum of eight hours of training on relationship-centered care[94] tenets such as making effective open-ended inquiries; eliciting patient stories and perspectives; listening and responding with empathy; using the ART (ask, respond, tell) communication technique to engage patients, and developing a shared care plan. The training may be conducted in formats such as, but not limited to: interactive simulations practicing the skills above, or didactic instructions on how to implement improvement action plans, monitor progress, and promote stability around improved clinician communication.

[91] American Psychological Association (APA) Collaborative Care Model training program information at https://www.psychiatry.org/psychiatrists/practice/professional-interests/integrated-care/get-trained.
[92] Centers for Medicare & Medicaid Services (CMS) Transforming Clinical Practice Initiative (TCPI) information at https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/.
[93] American Psychological Association (APA) Collaborative Care Model training program information at https://www.psychiatry.org/psychiatrists/practice/professional-interests/integrated-care/get-trained.
[94] Nundy, S. and J. Oswald (2014). "Relationship-centered care: A new paradigm for population health management." Healthcare 2(4): 216-219.

Proposed Weighting:	Medium
Rationale:	There is currently not an activity in the Inventory that addresses communication between patients and clinicians; this proposed activity would help fill a gap. We believe that this proposed activity meets the inclusion criteria of an activity that is likely to lead to improved beneficiary health outcomes based on research citing the importance of relationship-centered care to patient safety. [81] We proposed the weighting of this activity as medium because participation in an eight hour training on relationship-centered care, though beneficial, does not require substantial time or effort by clinicians.
Comments:	A few commenters supported the inclusion of this improvement activity. One commenter recommended this activity be weighted high due to the potential for the training to be burdensome to clinicians.
Response:	As stated in section III.I.3.h.(4)(d)(i)(C) of this final rule, the weighting of "medium" is in accordance with our policy, as high weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being and/or is of high intensity, requiring significant investment of time and resources. We do not believe relationship-centered trainings that can be completed in a minimum of eight hours is a significant investment of time and resources and therefore does not warrant a high weighting.
Final Action:	After consideration of the public comments received, we are finalizing this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_CC_18**
Subcategory:	Care Coordination
Activity Title:	Relationship-Centered Communication
Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must participate in a minimum of eight hours of training on relationship-centered care[95] tenets such as making effective open-ended inquiries; eliciting patient stories and perspectives; listening and responding with empathy; using the ART (ask, respond, tell) communication technique to engage patients, and developing a shared care plan. The training may be conducted in formats such as, but not limited to: interactive simulations practicing the skills above, or didactic instructions on how to implement improvement action plans; monitor progress; and promote stability around improved clinician communication.
Weighting:	Medium
Proposed Improvement Activity	
Proposed Activity ID:	**IA_PSPA_31**
Proposed Subcategory:	Patient Safety and Practice Assessment
Proposed Activity Title:	Patient Medication Risk Education
Proposed Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must provide both written and verbal education regarding the risks of concurrent opioid and benzodiazepine use for patients who are prescribed both benzodiazepines and opioids. Education must be completed for at least 75 percent of qualifying patients and occur: (1) at the time of initial co-prescribing and again following greater than 6 months of co-prescribing of benzodiazepines and opioids, or (2) at least once per MIPS performance period for patients taking concurrent opioid and benzodiazepine therapy.
Proposed Weighting:	High

[95] Nundy, S. and J. Oswald (2014). "Relationship-centered care: A new paradigm for population health management." Healthcare 2(4): 216-219.

Rationale:	This activity addresses the Meaningful Measures priority area of Prevention and Treatment of Opioid and Substance Use Disorders[96] and addresses the role of clinicians in management of concurrent prescriptions, a topic that is not currently represented in the Inventory. We believe this activity meets the inclusion criteria of an activity that is likely to lead to improved beneficiary health outcomes due to the prevalence of opioid and substance abuse disorders and the medical consequences of mismanagement of concurrent benzodiazepine and opioid prescription.[97] We proposed the weighting of this activity as high because it addresses a public health emergency[98] and may reduce preventable health conditions related to opioid abuse. High weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being, as explained in the CY 2017 Quality Payment Program final rule (81 FR 77194). We also refer readers to our clarifications regarding weighting at section III.I.3.h.(4) of this final rule. According to the CDC, about 63,000 people died in 2016 of a drug overdose, and well over half of them are attributed to opioids.[99] Additionally, according to the 2016 National Survey on Drug Use and Health (NSDUH), 11.8 million individuals ages 12 and older misused any opioid (that is, prescription and/or illicit opioids) and 11.5 million individuals misused prescription opioids. Of those who misused opioids, 2.1 million individuals meet the criteria for an opioid use disorder.[100] Since providing education regarding the risks of concurrent opioid and benzodiazepine use directly addresses the opioid epidemic, we believe this improvement activity meets our considerations for high-weighting.
Comments:	Several commenters supported the inclusion of this improvement activity. A couple commenters supported the improvement activity's high weighting due to it being part of addressing the increase in opioid drug use, abuse, and overdose deaths. Other commenters provided general support for new improvement activities that address the opioid crisis. Two commenters stated that there is a lack of evidence on when the risks of concurrent opioid and benzodiazepine prescribing outweigh the benefits and likewise when the benefits outweigh the risks.
Response:	We appreciate the comments of support for this improvement activity. We also appreciate the commenters who stated there is a lack of evidence on when the risks of concurrent opioid and benzodiazepine prescribing outweigh the benefits. However, this improvement activity does not require MIPS eligible clinicians to alter their prescribing protocol, except to provide written and verbal education regarding the known risks.
Rationale:	After consideration of the public comments received, we are finalizing this improvement activity as proposed.

[96] Meaningful Measures Framework information available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.

[97] McClure, F. L., Niles, J. K., Kaufman, H. W., & Gudin, J. (2017). Concurrent Use of Opioids and Benzodiazepines: Evaluation of Prescription Drug Monitoring by a United States Laboratory. Journal of Addiction Medicine, 11(6), 420–426. http://doi.org/10.1097/ADM.0000000000000354.

[98] Department of Health and Human Services. (2018) "HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis" Available at https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.

[99] Hedegaard, H., Warner, M., & Miniño, A. M. (2017). NCHS Data Brief No. 294. Center for Disease Control and Prevention National Center for Health Statistics. Available at https://www.cdc.gov/nchs/products/databriefs/db294.htm.

[100] Park-Lee, E., Lipari, R. N., Hedden, S. L., Kroutil, L. A., & Porter, J. D. (2017). Receipt of Services for Substance Use and Mental Health Issues among Adults: Results from the 2016 National Survey on Drug Use and Health. Substance Abuse and Mental Health Services Administration NSDUH Data Review. Available at https://www.samhsa.gov/data/sites/default/files/NSDUH-DR-FFR2-2016/NSDUH-DR-FFR2-2016.htm.

Finalized Improvement Activity	
Activity ID:	**IA_PSPA_31**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Patient Medication Risk Education
Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must provide both written and verbal education regarding the risks of concurrent opioid and benzodiazepine use for patients who are prescribed both benzodiazepines and opioids. Education must be completed for at least 75 percent of qualifying patients and occur: (1) at the time of initial co-prescribing and again following greater than 6 months of co-prescribing of benzodiazepines and opioids, or (2) at least once per MIPS performance period for patients taking concurrent opioid and benzodiazepine therapy.
Weighting:	High
Proposed Improvement Activity	
Proposed Activity ID:	**IA_PSPA_32**
Proposed Subcategory:	Patient Safety and Practice Assessment
Proposed Activity Title:	Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support
Proposed Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must utilize the Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain[101] via clinical decision support (CDS). For CDS to be most effective, it needs to be built directly into the clinician workflow and support decision making on a specific patient at the point of care. Specific examples of how the guideline could be incorporated into a CDS workflow include, but are not limited to: electronic health record (EHR)-based prescribing prompts, order sets that require review of guidelines before prescriptions can be entered, and prompts requiring review of guidelines before a subsequent action can be taken in the record.
Proposed Weighting:	High
Rationale:	This activity addresses the Meaningful Measures priority areas of Prevention and Treatment of Opioid and Substance Use Disorders and Transfer of Health Information and Interoperability[102]. Electronic tools like CDS can assist clinicians in preventing adverse patient outcomes. We believe this activity meets the inclusion criteria of an activity that is likely to lead to improved beneficiary health outcomes due to the prevalence of opioid and substance abuse disorders and evidence of CDS supporting improved outcomes and patient safety.[103] We proposed the weighting of this activity as high because it promotes interoperability and addresses a public health emergency and may reduce preventable health conditions related to opioid abuse. High weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being, as explained in the CY 2017 Quality Payment Program final rule (81 FR 77194). We also refer readers to our clarifications regarding weighting at section III.I.3.h.(4) of this

[101] CDC Prescribing Guidelines resource at https://www.cdc.gov/drugoverdose/prescribing/guideline.html.
[102] Centers for Medicare & Medicaid "Meaningful Measures Framework" resource available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.
[103] Hummel, J. Office of the National Coordinator for Health Information Technology (2013) "Integrating Clinical Decision Support Tools into Ambulatory Care Workflows for Improved Outcomes and Patient Safety" at https://www.healthit.gov/sites/default/files/clinical-decision-support-0913.pdf.

	final rule. According to the CDC, about 63,000 people died in 2016 of a drug overdose, and well over half of them are attributed to opioids.[104] Additionally, according to the 2016 National Survey on Drug Use and Health (NSDUH), 11.8 million individuals ages 12 and older misused any opioid (that is, prescription and/or illicit opioid) and 11.5 million individuals misused prescription opioids. Of those who misused opioids, 2.1 million individuals meet the criteria for an opioid use disorder.[105] Since providing education regarding the risks of concurrent opioid and benzodiazepine use directly helps to addresses the opioid epidemic, and use of CDS addresses CMS's policy focus on Promoting Interoperability,[106] we believe this improvement activity meets our considerations for high-weighting.
Comments:	Several commenters supported the inclusion of this improvement activity. A couple commenters provided general support for new improvement activities that address the opioid crisis. Two commenters noted that the CDC Guideline for Prescribing Opioids for Chronic Pain are "for primary care physicians prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care," and that including this improvement activity may exacerbate a tendency for specialists to use the Guideline for patient populations for which it is not intended.
Response:	Clinicians may meet this improvement activity by appropriately adhering to the CDC Guideline for Prescribing Opioids for Chronic Care and should pick activities applicable to their clinical practice and patient population.
Final Action:	After consideration of the public comments received, we are finalizing this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PSPA_32**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support
Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must utilize the Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain[107] via clinical decision support (CDS). For CDS to be most effective, it needs to be built directly into the clinician workflow and support decision making on a specific patient at the point of care. Specific examples of how the guideline could be incorporated into a CDS workflow include, but are not limited to: electronic health record (EHR)-based prescribing prompts, order sets that require review of guidelines before prescriptions can be entered, and prompts requiring review of guidelines before a subsequent action can be taken in the record.
Weighting:	High

[104] Hedegaard, H., Warner, M., & Miniño, A. M. (2017). NCHS Data Brief No. 294. Center for Disease Control and Prevention National Center for Health Statistics. Available at https://www.cdc.gov/nchs/products/databriefs/db294.htm.

[105] Park-Lee, E., Lipari, R. N., Hedden, S. L., Kroutil, L. A., & Porter, J. D. (2017). Receipt of Services for Substance Use and Mental Health Issues among Adults: Results from the 2016 National Survey on Drug Use and Health. Substance Abuse and Mental Health Services Administration NSDUH Data Review. Available at https://www.samhsa.gov/data/sites/default/files/NSDUH-DR-FFR2-2016/NSDUH-DR-FFR2-2016.htm.

[106] Centers for Medicare & Medicaid Services "Promoting Interoperability (PI)" resource available at https://www.cms.gov/Regulations-andGuidance/Legislation/EHRIncentivePrograms/index.html?redirect=/ehrincentiveprograms/.

[107] CDC Prescribing Guidelines resource at https://www.cdc.gov/drugoverdose/prescribing/guideline.html.

TABLE B: Changes to Previously Adopted Improvement Activities for the MIPS CY 2019 Performance Period and Future Years

Current Improvement Activity	
Current Activity ID:	**IA_CC_10**
Current Subcategory:	Care Coordination
Current Activity Title:	Care transition documentation practice improvements
Current Activity Description:	Implementation of practices/processes for care transition that include documentation of how a MIPS eligible clinician or group carried out a patient-centered action plan for first 30 days following a discharge (for example, staff involved, phone calls conducted in support of transition, accompaniments, navigation actions, home visits, patient information access).
Current Weighting:	Medium
Proposed Changes and Rationale:	Addition of "…real time communication between PCP and consulting clinicians; PCP included on specialist follow-up or transition communications" as additional examples of how a patient-centered action plan could be documented. Primary care physicians are considered the gatekeeper of patient care. Including them in communications from specialists to patients about their follow-up of transition-of-care promotes continuity between clinicians. Adding this example to this improvement activity underscores the important role specialists play in care transition documentation practice improvement. Other language was revised for clarity.
Proposed Revised Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must document practices/processes for care transition with documentation of how a MIPS eligible clinician or group carried out an action plan for the patient with the patient's preferences in mind (that is, a "patient-centered" plan) during the first 30 days following a discharge. Examples of these practices/processes for care transition include: staff involved in the care transition; phone calls conducted in support of transition; accompaniments of patients to appointments or other navigation actions; home visits; patient information access to their medical records; real time communication between PCP and consulting clinicians; PCP included on specialist follow-up or transition communications.
Comments:	One commenter supported the proposed modification to this improvement activity. One commenter stated that the addition of specialty-specific examples in the modified improvement activities will provide clarity for specialty clinicians. One commenter provided general concern that modifying an activity while it is still new makes it difficult for clinicians to become familiar with and implement activities. Another commenter requested we modify the activity description to explicitly state that this improvement activity applies to care transitions from acute care and rehabilitation facilities following a fracture, and includes follow-up care related to promoting mobility, reducing falls, and other related activities.
Response:	The proposed modifications to this activity provide examples for further clarification of the role specialists play in care transition documentation practice improvement. Therefore, we do not believe this modification makes it more difficult for clinicians to become familiar with and implement the activity. Additionally, we disagree that we should modify the activity description to explicitly state that this improvement activity applies to certain care transitions, for example those from acute care and rehabilitation facilities, because, we would like to keep the activity description broad. We believe specifying certain care settings without including all others may lead some clinicians to believe they are not eligible to attest to this improvement activity. We will add fracture-related care to subregulatory guidance available on the Quality Payment Program website[108] so clinicians attesting to this activity are aware this is an allowable service to meet this improvement activity.
Final Action:	After consideration of the public comments received, we are finalizing our changes to

[108] Improvement Activities Data Validation Criteria at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Resources.html.

	this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_CC_10**
Subcategory:	Care Coordination
Activity Title:	Care transition documentation practice improvements
Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must document practices/processes for care transition with documentation of how a MIPS eligible clinician or group carried out an action plan for the patient with the patient's preferences in mind (that is, a "patient-centered" plan) during the first 30 days following a discharge. Examples of these practices/processes for care transition include: staff involved in the care transition; phone calls conducted in support of transition; accompaniments of patients to appointments or other navigation actions; home visits; patient information access to their medical records; real time communication between PCP and consulting clinicians; PCP included on specialist follow-up or transition communications.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_PM_9**
Current Subcategory:	Population Management
Current Activity Title:	Participation in Population Health Research
Current Activity Description:	Participation in research that identifies interventions, tools or processes that can improve a targeted patient population.
Current Weighting:	Medium
Proposed Change and Rationale:	We proposed to remove PM_9, because we believe IA_PM_9 and IA_PM_17 are duplicative and provide improvement activity credit for the same activity. In the CY 2017 Quality Payment Program final rule (81 FR 77820), we finalized IA_PM_9: Participation in Population Health Research (activity title); Participation in research that identifies interventions, tools or processes that can improve a targeted patient population (activity description). In the CY 2018 Quality Payment Program final rule (82 FR 54481), we finalized IA_PM_17: Participation in Population Health Research (activity title); participation in federally and/or privately funded research that identifies interventions tools, or processes that can improve a targeted patient population (activity description). We believe IA_PM_9 and IA_PM_17 are duplicative because they include the same subcategory and activity title, and nearly an identical description of the activity; participation in "research that identifies interventions, tools, or processes that can improve a targeted patient population." The two activities are only distinguished by the inclusion in the description for IA_PM_17 specifying that clinicians can meet this activity through participation in federally and/or privately funded research that IA_PM_9 does not. Therefore, we proposed to remove IA_PM_9 and preserve IA_PM_17 so that we will have a consolidated activity that encompasses both improvement activities.
Comments:	Several commenters supported the removal of this improvement activity, due to it being duplicative to IA_PM_17 with the only difference being IA_PM_17 stating that this activity can be met through participation in federally and/or privately funded research. One commenter expressed concern that removing an improvement activity while it is still new makes it difficult for clinicians to become familiar with and implement improvement activities. An additional commenter recommended that if an improvement activity is removed from the Inventory it should be replaced by another improvement activity applicable to clinicians who could attest to the removed one.
Response:	We believe that while consistency in available improvement activities is important, it is confusing to have nearly identical activities that clinicians can attest to. Since these improvement activities are duplicative, a clinician may report IA_PM_17 in the place of IA_PM_9. We do not believe this change will make it more difficult for clinicians to become familiar with or implement improvement activities. Additionally, we do not believe it is necessary to add a new improvement activity to replace one that is being

	removed. We refer readers to section III.I.3.h.(d)(i) of this final rule where we discuss our criteria for nominating new improvement activities. We also clarified that we use the criteria for nominating new improvement activities in selecting improvement activities for inclusion in the program. Stakeholders can propose new activities through our Annual Call for Activities.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_PM_13**
Current Subcategory:	Population Management
Current Activity Title:	Chronic Care and Preventative Care Management for Empaneled Patients
Current Activity Description:	Proactively manage chronic and preventive care for empaneled patients that could include one or more of the following: ● Provide patients annually with an opportunity for development and/or adjustment of an individualized plan of care as appropriate to age and health status, including health risk appraisal; gender, age and condition-specific preventive care services; and plan of care for chronic conditions; ● Use condition-specific pathways for care of chronic conditions (for example, hypertension, diabetes, depression, asthma and heart failure) with evidence-based protocols to guide treatment to target; such as a CDC-recognized diabetes prevention program; ● Use pre-visit planning to optimize preventive care and team management of patients with chronic conditions; ● Use panel support tools (registry functionality) to identify services due; ● Use predictive analytical models to predict risk, onset and progression of chronic diseases; or ● Use reminders and outreach (for example, phone calls, emails, postcards, patient portals and community health workers where available) to alert and educate patients about services due; and/or routine medication reconciliation.
Current Weighting:	Medium
Proposed Change and Rationale:	Addition of examples of evidence based, condition-specific pathways for care of chronic conditions: "These might include, but are not limited to, the NCQA Diabetes Recognition Program (DRP) and the NCQA Heart/Stroke Recognition Program (HSRP)." These examples relating to diabetes, heart, and stroke pathways are examples of evidence based, condition-specific pathways for care of chronic conditions. These additions to this activity provide specialist-specific examples of actions that can be taken to meet the intent of this activity. We have received stakeholder feedback that additional specialty-specific activities would be welcome in the improvement activities inventory. Other language was revised for clarity.
Proposed Revised	Chronic Care and Preventative Care Management for Empaneled Patients In order to receive credit for this activity, a MIPS eligible clinician must manage chronic and preventive care for empaneled patients (that is, patients assigned to care teams for the purpose of population health management), which could include one or more of the following actions: ● Provide patients annually with an opportunity for development and/or adjustment of an individualized plan of care as appropriate to age and health status, including health risk appraisal; gender, age and condition-specific preventive care services; and plan of care for chronic conditions; ● Use evidence based, condition-specific pathways for care of chronic conditions (for

	example, hypertension, diabetes, depression, asthma, and heart failure). These might include, but are not limited to, the NCQA Diabetes Recognition Program (DRP) [109] and the NCQA Heart/Stroke Recognition Program (HSRP). [110] ● Use pre-visit planning, that is, preparations for conversations or actions to propose with patient before an in-office visit to optimize preventive care and team management of patients with chronic conditions; ● Use panel support tools, (that is, registry functionality) or other technology that can use clinical data to identify trends or data points in patient records to identify services due; ● Use predictive analytical models to predict risk, onset and progression of chronic diseases; and/or ● Use reminders and outreach (for example, phone calls, emails, postcards, patient portals, and community health workers where available) to alert and educate patients about services due; and/or routine medication reconciliation.
Comments:	Several commenters supported the proposed modifications to this improvement activity. One commenter stated that the addition of specialty-specific examples in the modified improvement activities will provide clarity for specialty clinicians. Another commenter recommended additional diabetes-related services, Diabetes Self Management Education and Support (DSME/S) services and Medical Nutrition Therapy (MNT), be included in the description as examples of appropriate services to be included in an individualized plan of care for patients with diabetes. One commenter provided general concern that modifying an activity while it is still new makes it difficult for clinicians to become familiar with and implement improvement activities.
Response:	The proposed modifications to this activity provide additional examples specialists may take to meet this activity. Therefore, we do not believe this modification makes it more difficult for clinicians to become familiar with and implement the activity. Additional diabetes-related services may be eligible for this improvement activity if they are part of a clinician's management of chronic and preventive care for empaneled patients. It is important to note that the examples provided in the description of the improvement activity are not all inclusive and do not preclude clinicians from providing other services to meet this improvement activity. We want this activity to be applicable to all MIPS eligible clinicians providing chronic care and preventative care management to empaneled patients, and since we cannot include all possible activities that could meet this improvement activity and one diabetes-related example is already included, we do not believe adding additional diabetes-related examples to the activity description assists in making the improvement activity applicable to a wide array of clinicians. Upon review of the evidence for DSME/S services and MNT, those examples will be added to the subregulatory guidance available on the Quality Payment Program website [111] for the improvement activity.
Final Action:	After consideration of the public comments received, we are finalizing our changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PM_13**
Subcategory:	Population Management
Activity Title:	Chronic Care and Preventative Care Management for Empaneled Patients
Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must manage chronic and preventive care for empaneled patients (that is, patients assigned to care teams for the purpose of population health management), which could include one or

[109] Diabetes Recognition Program information at http://www.ncqa.org/programs/recognition/clinicians/diabetes-recognition-program-drp.
[110] NCQA Heart/Stroke Recognition Program information at http://www.ncqa.org/programs/recognition/clinicians/heart-stroke-recognition-program-hsrp.
[111] Improvement Activity Data Validation Criteria at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Resources.html.

	more of the following actions: ● Provide patients annually with an opportunity for development and/or adjustment of an individualized plan of care as appropriate to age and health status, including health risk appraisal; gender, age and condition-specific preventive care services; and plan of care for chronic conditions; ● Use evidence based, condition-specific pathways for care of chronic conditions (for example, hypertension, diabetes, depression, asthma, and heart failure). These might include, but are not limited to, the NCQA Diabetes Recognition Program (DRP)[112] and the NCQA Heart/Stroke Recognition Program (HSRP).[113] ● Use pre-visit planning, that is, preparations for conversations or actions to propose with patient before an in-office visit to optimize preventive care and team management of patients with chronic conditions; ● Use panel support tools, (that is, registry functionality) or other technology that can use clinical data to identify trends or data points in patient records to identify services due; ● Use predictive analytical models to predict risk, onset and progression of chronic diseases; and/or ● Use reminders and outreach (for example, phone calls, emails, postcards, patient portals, and community health workers where available) to alert and educate patients about services due; and/or routine medication reconciliation.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_2**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Participation in MOC Part IV
Current Activity Description:	Participation in Maintenance of Certification (MOC) Part IV, such as the American Board of Internal Medicine (ABIM) Approved Quality Improvement (AQI) Program, National Cardiovascular Data Registry (NCDR) Clinical Quality Coach, Quality Practice Initiative Certification Program, American Board of Medical Specialties Practice Performance Improvement Module or American Society of Anesthesiologists (ASA) Simulation Education Network, for improving professional practice including participation in a local, regional or national outcomes registry or quality assessment program. Performance of monthly activities across practice to regularly assess performance in practice, by reviewing outcomes addressing identified areas for improvement and evaluating the results.
Current Weighting:	Medium
Proposed Change and Rationale:	Added two examples of ways in which a MIPS eligible clinician can participate in Maintenance of Certification (MOC) Part IV: participation in "specialty-specific activities including Safety Certification in Outpatient Practice Excellence (SCOPE);"[114] and "American Psychiatric Association (APA) Performance in Practice modules."[115] These additions to the activity provide specialist-specific examples of actions that can be taken to meet this activity. We have received stakeholder feedback through listening sessions and meetings with various stakeholder entities that additional specialty-specific activities would be welcome in the Inventory. Specifically, adding these examples of activities in psychiatry and obstetrics and gynecology, respectively, fill a gap in the

[112] Diabetes Recognition Program information at http://www.ncqa.org/programs/recognition/clinicians/diabetes-recognition-program-drp.
[113] NCQA Heart/Stroke Recognition Program information at http://www.ncqa.org/programs/recognition/clinicians/heart-stroke-recognition-program-hsrp.
[114] Safety Certification in Outpatient Practice Excellence for Women's Health resource at https://psnet.ahrq.gov/resources/resource/24964/acog-scope-safety-certification-in-outpatient-practice-excellence-for-womens-health.
[115] Certification and Licensure in Psychiatry, for ABMS Maintenance of Certification Part IV resource at https://www.psychiatry.org/psychiatrists/education/certification-and-licensure/moc-part-4.

	Inventory. Other language was revised for clarity.
Proposed Revised Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must participate in Maintenance of Certification (MOC) Part IV.[116] MOC Part IV requires clinicians to perform monthly activities across practice to regularly assess performance by reviewing outcomes addressing identified areas for improvement and evaluating the results. Some examples of activities that can be completed to receive MOC Part IV credit are: the American Board of Internal Medicine (ABIM) Approved Quality Improvement (AQI) Program,[117] National Cardiovascular Data Registry (NCDR) Clinical Quality Coach,[118] Quality Practice Initiative Certification Program,[119] American Board of Medical Specialties Practice Performance Improvement Module[120] or American Society of Anesthesiologists (ASA) Simulation Education Network,[121] for improving professional practice including participation in a local, regional or national outcomes registry or quality assessment program; specialty-specific activities including Safety Certification in Outpatient Practice Excellence (SCOPE);[122] American Psychiatric Association (APA) Performance in Practice modules.[123]
Comments:	One commenter supported the proposed modifications to this improvement activity. Another commenter stated that the addition of specialty-specific examples in the modified improvement activities will provide clarity for specialty clinicians. A few commenters supported the addition of the specialist examples for this improvement activity, and one commenter provided general concern that modifying an activity while it is still new makes it difficult for clinicians to become familiar with and implement improvement activities. An additional commenter requested the inclusion of a reference to specific practice activities related to comprehensive pediatric eye and vision examination clinical practice guidelines to meet this improvement activity.
Response:	The proposed modifications to this improvement activity provide additional examples of activities that can be completed to receive MOC Part IV credit. Therefore, we do not believe this modification makes it more difficult for clinicians to become familiar with and implement the activity. We appreciate the recommendation to include an additional example related to eye examinations, but we have included several examples and do not believe an additional example is needed in the activity description to describe the various ways clinicians can meet this improvement activity. We will add the American Board of Optometry's Performance in Practice activities, within which the comprehensive pediatric eye and vision examination clinical practice guidelines falls, to the subregulatory guidance available on the Quality Payment Program website [124] so

[116] American Board of Medical Specialties Maintenance of Certification Part IV resource at http://www.abms.org/board-certification/steps-toward-initial-certification-and-moc/.
[117] American Board of Internal Medicine Approved Quality Improvement Program resource at http://www.abim.org/reference-pages/approved-activities.aspx.
[118] American College of Cardiology National Cardiovascular Data Registry Clinical Quality Coach Practice Dashboard resource at https://cvquality.acc.org/NCDR-Home/clinical-quality-coach/marketing.
[119] American Society of Clinical Oncology Quality Oncology Practice Initiative Certification Program resource at https://practice.asco.org/quality-improvement/quality-programs/qopi-certification-program.
[120] American Board of Medical Specialties Multi-Specialty Portfolio Program resource at https://mocportfolioprogram.org/about-us/.
[121] American Society of Anesthesiologists Simulation Education Network resource at https://www.asahq.org/education/simulation-education.
[122] American College of Obstetricians and Gynecologists Safety Certification in Outpatient Practice Excellence for Women's Health resource at https://www.acog.org/About-ACOG/ACOG-Departments/VRQC-and-SCOPE/SCOPE-Program-Overview.
[123] American Psychiatric Association Learning Center resource at https://education.psychiatry.org/Users/ProductList.aspx?TypeID=8.
[124] Improvement Activities Data Validation Criteria at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Resources.html.

	clinicians attesting to this activity are aware these are allowable services to meet this improvement activity.
Final Action:	After consideration of the public comments received, we are finalizing our changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PSPA_2**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Participation in MOC Part IV
Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must participate in Maintenance of Certification (MOC) Part IV.[125] MOC Part IV requires clinicians to perform monthly activities across practice to regularly assess performance by reviewing outcomes addressing identified areas for improvement and evaluating the results. Some examples of activities that can be completed to receive MOC Part IV credit are: the American Board of Internal Medicine (ABIM) Approved Quality Improvement (AQI) Program,[126] National Cardiovascular Data Registry (NCDR) Clinical Quality Coach,[127] Quality Practice Initiative Certification Program,[128] American Board of Medical Specialties Practice Performance Improvement Module[129] or American Society of Anesthesiologists (ASA) Simulation Education Network,[130] for improving professional practice including participation in a local, regional or national outcomes registry or quality assessment program; specialty-specific activities including Safety Certification in Outpatient Practice Excellence (SCOPE);[131] American Psychiatric Association (APA) Performance in Practice modules.[132]
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_8**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Use of Patient Safety Tools
Current Activity Description:	Use of tools that assist specialty practices in tracking specific measures that are meaningful to their practice, such as use of a surgical risk calculator, evidence based protocols such as Enhanced Recovery After Surgery (ERAS) protocols, the CDC Guide for Infection Prevention for Outpatient Settings, (https://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html), predictive algorithms, or similar tools.
Current Weighting:	Medium
Proposed Change and	Addition of "opiate risk tool (ORT), or other similar tools" as an additional

[125] American Board of Medical Specialties Maintenance of Certification Part IV resource at http://www.abms.org/board-certification/steps-toward-initial-certification-and-moc/.
[126] American Board of Internal Medicine Approved Quality Improvement Program resource at http://www.abim.org/reference-pages/approved-activities.aspx.
[127] American College of Cardiology National Cardiovascular Data Registry Clinical Quality Coach Practice Dashboard resource at https://cvquality.acc.org/NCDR-Home/clinical-quality-coach/marketing.
[128] American Society of Clinical Oncology Quality Oncology Practice Initiative Certification Program resource at https://practice.asco.org/quality-improvement/quality-programs/qopi-certification-program.
[129] American Board of Medical Specialties Multi-Specialty Portfolio Program resource at https://mocportfolioprogram.org/about-us/.
[130] American Society of Anesthesiologists Simulation Education Network resource at https://www.asahq.org/education/simulation-education.
[131] American College of Obstetricians and Gynecologists Safety Certification in Outpatient Practice Excellence for Women's Health resource at https://www.acog.org/About-ACOG/ACOG-Departments/VRQC-and-SCOPE/SCOPE-Program-Overview.
[132] American Psychiatric Association Learning Center resource at https://education.psychiatry.org/Users/ProductList.aspx?TypeID=8.

Rationale:	example/category of an action that can be undertaken to meet the requirements of this activity. This addition highlights an evidence-based tool that can be deployed to assess opiate risk and addresses the CMS Meaningful Measures area of Prevention and Treatment of Opioid and Substance Use Disorders.[133] Other language was revised for clarity.
Proposed Revised Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must use tools that assist specialty practices in tracking specific measures that are meaningful to their practice. Some examples of tools that could satisfy this activity are: a surgical risk calculator; evidence based protocols, such as Enhanced Recovery After Surgery (ERAS) protocols;[134] the Centers for Disease Control (CDC) Guide for Infection Prevention for Outpatient Settings predictive algorithms;[135] and the opiate risk tool (ORT)[136] or similar tool.
Comments:	One commenter stated that the addition of specialty-specific examples in the modified improvement activities will provide clarity for specialty clinicians. A couple of commenters provided support for the addition of the opiate risk tool or other similar tools as a way of addressing the opioid crisis. One commenter provided general concern that modifying an activity while it is still new makes it difficult for clinicians to become familiar with and implement improvement activities.
Response:	The proposed modification to this improvement activity provides an additional tool as an example that can be undertaken to meet the requirements of this improvement activity. Therefore, we do not believe this modification makes it more difficult for clinicians to become familiar with and implement the activity.
Final Action:	After consideration of the public comments received, we are finalizing our changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PSPA_8**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Use of Patient Safety Tools
Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must use tools that assist specialty practices in tracking specific measures that are meaningful to their practice. Some examples of tools that could satisfy this activity are: a surgical risk calculator; evidence based protocols, such as Enhanced Recovery After Surgery (ERAS) protocols;[137] the Centers for Disease Control (CDC) Guide for Infection Prevention for Outpatient Settings predictive algorithms;[138] and the opiate risk tool (ORT)[139] or similar tool.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_17**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Implementation of analytic capabilities to manage total cost of care for practice population

[133] Centers for Medicare & Medicaid Services "Meaningful Measures Hub" resource at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html #MeasureAreasDefined.
[134] Enhanced Recovery After Surgery (ERAS) protocols at http://aserhq.org/protocols/.
[135] The Centers for Disease Control (CDC) Guide for Infection Prevention for Outpatient Settings at https://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html.
[136] The Opiate Risk Tool at https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf.
[137] Enhanced Recovery After Surgery (ERAS) protocols at http://aserhq.org/protocols/.
[138] The Centers for Disease Control (CDC) Guide for Infection Prevention for Outpatient Settings at https://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html.
[139] The Opiate Risk Tool at https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf.

Current Activity Description:	Build the analytic capability required to manage total cost of care for the practice population that could include one or more of the following: ● Train appropriate staff on interpretation of cost and utilization information; and/or ● Use available data regularly to analyze opportunities to reduce cost through improved care.
Current Weighting:	Medium
Proposed Change and Rationale:	We added an example platform that uses available data to analyze opportunities to reduce cost through improved care: "An example of a platform with the necessary analytic capability is the American Society for Gastrointestinal (GI) Endoscopy's GI Operations Benchmarking Platform."[140] Based on stakeholder feedback, we proposed to add this example to clarify what type of a platform has the analytic capability to improve and manage total cost of care for the practice population described. Other language was revised for clarity.
Proposed Revised Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must conduct or build the capacity to conduct analytic activities to manage total cost of care for the practice population. Examples of these activities could include: ● Train appropriate staff on interpretation of cost and utilization information; ● Use available data regularly to analyze opportunities to reduce cost through improved care. An example of a platform with the necessary analytic capability to do this is the American Society for Gastrointestinal (GI) Endoscopy's GI Operations Benchmarking Platform.
Comments:	One commenter supported the modification of this improvement activity. Another commenter stated that the addition of specialty-specific examples in the modified improvement activities will provide clarity for specialty clinicians. One commenter provided general concern that modifying an improvement activity while it is still new makes it difficult for clinicians to become familiar with and implement improvement activities. One commenter suggested including Fracture Liaison Service (FLS) programs as an example of a model to manage fracture recovery and risk.
Response:	We appreciate the commenters' support and the additional suggested example to provide greater clarification for this improvement activity. The modifications to this activity provide an example to clarify the type of platform that has the analytic capability to improve and manage total cost of care for the practice population described. Therefore, we do not believe this modification makes it more difficult for clinicians to become familiar with and implement the activity. We do not believe the FLS program meets the requirements of this improvement activity, as we do not agree that it provides analytic capability to manage population cost of care.
Final Action:	After consideration of the public comments received, we are finalizing our changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PSPA_17**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Implementation of analytic capabilities to manage total cost of care for practice population
Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must conduct or build the capacity to conduct analytic activities to manage total cost of care for the practice population. Examples of these activities could include: ● Train appropriate staff on interpretation of cost and utilization information; ● Use available data regularly to analyze opportunities to reduce cost through improved care. An example of a platform with the necessary analytic capability to do this is the American Society for Gastrointestinal (GI) Endoscopy's GI Operations Benchmarking Platform.
Weighting:	Medium

[140] American Society for Gastrointestinal Endoscopy GI Operations Benchmarking at https://www.asge.org/home/practice-support/gi-operations-benchmarking.

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Part III

Department of Justice

Antitrust Division

United States v. GS Caltex Corp. et al.; Proposed Final Judgments and Competitive Impact Statement; Notice

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. GS Caltex Corp. et al.; Proposed Final Judgments and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16(b)–(h), that proposed Final Judgments, Stipulations, and a Competitive Impact Statement have been filed with the United States District Court for the Southern District of Ohio in *United States* v. *GS Caltex et al.,* Case No. 2:18–cv–01456–ALM–CMV. On November 14, 2018, the United States filed a Complaint alleging that between 2005 and 2016, GS Caltex Corporation (''GS Caltex''), Hanjin Transportation Co., Ltd. (''Hanjin''), and SK Energy Co., Ltd. (''SK Energy''), along with unnamed co-conspirators, conspired to rig bids for Posts, Camps & Stations (PC&S) and Army and Air Force Exchange Service (AAFES) fuel supply contracts with the U.S. military in South Korea, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. A proposed Final Judgment for each Defendant, filed at the same time as the Complaint, requires GS Caltex, Hanjin, and SK Energy to pay the United States, respectively, $57,500,000, $6,182,000, and $90,384,872. In addition, each Defendant has agreed to cooperate with further civil investigative and judicial proceedings and to institute an antitrust compliance program.

Copies of the Complaint, proposed Final Judgments, and Competitive Impact Statement are available for inspection on the Antitrust Division's website at *http://www.justice.gov/atr* and at the Office of the Clerk of the United States District Court for the Southern District of Ohio. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, including the name of the submitter, and responses thereto, will be posted on the Antitrust Division's website, filed with the Court, and, under certain circumstances, published in the **Federal Register**. Comments should be directed to Kathleen S. O'Neill, Chief, Transportation, Energy & Agriculture Section, Antitrust Division, Department of Justice, 450 5th Street NW, Suite 8000, Washington, DC 20530.

Patricia A. Brink,

Director of Civil Enforcement.

United States District Court for the Southern District of Ohio Eastern Division

United States Of America, Plaintiff, v. *GS Caltex Corporation, GS Tower, 508, Nonhyeon-ro, Gangnam-gu, Seoul, South Korea*

Hanjin Transportation Co., Ltd., 20th Floor Hanjin New Bldg. 63, Namdaemun-ro, Jung-gu, Seoul, South Korea
and
SK Energy Co., Ltd., SK Bldg., 26, Jong-ro, Jongno-gu, Seoul, South Korea,
Defendants.

Case No. 2:18–cv–01456–ALM–CMV
Complaint: Violation of Section 1 of the Sherman Act, 15 U.S.C. § 1
Judge: Algenon L. Marbley

COMPLAINT

The United States of America, acting under the direction of the Acting Attorney General of the United States, brings this civil antitrust action to obtain equitable monetary relief and recover damages from GS Caltex Corporation, Hanjin Transportation Co., Ltd., and SK Energy Co., Ltd., for conspiring to rig bids and fix prices, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, on the supply of fuel to the U.S. military for its operations in South Korea.

I. INTRODUCTION

1. Since the end of the Korean War, the U.S. armed forces have maintained a significant presence in South Korea, protecting American interests in the region and safeguarding peace for the Korean people. To perform this important mission, American service members depend on fuel to power their bases and military vehicles. The U.S. military procures this fuel from oil refiners located in South Korea through a competitive bidding process.

2. For at least a decade, rather than engage in fair and honest competition, Defendants and their co-conspirators defrauded the U.S. military by fixing prices and rigging bids for the contracts to supply this fuel. Defendants met and communicated in secret with other large South Korean oil refiners and logistics companies, and pre-determined which conspirator would win each contract. Defendants and their co-conspirators then fraudulently submitted collusive bids to the U.S. military. Through this scheme, Defendants reaped vastly higher profit margins on the fuel they supplied to the U.S. military than on the fuel they sold to the South Korean military and to private parties.

3. As a result of this conduct, Defendants and their co-conspirators illegally overcharged American taxpayers by well over $100 million. This conspiracy unreasonably restrained trade and commerce, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. Defendants have agreed to plead guilty to an information charging a criminal violation of Section 1 of the Sherman Act for this unlawful conduct, and in this civil action, the United States seeks compensation for the injuries it incurred as a result of this conspiracy.

II. DEFENDANTS

4. GS Caltex Corporation (''GS Caltex'') is an oil company headquartered in Seoul, South Korea. GS Caltex is a joint venture between GS Energy, a South Korean corporation, and Chevron Corp., a Delaware corporation; each owns a 50 percent interest in GS Caltex. GS Caltex refines and supplies gasoline, diesel, kerosene, and other petroleum products for sale internationally. During the conspiracy, GS Caltex supplied fuel to U.S. military installations in South Korea.

5. Hanjin Transportation Co., Ltd. (''Hanjin'') is a global transportation and logistics company based in Seoul, South Korea. Hanjin is a member of Hanjin Group, a South Korean conglomerate with U.S. subsidiaries, including Hanjin International America. Beginning in 2009, Hanjin partnered with oil companies, including a co-conspirator oil company (''Company A''), to supply fuel to U.S. military installations in South Korea.

6. SK Energy Co., Ltd. (''SK Energy'') is an oil company headquartered in Seoul, South Korea. SK Energy is a wholly-owned subsidiary of SK Innovation Co., Ltd., a South Korean company with U.S. subsidiaries, including SK Energy Americas Inc. SK Energy refines and supplies gasoline, diesel, kerosene, and other petroleum products for sale internationally. During the conspiracy, SK Energy supplied fuel to U.S. military installations in South Korea.

7. Other persons, not named as defendants in this action, participated as co-conspirators in the offense alleged in this Complaint and performed acts and made statements in furtherance thereof. These co-conspirators include, among others, a logistics firm (''Company B'') and an oil company (''Company C'') that jointly supplied fuel to the U.S. military.

8. Whenever this Complaint refers to any act, deed, or transaction of any

business entity, it means that the business entity engaged in the act, deed, or transaction by or through its officers, directors, employees, agents, or other representatives while they were actively engaged in the management, direction, control, or transaction of its business or affairs.

III. JURISDICTION AND VENUE

9. The United States brings this action under Section 4 of the Sherman Act, 15 U.S.C. § 4, and Section 4A of the Clayton Act, 15 U.S.C. § 15a, seeking equitable relief, including equitable monetary remedies, and damages from Defendants' violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

10. This Court has subject matter jurisdiction over this action under 15 U.S.C. §§ 4 and 15a and 28 U.S.C. §§ 1331 and 1337.

11. Defendants have consented to venue and personal jurisdiction in this district for the purpose of this Complaint.

12. Defendants entered into contracts with the U.S. military to supply and deliver fuel to U.S. military installations in South Korea. Under the terms of these contracts, Defendants agreed that the laws of the United States would govern all contractual disputes and that U.S. administrative bodies and courts would have exclusive jurisdiction to resolve all such disputes. To be eligible to enter into these contracts, Defendants registered in databases located in the United States. For certain contracts, Defendants submitted bids to U.S. Department of Defense offices in the United States. After being awarded these contracts, Defendants submitted invoices to and received payments from U.S. Department of Defense offices in Columbus, Ohio, which included use of wires and mails located in the United States.

13. Through its contracts with the U.S. military, Defendants' activities had a direct, substantial, and reasonably foreseeable effect on interstate commerce, import trade or commerce, and commerce with foreign nations. Defendants' conspiracy had a substantial and intended effect in the United States. Defendants caused U.S. Department of Defense agencies to pay non-competitive prices for the supply of fuel to U.S. military installations. Defendants also caused a U.S. Department of Defense agency located in the Southern District of Ohio to transfer U.S. dollars to their foreign bank accounts.

IV. BACKGROUND

14. From at least March 2005 and continuing until at least October 2016 (''the Relevant Period''), the U.S. military procured fuel for its installations in South Korea through competitive solicitation processes. Oil companies, either independently or in conjunction with a logistics company, submitted bids in response to these solicitations.

15. The conduct at issue relates to two types of contracts to supply fuel to the U.S. military for use in South Korea: Post, Camps, and Stations (''PC&S'') contracts and Army and Air Force Exchange Services (''AAFES'') contracts.

16. PC&S contracts are issued and administered by the Defense Logistics Agency (''DLA''), a combat support agency in the U.S. Department of Defense. DLA, formerly known as the Defense Energy Support Center, is headquartered in Fort Belvoir, Virginia. The fuel procured under PC&S contracts is used for military vehicles and to heat U.S. military buildings. During the Relevant Period, PC&S contracts ran for a term of three or four years. DLA issued PC&S solicitations listing the fuel requirements for installations across South Korea, with each delivery location identified by a separate line item. Bidders offered a price for each line item on which they chose to bid. DLA awarded contracts to the bidders offering the lowest price for each line item. The Defense Finance and Accounting Service (''DFAS''), a finance and accounting agency of the U.S. Department of Defense, wired payments to the PC&S contract awardees from its office in Columbus, Ohio.

17. AAFES is an agency of the Department of Defense headquartered in Dallas, Texas. AAFES operates official retail stores (known as ''exchanges'') on U.S. Army and Air Force installations worldwide, which U.S. military personnel and their families use to purchase everyday goods and services, including gasoline for use in their personal vehicles. AAFES procures fuel for these stores via contracts awarded through a competitive solicitation process. The term of AAFES contracts is typically two years, but may be extended for additional years. In 2008, AAFES issued a solicitation that listed the fuel requirements for installations in South Korea. Unlike DLA, AAFES awarded the entire 2008 contract to the bidder offering the lowest price across all the listed locations.

V. DEFENDANTS' UNLAWFUL CONDUCT

18. From at least March 2005 and continuing until at least October 2016, Defendants and their co-conspirators engaged in a series of meetings, telephone conversations, e-mails, and other communications to rig bids and fix prices for the supply of fuel to U.S. military installations in South Korea.

2006 PC&S and 2008 AAFES Contracts

19. GS Caltex, SK Energy, and Companies B and C conspired to rig bids and fix prices on the 2006 PC&S contracts, which were issued in response to solicitation SP0600–05–R–0063, supplemental solicitation SP0600–05–0063–0001, and their amendments. The term of the 2006 PC&S contracts covered the supply of fuel from February 2006 through July 2009.

20. Between early 2005 and mid-2006, GS Caltex, SK Energy, and other conspirators met multiple times and exchanged phone calls and e-mails to allocate the line items in the solicitations for the 2006 PC&S contracts. For each line item allocated to a different co-conspirator, the other conspirators agreed not to bid or to bid high enough to ensure that they would not win that item. Through these communications, these conspirators agreed to inflate their bids to produce higher profit margins. DLA awarded the 2006 PC&S line items according to the allocations made by the conspiracy.

21. As part of their discussions related to the 2006 PC&S contracts, GS Caltex and other conspirators agreed not to compete with SK Energy in bidding for the 2008 AAFES contract. In 2008, GS Caltex and other conspirators honored their agreement: GS Caltex bid significantly above the bid submitted by SK Energy for the AAFES contract, while Companies B and C declined to bid even after AAFES explicitly requested their participation in the bidding. The initial term of the 2008 AAFES contract ran from July 2008 to July 2010; the contract was later extended through July 2013. As envisioned by the conspiracy, AAFES awarded the 2008 contract to SK Energy.

2009 PC&S Contracts

22. Continuing their conspiracy, Defendants and other co-conspirators conspired to rig bids and fix prices for the 2009 PC&S contracts, which were issued in response to solicitation SP0600–08–R–0233. Hanjin and Company A joined the conspiracy for the purpose of bidding on the solicitation for the 2009 PC&S contracts. Hanjin and Company A partnered to bid jointly on the 2009 PC&S contracts, with Company A providing the fuel and Hanjin providing transportation and logistics. The term of the 2009 PC&S contracts covered the supply of fuel from October 2009 through August 2013.

23. Between late 2008 and mid-2009, Defendants and other co-conspirators met multiple times and exchanged phone calls and e-mails to allocate the line items in the solicitation for the 2009 PC&S contracts. As in 2006, these conspirators agreed to bid high so as to not win line items allocated to other co-conspirators. The original conspirators agreed to allocate to Hanjin and Company A certain line items that had previously been allocated to the original conspirators.

24. With one exception, DLA awarded the 2009 PC&S contracts in line with the allocations made by the Defendants and other co-conspirators. Companies B and C accidentally won one line item that the conspiracy had allocated to GS Caltex. To remedy this misallocation, Company B and GS Caltex agreed that GS Caltex, rather than Company C, would supply Company B with the fuel procured under this line item.

2013 PC&S Contracts

25. Similar to 2006 and 2009, Defendants and other co-conspirators conspired to rig bids and fix prices for the 2013 PC&S contracts, which were issued in response to solicitation SP0600–12–R–0332. The term of the 2013 PC&S Contract covered the supply of fuel from August 2013 through July 2016.

26. Defendants and other co-conspirators communicated via phone calls and e-mails to allocate and set the price for each line item in the solicitation for the 2013 PC&S contracts. Defendants and other co-conspirators believed that they had an agreement as to their bidding strategy and pricing for the 2013 PC&S contracts. As a result of this agreement, they bid higher prices than they would have in a competitive process.

27. However, Hanjin and Company A submitted bids for the 2013 PC&S contracts below the prices set by the other co-conspirators. Although lower than the pricing agreed upon by the conspirators, Hanjin and Company A still submitted bids above a competitive, non-collusive price, knowing that they would likely win the contracts because the other conspirators would bid even higher prices.

28. As a result of their bidding strategy, Hanjin and Company A jointly won nearly all the line items in the 2013 PC&S contracts. As in 2009, Company A was to provide the fuel for these line items, and Hanjin was to provide transportation and logistics. GS Caltex and other co-conspirators won a few, small line items; SK Energy won none. DLA made inflated payments under the 2013 PC&S contracts through October 2016.

29. After the award of the 2013 PC&S contracts, Hanjin, Company A, and GS Caltex reached an understanding that GS Caltex, rather than Company A, would supply Hanjin with fuel for certain line items. Under this side agreement, Hanjin paid a much lower price to GS Caltex for fuel than the price it previously had agreed to pay Company A to acquire fuel for those line items. However, the price that Hanjin paid to GS Caltex exceeded a competitive price for fuel.

VI. VIOLATIONS ALLEGED

30. The United States incorporates by reference the allegations in paragraphs 1 through 29.

31. The conduct of Defendants and their co-conspirators unreasonably restrained trade and harmed competition for the supply of fuel to the U.S. military in South Korea in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

32. The United States was injured as a result of the unlawful conduct because it paid more for the supply of fuel than it would have had the Defendants and their co-conspirators engaged in fair competition.

VIII. REQUEST FOR RELIEF

33. The United States requests that this Court:

(a) adjudge that Defendants' and their co-conspirators' conduct constitutes an unreasonable restraint of interstate commerce, import trade or commerce, and commerce with foreign nations in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1;

(b) award the United States damages to which it is entitled for the losses incurred as the result of Defendants' and their co-conspirators' conduct;

(c) award the United States equitable disgorgement of the ill-gotten gains obtained by Defendants;

(d) award the United States its costs of this action; and

(e) award the United States other relief that the Court deems just and proper.

Dated: November 14, 2018

Respectfully submitted,

FOR PLAINTIFF UNITED STATES OF AMERICA:

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Dated: November 14, 2018

Respectfully submitted,

FOR PLAINTIFF UNITED STATES OF AMERICA

Benjamin C. Glassman,
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By:

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United States District Court for the Southern District of Ohio Eastern Division

United States of America, Plaintiff, v. *GS Caltex Corporation, Defendant.*

Case No. 2:18–cv–01456–ALM–CMV

PROPOSED FINAL JUDGMENT AS TO DEFENDANT GS CALTEX CORPORATION

WHEREAS Plaintiff, United States of America, filed its Complaint on November 14, 2018, the United States and Defendant GS Caltex Corporation (''GS Caltex''), by their respective attorneys, have consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law;

WHEREAS, on such date as may be determined by the Court, GS Caltex will plead guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) (the ''Plea Agreement'') to an Information to be filed in *United States* v. *GS Caltex Corporation* [to be assigned] (S.D.Ohio) (the ''Criminal Action'') that will allege a violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, relating to the same events giving rise to the allegations described in the Complaint;

WHEREAS, this Final Judgment does not constitute any evidence against or admission by any party regarding any issue of fact or law;

NOW, THEREFORE, before the taking of any testimony and without trial or final adjudication of any issue of fact or law herein, and upon consent of the parties hereto, it is hereby ORDERED, ADJUDGED, AND DECREED:

I. JURISDICTION

This Court has jurisdiction of the subject matter of this action and each of the parties consenting hereto. The Complaint states a claim upon which relief may be granted to the United States against GS Caltex under Section 1 of the Sherman Act, 15 U.S.C. § 1.

II. APPLICABILITY

This Final Judgment applies to GS Caltex, as defined above, and all other persons in active concert or participation with any of them who receive actual notice of this Final Judgment by personal service or otherwise.

III. PAYMENT

GS Caltex shall pay to the United States within ten (10) business days of the entry of this Final Judgment the amount of fifty-seven million, five hundred thousand dollars ($57,500,000), less the amount paid (excluding any interest) pursuant to the settlement agreement attached hereto as Attachment 1, to satisfy all civil antitrust claims alleged against GS Caltex by the United States in the Complaint. Payment of the amount ordered hereby shall be made by wire transfer of funds or cashier's check. If the payment is made by wire transfer, GS Caltex shall contact Janie Ingalls of the Antitrust Division's Antitrust Documents Group at (202) 514–2481 for instructions before making the transfer. If the payment is made by cashier's check, the check shall be made payable to the United States Department of Justice and delivered to: Janie Ingalls, United States Department of Justice Antitrust Division, Antitrust Documents Group, 450 5th Street, NW, Suite 1024, Washington, D.C. 20530. In the event of a default in payment, interest at the rate of eighteen (18) percent per annum shall accrue thereon from the date of default to the date of payment.

IV. COOPERATION

GS Caltex shall cooperate fully with the United States regarding any matter about which GS Caltex has knowledge or information relating to any ongoing civil investigation, litigation, or other proceeding arising out of any ongoing federal investigation of the subject matter discussed in the Complaint (hereinafter, any such investigation, litigation, or proceeding shall be referred to as a ''Civil Federal Proceeding'').

The United States agrees that any cooperation provided in connection with the Plea Agreement and/or pursuant to the settlement agreement attached hereto as Attachment 1 will be considered cooperation for purposes of this Final Judgment, and the United States will use its reasonable best efforts, where appropriate, to coordinate any requests for cooperation in connection with the Civil Federal Proceeding with requests for cooperation in connection with the Plea Agreement and the settlement agreement attached hereto as Attachment 1, so as to avoid unnecessary duplication and expense.

GS Caltex's cooperation shall include, but not be limited to, the following:

(a) Upon request, completely and truthfully disclosing and producing, to the offices of the United States and at no expense to the United States, copies of all non-privileged information, documents, materials, and records in its possession (and for any foreign-language information, documents, materials, or records, copies must be produced with an English translation), regardless of their geographic location, about which the United States may inquire in connection with any Civil Federal Proceeding, including but not limited to all information about activities of GS Caltex and present and former officers, directors, employees, and agents of GS Caltex;

(b) Making available in the United States, at no expense to the United States, its present officers, directors, employees, and agents to provide information and/or testimony as requested by the United States in connection with any Civil Federal Proceeding, including the provision of testimony in trial and other judicial proceedings, as well as interviews with law enforcement authorities, consistent with the rights and privileges of those individuals;

(c) Using its best efforts to make available in the United States, at no expense to the United States, its former officers, directors, employees, and agents to provide information and/or testimony as requested by the United States in connection with any Civil Federal Proceeding, including the provision of testimony in trial and other judicial proceedings, as well as interviews with law enforcement authorities, consistent with the rights and privileges of those individuals;

(d) Providing testimony or information necessary to identify or establish the original location, authenticity, or other basis for admission into evidence of documents or physical evidence produced by GS Caltex in any Civil Federal Proceeding as requested by the United States; and

(e) Completely and truthfully responding to all other inquiries of the United States in connection with any Civil Federal Proceeding.

However, notwithstanding any provision of this Final Judgment, GS Caltex is not required to: (1) Request of its current or former officers, directors, employees, or agents that they forgo seeking the advice of an attorney nor that they act contrary to that advice; (2) take any action against its officers, directors, employees, or agents for following their attorney's advice; or (3) waive any claim of privilege or work product protection.

The obligations of GS Caltex to cooperate fully with the United States as described in this Section shall cease upon the conclusion of all Civil Federal Proceedings (which may include Civil Federal Proceedings related to the conduct of third parties), including exhaustion of all appeals or expiration of time for all appeals of any Court ruling in each such Civil Federal Proceeding, at which point the United States will provide written notice to GS Caltex that its obligations under this Section have expired.

V. ANTITRUST COMPLIANCE PROGRAM

A. Within thirty (30) days after entry of this Final Judgment, GS Caltex shall appoint an Antitrust Compliance Officer and identify to the United States his or her name, business address, telephone number, and email address. Within forty-five (45) days of a vacancy in the Antitrust Compliance Officer position, GS Caltex shall appoint a replacement, and shall identify to the United States the Antitrust Compliance Officer's name, business address, telephone number, and email address. GS Caltex's initial or replacement appointment of an Antitrust Compliance Officer is subject to the approval of the United States, in its sole discretion.

B. The Antitrust Compliance Officer shall institute an antitrust compliance program for the company's employees and directors with responsibility for bidding for any contract with the United States. The antitrust compliance program shall provide at least two hours of training annually on the antitrust laws of the United States, such training to be delivered by an attorney with

relevant experience in the field of United States antitrust law.

C. Each Antitrust Compliance Officer shall obtain, within six months after entry of this Final Judgment, and on an annual basis thereafter, on or before each anniversary of the entry of this Final Judgment, from each person subject to Paragraph V.B of this Final Judgment, and thereafter maintaining, a certification that each such person has received the required two hours of annual antitrust training.

D. Each Antitrust Compliance Officer shall communicate annually to all employees that they may disclose to the Antitrust Compliance Officer, without reprisal, information concerning any potential violation of the United States antitrust laws.

E. Each Antitrust Compliance Offer shall provide to the United States within six months after entry of this Final Judgment, and on an annual basis thereafter, on or before each anniversary of the entry of this Final Judgment, a written statement as to the fact and manner of GS Caltex's compliance with Section V of this Final Judgment.

VI. RETENTION OF JURISDICTION

This Court retains jurisdiction to enable any of the parties to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify or terminate any of its provisions, to enforce compliance, and to punish violations of its provisions.

VII. ENFORCEMENT OF FINAL JUDGMENT

A. The United States retains and reserves all rights to enforce the provisions of this Final Judgment, including the right to seek an order of contempt from the Court. GS Caltex agrees that in any civil contempt action, any motion to show cause, or any similar action brought by the United States regarding an alleged violation of this Final Judgment, the United States may establish a violation of the decree and the appropriateness of any remedy therefor by a preponderance of the evidence, and GS Caltex waives any argument that a different standard of proof should apply.

B. The Final Judgment should be interpreted to give full effect to the procompetitive purposes of the antitrust laws and to restore all competition the United States alleged was harmed by the challenged conduct. GS Caltex agrees that they may be held in contempt of, and that the Court may enforce, any provision of this Final Judgment that, as interpreted by the Court in light of these procompetitive principles and applying ordinary tools of interpretation, is stated specifically and in reasonable detail, whether or not it is clear and unambiguous on its face. In any such interpretation, the terms of this Final Judgment should not be construed against either party as the drafter.

C. In any enforcement proceeding in which the Court finds that GS Caltex has violated this Final Judgment, the United States may apply to the Court for a one-time extension of this Final Judgment, together with such other relief as may be appropriate. In connection with any successful effort by the United States to enforce this Final Judgment against GS Caltex, whether litigated or resolved prior to litigation, GS Caltex agrees to reimburse the United States for the fees and expenses of its attorneys, as well as any other costs including experts' fees, incurred in connection with that enforcement effort, including in the investigation of the potential violation.

VIII. EXPIRATION OF FINAL JUDGMENT

Unless this Court grants an extension, this Final Judgment shall expire seven (7) years from the date of its entry, except that after five (5) years from the date of its entry, this Final Judgment may be terminated upon notice by the United States to the Court and GS Caltex that the continuation of the Final Judgment no longer is necessary or in the public interest.

IX. PUBLIC INTEREST DETERMINATION

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16, including making copies available to the public of this Final Judgment, the Competitive Impact Statement, and any comments thereon and the United States' responses to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and response to comments filed with the Court, entry of this Final Judgment is in the public interest.

Dated: _____

_____

United States District Judge

ATTACHMENT 1

SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the Civil Division of the United States Department of Justice and the United States Attorney's Office for the Southern District of Ohio, on behalf of the Defense Logistics Agency (DLA) and the Army and Air Force Exchange Service (AAFES) (collectively the ''United States''), GS Caltex Corporation (GS Caltex), and Relator [REDACTED] (hereafter collectively referred to as ''the Parties''), through their authorized representatives.

RECITALS

A. GS Caltex is a South Korea-based energy company that produces various petroleum products that it sells to South Korean and international customers, including the United States Department of Defense (DoD).

B. On February 28, 2018, Relator, a resident and citizen of South Korea, filed a *qui tam* action in the United States District Court for the Southern District of Ohio captioned *United States ex rel. [REDACTED]* v. *GS Caltex, et al.,* Civil Action No. [REDACTED], pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the Civil FCA Action). Relator contends that GS Caltex conspired with other South Korean entities to rig bids on DoD contracts to supply fuel to U.S. military bases throughout South Korea beginning in 2005 and continuing until 2016, including DLA Post, Camps, and Stations contracts and/or contract amendments (''PC&S contracts'') executed in 2006, 2009, 2011, and 2013, and AAFES contracts executed in 2008.

C. On such date as may be determined by the Court, GS Caltex will plead guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) (the ''Plea Agreement'') to an Information to be filed in *United States* v. *GS Caltex Corporation,* Criminal Action No. [to be assigned] (S.D. Ohio) (the ''Criminal Action'') that will allege that GS Caltex participated in a combination and conspiracy beginning at least in or around March 2005 and continuing until at least in or around October 2016, to suppress and eliminate competition on certain contracts solicited by the DoD to supply ultra-low sulfur diesel and gasoline to numerous U.S. Army, Navy, Marine, and Air Force installations in Korea, known as PC&S contracts, in violation of the Sherman Antitrust Act, 15 U.S.C. § 1.

D. GS Caltex will execute a Stipulation with the Antitrust Division of the United States Department of Justice in which GS Caltex will consent to the entry of a Final Judgment to be filed in *United States* v. *GS Caltex Corporation,* Civil Action No. [to be assigned] (S.D. Ohio) (the Civil Antitrust Action) that will settle any and all civil antitrust claims of the United States

against GS Caltex arising from any act or offense committed before the date of the Stipulation that was undertaken in furtherance of an attempted or completed antitrust conspiracy involving PC&S and/or AAFES fuel supply contracts with the U.S. military in South Korea during the period 2005 through 2016.

E. The United States contends that it has certain civil claims against GS Caltex arising from a conspiracy with other South Korean entities to rig bids on DoD contracts to supply fuel to U.S. military bases throughout South Korea executed between 2005 and 2013, including DLA PC&S contracts and AAFES contracts, as well as the conduct described in the Plea Agreement in the Criminal Action. The conduct referenced in this Paragraph, as well as the conduct, actions, and claims alleged by Relator in the Civil FCA Action is referred to below as the Covered Conduct.

F. With the exception of any admissions that are made by GS Caltex in connection with the Plea Agreement in the Criminal Action, this Settlement Agreement is neither an admission of liability by GS Caltex nor a concession by the United States or Relator that their claims are not well founded.

G. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1.a. GS Caltex shall pay to the United States $42,621,000 (FCA Settlement Amount), of which $28,414,474 is restitution. Relator's right pursuant to 31 U.S.C. § 3730(d) to reasonable expenses, attorneys' fees and costs will be addressed separately by Relator, Relator's counsel and GS Caltex.

1.b. Interest at an annual rate of three (3) percent shall accrue on the FCA Settlement Amount beginning on the Effective Date of this Agreement and continuing until the date that both of the following events have occurred: (i) the Plea Agreement is accepted by the Court in the Criminal Action; and (ii) the proposed Final Judgment is entered by the Court in the Civil Antitrust Action (Accrued Interest).

1.c. The total FCA payment due from GS Caltex shall be the FCA Settlement Amount plus any Accrued Interest (Total FCA Settlement Amount). GS Caltex shall pay the Total FCA Settlement Amount by electronic funds transfer no later than seven (7) business days after both events identified above in Paragraph 1.b. have occurred (Payment Due Date). The Civil Division of the United States Department of Justice shall provide to counsel for GS Caltex written payment instructions and confirmation of the Total FCA Settlement Amount no later than five (5) business days before the Payment Due Date. If GS Caltex does not pay the Total FCA Settlement Amount on or before the Payment Due Date, interest at an annual rate of nine (9) percent shall accrue on the Total FCA Settlement Amount beginning on the first calendar day after the Payment Due Date and shall continue to accrue until paid.

1.d. If GS Caltex's Plea Agreement in the Criminal Action is not accepted by the Court or the Court does not enter the Final Judgment in the Civil Antitrust Action, this Agreement shall be null and void at the option of either the United States or GS Caltex. If either the United States or GS Caltex exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within five (5) business days of the Court's decision, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, GS Caltex will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims, actions or proceedings arising from the Covered Conduct that are brought by the United States within ninety (90) calendar days of rescission, except to the extent such defenses were available on the day on which Relator's *qui tam* complaint in the Civil FCA Action was filed.

2. Subject to the exceptions in Paragraph 3 (concerning excluded claims) below, and conditioned upon GS Caltex's full payment of the Total FCA Settlement Amount, the United States releases GS Caltex together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729–3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801–3812; Contract Disputes Act, 41 U.S.C. §§ 7101–7109; or the common law theories of breach of contract, payment by mistake, unjust enrichment, and fraud, or under any statute creating causes of action for civil damages or civil penalties which the Civil Division of the United States Department of Justice has authority to assert and compromise pursuant to 28 C.F.R. Part O, Subpart I, § 0.45(d).

3. Notwithstanding the release given in paragraph 2 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability, except to the extent detailed in the Plea Agreement;

c. Except as explicitly stated in this Agreement, any administrative liability, including the suspension and debarment rights of any federal agency;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability of individuals;

g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

h. Any liability for failure to deliver goods or services due; and

i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

4. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). The determination of Relator's share, if any, of the FCA Settlement Amount pursuant to 31 U.S.C. § 3730(d) is a matter that shall be handled separately by and between the Relator and the United States, without any direct involvement or input from GS Caltex. In connection with this Agreement and this Civil FCA Action, Relator, on behalf of himself and his heirs, successors, attorneys, agents, and assigns agrees that neither this Agreement, nor any intervention by the United States in the Civil FCA Action in order to dismiss the Civil FCA Action, nor any dismissal of the Civil FCA Action, shall waive or otherwise affect the ability of the United States to contend that provisions in the False Claims Act, including 31 U.S.C. § 3730(d)(3), bar Relator from sharing in the proceeds of this Agreement, except that the United States will not contend that Relator is barred from sharing in the proceeds of this Agreement pursuant to

31 U.S.C. § 3730(e)(4). Moreover, the United States and Relator, on behalf of himself and his heirs, successors, attorneys, agents, and assigns agree that they each retain all of their rights pursuant to the False Claims Act on the issue of the share percentage, if any, that Relator should receive of any proceeds of the settlement of his claims, and that no agreements concerning Relator share have been reached to date.

5. Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns, releases GS Caltex, together with its predecessors, successors, assigns, shareholders, subsidiaries, businesses, affiliates, divisions, sister companies, owners, directors, officers, agents, employees, and counsel, from any action, in law or in equity, suits, debts, liens, contracts, agreements, covenants, promises, liability, obligations, claims, demands, rights of subrogation, contribution and indemnity, damages, loss, cost or expenses, direct or indirect, of any kind or nature whatsoever (including without limitation any civil monetary claim Relator has on behalf of the United States for the Covered Conduct under the False Claims Act. 31 U.S.C. §§ 3729–3733), known or unknown, fixed or contingent, foreign (including Korean), state or federal, under common law, statute or regulation, liquidated or unliquidated, claimed or concealed, and without regard to the date of occurrence, which Relator ever had, now has, may assert, or may in the future claim to have, against GS Caltex by reason of any act, cause, matter, or thing whatsoever from the beginning of time to the date hereof. Relator represents and warrants that he and his counsel are the exclusive owner of the rights, claims, and causes of action herein released and none of them have previously assigned, reassigned, or transferred or purported to assign, reassign or transfer, through bankruptcy or by any other means, any or any portion of any claim, demand, action, cause of action, or other right released or discharged under this Agreement except between themselves and their counsel. Notwithstanding the foregoing, or any other terms of this Agreement, this Agreement does not resolve or release Relator's right pursuant to 31 U.S.C. § 3730(d) to reasonable expenses necessarily incurred, plus reasonable attorneys' fees and costs relating to the Covered Conduct, the amount of which will be addressed separately by Relator, Relator's counsel, and GS Caltex.

6. GS Caltex waives and shall not assert any defenses GS Caltex may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

7. GS Caltex fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that GS Caltex has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

8. GS Caltex, for itself and on behalf of its predecessors, successors, assigns, shareholders, subsidiaries, businesses, affiliates, divisions, sister companies, owners, directors, officers, agents, employees, and counsel, releases Relator, together with his heirs, successors, attorneys, agents, and assigns from any action, in law or in equity, suits, debts, liens, contracts, agreements, covenants, promises, liability, obligations, claims, demands, rights of subrogation, contribution and indemnity, damages, loss, cost or expenses, direct or indirect, of any kind or nature whatsoever, known or unknown, fixed or contingent, foreign (including Korean), state or federal, under common law, statute or regulation, liquidated or unliquidated, claimed or concealed, and without regard to the date of occurrence, which GS Caltex ever had, now has, may assert, or may in the future claim to have, against Relator by reason of any act, cause, matter, or thing whatsoever from the beginning of time to the date hereof. GS Caltex represents and warrants that it and its counsel are the exclusive owner of the rights, claims, and causes of action herein released and none of them have previously assigned, reassigned, or transferred or purported to assign, reassign or transfer, through bankruptcy or by any other means, any or any portion of any claim, demand, action, cause of action, or other right released or discharged under this Agreement except between themselves and their counsel. Notwithstanding the foregoing, or any other terms of this Agreement, this Agreement does not resolve or release GS Caltex's right pursuant to 31 U.S.C. § 3730(d) to assert defenses to Relator's claimed attorneys' fees, expenses, and costs relating to the Covered Conduct, the amount of which will be addressed separately by Relator, Relator's counsel, and GS Caltex.

9. a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205–47) incurred by or on behalf of GS Caltex, and its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement, any related plea agreement, and any related civil antitrust agreement;

(2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;

(3) GS Caltex's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);

(4) the negotiation and performance of this Agreement, any related plea agreement, and any related civil antitrust agreement;

(5) the payment GS Caltex makes to the United States pursuant to this Agreement and any payments that GS Caltex may make to Relator, including costs and attorneys' fees, are unallowable costs for government contracting purposes (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs will be separately determined and accounted for by GS Caltex, and GS Caltex shall not charge such Unallowable Costs directly or indirectly to any contract with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Agreement, GS Caltex shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs included in payments previously sought by GS Caltex or any of its subsidiaries or affiliates from the United States. GS Caltex agrees that the United States, at a minimum, shall be entitled to recoup from GS Caltex any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. The United States, including the Department of Justice and/or the affected agencies, reserves its rights to audit, examine, or re-examine GS Caltex's books and records and to disagree with any calculations submitted by GS Caltex or any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought

by GS Caltex, or the effect of any such Unallowable Costs on the amount of such payments.

10. GS Caltex agrees to cooperate fully and truthfully with the United States in connection with the Civil FCA Action. The Civil Division of the United States Department of Justice will use reasonable best efforts, where appropriate, to coordinate any requests for cooperation in connection with the Civil FCA Action with requests for cooperation in connection with the Plea Agreement in the Criminal Action and the Civil Antitrust Action, so as to avoid unnecessary duplication and expense. GS Caltex's ongoing, full, and truthful cooperation shall include, but not be limited to:

a. upon request by the United States with reasonable notice, producing at the offices of counsel for the United States in Washington, D.C. and not at the expense of the United States, complete and un-redacted copies of all non-privileged documents related to the Covered Conduct wherever located in GS Caltex's possession, custody, or control;

b. upon request by the United States with reasonable notice, making current GS Caltex directors, officers, and employees available for interviews, consistent with the rights and privileges of such individuals, by counsel for the United States and/or their investigative agents, not at the expense of the United States, in the United States or Hong Kong unless another place is mutually agreed upon;

c. upon request by the United States with reasonable notice, (i) using best efforts to assist in locating former GS Caltex directors, officers, and employees identified by attorneys and/or investigative agents of the United States, and (ii) using best efforts to make any such former GS Caltex directors, officers, and employees available for interviews, consistent with the rights and privileges of such individuals, by counsel for the United States and/or their investigative agents, not at the expense of the United States, in the United States or Hong Kong unless another place is mutually agreed upon; and

d. upon request by the United States with reasonable notice, making current GS Caltex directors, officers, and employees available, and using best efforts to make former GS Caltex directors, officers, employees available, to testify, consistent with the rights and privileges of such individuals, fully, truthfully, and under oath, without falsely implicating any person or withholding any information, (i) at depositions in the United States, Hong Kong, or any other mutually agreed upon place, (ii) at trial in the United States, and (iii) at any other judicial proceedings wherever located related to the Civil FCA Action.

11. This Agreement is intended to be for the benefit of the Parties only.

12. Upon receipt of the payment of the Total FCA Settlement Amount described in Paragraph 1.a-c., above, or receipt of the Total FCA Settlement Amount and any additional interest that accrues if GS Caltex does not pay on or before the Payment Due Date, the United States and Relator shall promptly sign and file a Joint Stipulation of Dismissal, with prejudice, of the claims filed against GS Caltex in the Civil FCA Action, pursuant to Rule 41(a)(1), which dismissal shall be conditioned on the Court retaining jurisdiction over Relator's claims to a relator's share and recovery of attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d).

13. Except as provided herein, each Party shall bear its own legal and other costs incurred in connection with this matter. The Parties agree that Relator and GS Caltex will not seek to recover from the United States any costs or fees related to the preparation and performance of this Agreement.

14. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

15. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Southern District of Ohio. GS Caltex agrees that the United States District Court for the Southern District of Ohio has jurisdiction over it for purposes of the Civil FCA Action. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

16. This Agreement constitutes the complete agreement between the Parties on the subject matters addressed herein. This Agreement may not be amended except by written consent of the Parties.

17. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

18. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

19. This Agreement is binding on GS Caltex's successors, transferees, heirs, and assigns.

20. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

21. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public, as permitted by order of the Court. This Agreement shall not be released in un-redacted form until the Court unseals the entire Civil FCA Action.

22. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Electronic copies of signatures shall constitute acceptable, binding signatures for purposes of this Agreement

The United States of America

Dated: _____

By: _____

Andrew A. Steinberg,
Trial Attorney, Commercial Litigation Branch, Civil Division, U.S. Department of Justice

Dated: _____

By: _____

Mark T. D'Alessandro,
Civil Chief
Andrew Malek,
Assistant United States Attorney, U.S. Attorney's Office for the Southern District of Ohio

GS Caltex Corporation—Defendant

Dated: _____

By: _____

Authorized Representative of GS Caltex Corporation

Dated: _____

By: _____

Marguerite M. Sullivan,
Latham & Watkins LLP

Scott D. Hammond, *Gibson, Dunn & Crutcher LLP, Counsel for GS Caltex Corporation*

[Redacted]—Relator

Dated: _____

By: _____

[redacted]

Dated: _____

By: _____

Eric Havian,
Constantine Cannon LLP, Counsel for Relator

United States District Court for the Southern District of Ohio Eastern Division

United States of America, Plaintiff, v. *Hanjin Transportation Co., Ltd.* Defendant.

Case No. 2:18–cv–01456–ALM–CMV

PROPOSED FINAL JUDGMENT AS TO DEFENDANT HANJIN TRANSPORTATION CO., LTD.

WHEREAS Plaintiff, United States of America, filed its Complaint on November 14, 2018, the United States and Defendant Hanjin Transportation Co., Ltd. (''Hanjin''), by their respective attorneys, have consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law;

WHEREAS, on such date as may be determined by the Court, Hanjin will plead guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) (the ''Plea Agreement'') to an Information to be filed in United States v. Hanjin Transportation Co., Ltd. [to be assigned] (S.D.Ohio) (the ''Criminal Action'') that will allege a violation of Section 1 of the Sherman Act, 15 U.S. C. § 1, relating to the same events giving rise to the allegations described in the Complaint;

WHEREAS, this Final Judgment does not constitute any evidence against or admission by any party regarding any issue of fact or law;

NOW, THEREFORE, before the taking of any testimony and without trial or final adjudication of any issue of fact or law herein, and upon consent of the parties hereto, it is hereby ORDERED, ADJUDGED, AND DECREED:

I. JURISDICTION

This Court has jurisdiction of the subject matter of this action and each of the parties consenting hereto. The Complaint states a claim upon which relief may be granted to the United States against Hanjin under Section 1 of the Sherman Act, 15 U.S.C. § 1.

II. APPLICABILITY

This Final Judgment applies to Hanjin, as defined above, and all other persons in active concert or participation with any of them who receive actual notice of this Final Judgment by personal service or otherwise.

III. PAYMENT

Hanjin shall pay to the United States within ten (10) business days of the entry of this Final Judgment the amount of six million, one hundred eighty-two thousand ($6,182,000), less the amount paid (excluding any interest) pursuant to the settlement agreement attached hereto as Attachment 1, to satisfy all civil antitrust claims alleged against Hanjin by the United States in the Complaint. Payment of the amount ordered hereby shall be made by wire transfer of funds or cashier's check. If the payment is made by wire transfer, Hanjin shall contact Janie Ingalls of the Antitrust Division's Antitrust Documents Group at (202) 514–2481 for instructions before making the transfer. If the payment is made by cashier's check, the check shall be made payable to the United States Department of Justice and delivered to: Janie Ingalls, United States Department of Justice Antitrust Division, Antitrust Documents Group, 450 5th Street, NW, Suite 1024, Washington, D.C. 20530. In the event of a default in payment, interest at the rate of eighteen (18) percent per annum shall accrue thereon from the date of default to the date of payment.

IV. COOPERATION

Hanjin shall cooperate fully with the United States regarding any matter about which Hanjin has knowledge or information relating to any ongoing civil investigation, litigation, or other proceeding arising out of any ongoing federal investigation of the subject matter discussed in the Complaint (hereinafter, any such investigation, litigation, or proceeding shall be referred to as a ''Civil Federal Proceeding'').

The United States agrees that any cooperation provided in connection with the Plea Agreement and/or pursuant to the settlement agreement attached hereto as Attachment 1 will be considered cooperation for purposes of this Final Judgment, and the United States will use its reasonable best efforts, where appropriate, to coordinate any requests for cooperation in connection with the Civil Federal Proceeding with requests for cooperation in connection with the Plea Agreement and the settlement agreement attached hereto as Attachment 1, so as to avoid unnecessary duplication and expense. Hanjin's cooperation shall include, but not be limited to, the following:

(a) Upon request, completely and truthfully disclosing and producing, to the offices of the United States and at no expense to the United States, copies of all non-privileged information, documents, materials, and records in its possession (and for any foreign-language information, documents, materials, or records, copies must be produced with an English translation), regardless of their geographic location, about which the United States may inquire in connection with any Civil Federal Proceeding, including but not limited to all information about activities of Hanjin and present and former officers, directors, employees, and agents of Hanjin;

(b) Making available in the United States, at no expense to the United States, its present officers, directors, employees, and agents to provide information and/or testimony as requested by the United States in connection with any Civil Federal Proceeding, including the provision of testimony in trial and other judicial proceedings, as well as interviews with law enforcement authorities, consistent with the rights and privileges of those individuals;

(c) Using its best efforts to make available in the United States, at no expense to the United States, its former officers, directors, employees, and agents to provide information and/or testimony as requested by the United States in connection with any Civil Federal Proceeding, including the provision of testimony in trial and other judicial proceedings, as well as interviews with law enforcement authorities, consistent with the rights and privileges of those individuals;

(d) Providing testimony or information necessary to identify or establish the original location, authenticity, or other basis for admission into evidence of documents or physical evidence produced by Hanjin in any Civil Federal Proceeding as requested by the United States; and

(e) Completely and truthfully responding to all other inquiries of the United States in connection with any Civil Federal Proceeding.

However, notwithstanding any provision of this Final Judgment, Hanjin is not required to: (1) request of its current or former officers, directors, employees, or agents that they forgo seeking the advice of an attorney nor that they act contrary to that advice; (2) take any action against its officers, directors, employees, or agents for following their attorney's advice; or (3) waive any claim of privilege or work product protection.

The obligations of Hanjin to cooperate fully with the United States as described in this Section shall cease upon the conclusion of all Civil Federal Proceedings (which may include Civil Federal Proceedings related to the conduct of third parties), including exhaustion of all appeals or expiration of time for all appeals of any Court ruling in each such Civil Federal Proceeding, at which point the United States will provide written notice to Hanjin that its obligations under this Section have expired.

V. ANTITRUST COMPLIANCE PROGRAM

A. Within thirty (30) days after entry of this Final Judgment, Hanjin shall appoint an Antitrust Compliance Officer and identify to the United States his or her name, business address, telephone number, and email address. Within

forty-five (45) days of a vacancy in the Antitrust Compliance Officer position, Hanjin shall appoint a replacement, and shall identify to the United States the Antitrust Compliance Officer's name, business address, telephone number, and email address. Hanjin's initial or replacement appointment of an Antitrust Compliance Officer is subject to the approval of the United States, in its sole discretion.

B. The Antitrust Compliance Officer shall institute an antitrust compliance program for the company's employees and directors with responsibility for bidding for any contract with the United States. The antitrust compliance program shall provide at least two hours of training annually on the antitrust laws of the United States, such training to be delivered by an attorney with relevant experience in the field of United States antitrust law.

C. Each Antitrust Compliance Officer shall obtain, within six months after entry of this Final Judgment, and on an annual basis thereafter, on or before each anniversary of the entry of this Final Judgment, from each person subject to Paragraph V.B of this Final Judgment, and thereafter maintaining, a certification that each such person has received the required two hours of annual antitrust training.

D. Each Antitrust Compliance Officer shall communicate annually to all employees that they may disclose to the Antitrust Compliance Officer, without reprisal, information concerning any potential violation of the United States antitrust laws.

E. Each Antitrust Compliance Offer shall provide to the United States within six months after entry of this Final Judgment, and on an annual basis thereafter, on or before each anniversary of the entry of this Final Judgment, a written statement as to the fact and manner of Hanjin's compliance with Section V of this Final Judgment.

VI. RETENTION OF JURISDICTION

This Court retains jurisdiction to enable any of the parties to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify or terminate any of its provisions, to enforce compliance, and to punish violations of its provisions.

VII. ENFORCEMENT OF FINAL JUDGMENT

A. The United States retains and reserves all rights to enforce the provisions of this Final Judgment, including the right to seek an order of contempt from the Court. Hanjin agrees that in any civil contempt action, any motion to show cause, or any similar action brought by the United States regarding an alleged violation of this Final Judgment, the United States may establish a violation of the decree and the appropriateness of any remedy therefor by a preponderance of the evidence, and Hanjin waives any argument that a different standard of proof should apply.

B. The Final Judgment should be interpreted to give full effect to the procompetitive purposes of the antitrust laws and to restore all competition the United States alleged was harmed by the challenged conduct. Hanjin agrees that they may be held in contempt of, and that the Court may enforce, any provision of this Final Judgment that, as interpreted by the Court in light of these procompetitive principles and applying ordinary tools of interpretation, is stated specifically and in reasonable detail, whether or not it is clear and unambiguous on its face. In any such interpretation, the terms of this Final Judgment should not be construed against either party as the drafter.

C. In any enforcement proceeding in which the Court finds that Hanjin has violated this Final Judgment, the United States may apply to the Court for a one-time extension of this Final Judgment, together with such other relief as may be appropriate. In connection with any successful effort by the United States to enforce this Final Judgment against Hanjin, whether litigated or resolved prior to litigation, Hanjin agrees to reimburse the United States for the fees and expenses of its attorneys, as well as any other costs including experts' fees, incurred in connection with that enforcement effort, including in the investigation of the potential violation.

VIII. EXPIRATION OF FINAL JUDGMENT

Unless this Court grants an extension, this Final Judgment shall expire seven (7) years from the date of its entry, except that after five (5) years from the date of its entry, this Final Judgment may be terminated upon notice by the United States to the Court and Hanjin that the continuation of the Final Judgment no longer is necessary or in the public interest.

IX. PUBLIC INTEREST DETERMINATION

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16, including making copies available to the public of this Final Judgment, the Competitive Impact Statement, and any comments thereon and the United States' responses to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and response to comments filed with the Court, entry of this Final Judgment is in the public interest.

Dated: _____

_____

United States District Judge

ATTACHMENT 1

SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the Civil Division of the United States Department of Justice and the United States Attorney's Office for the Southern District of Ohio, on behalf of the Defense Logistics Agency (DLA) and the Army and Air Force Exchange Service (AAFES) (collectively the ''United States''), Hanjin Transportation Co., Ltd. (Hanjin), and Relator [REDACTED] (hereafter collectively referred to as ''the Parties''), through their authorized representatives.

RECITALS

A. Hanjin is a South Korea-based logistics company with South Korean and international customers, including the United States Department of Defense (DoD).

B. On February 28, 2018, Relator, a resident and citizen of South Korea, filed a *qui tam* action in the United States District Court for the Southern District of Ohio captioned *United States ex rel. [REDACTED]* v. *GS Caltex, et al.,* Civil Action No. [REDACTED], pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the Civil FCA Action). Relator contends that Hanjin conspired with other South Korean entities to rig bids on DoD contracts to supply fuel to U.S. military bases throughout South Korea beginning in 2008 and continuing until 2016, including DLA Post, Camps, and Stations contracts executed in 2009 and 2013, and AAFES contracts executed in 2008.

C. On such date as may be determined by the Court, Hanjin will plead guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) (the ''Plea Agreement'') to an Information to be filed in *United States* v. *Hanjin Transportation Co., Ltd.,* Criminal Action No. [to be assigned] (S.D. Ohio) (the ''Criminal Action'') that will allege that Hanjin participated in a combination and conspiracy beginning at least in or around March 2005 and continuing until at least in or around October 2016, to suppress and eliminate

competition on certain contracts solicited by the DoD to supply ultra-low sulfur diesel and gasoline to numerous U.S. Army, Navy, Marine, and Air Force installations in Korea, including PC&S contracts, in violation of the Sherman Antitrust Act, 15 U.S.C. § 1.

D. Hanjin will execute a Stipulation with the Antitrust Division of the United States Department of Justice in which Hanjin will consent to the entry of a Final Judgment to be filed in *United States* v. *Hanjin Transportation Co., Ltd.,* Civil Action No. [to be assigned] (S.D. Ohio) (the Civil Antitrust Action) that will settle any and all civil antitrust claims of the United States against Hanjin arising from any act or offense committed before the date of the Stipulation that was undertaken in furtherance of an attempted or completed antitrust conspiracy involving PC&S and/or AAFES fuel supply contracts with the U.S. military in South Korea during the period 2005 through 2016.

E. The United States contends that it has certain civil claims against Hanjin arising from a conspiracy with other South Korean entities to rig bids on DoD contracts to supply fuel to U.S. military bases throughout South Korea beginning in 2008 and continuing to 2016, including DLA Post, Camps, and Stations contracts executed in 2009 and 2013, and AAFES contracts executed in 2008. The conduct described in in this Paragraph, as well as the conduct, actions, and claims alleged by Relator in the Civil FCA Action is referred to below as the Covered Conduct.

F. With the exception of any admissions that are made by Hanjin in connection with the Plea Agreement in the Criminal Action, this Settlement Agreement is neither an admission of liability by Hanjin nor a concession by the United States or Relator that their claims are not well founded.

G. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees, and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Hanjin agrees to pay to the United States $6,182,000 (FCA Settlement Amount) by electronic funds transfer no later than thirteen (13) business days after the Effective Date of this Agreement pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice. Relator claims entitlement under 31 U.S.C. § 3730(d) to Relator's reasonable expenses, attorneys' fees and costs. The FCA Settlement Amount does not include the Relator's fees and costs, and Hanjin acknowledges (without waiving any applicable arguments or defenses) that Relator retains all rights to seek to recover such expenses, attorneys' fees, and costs from Hanjin pursuant to 31 U.S.C. § 3730(d).

2. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon Hanjin's full payment of the FCA Settlement Amount, the United States releases Hanjin together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729–3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801–3812; Contract Disputes Act, 41 U.S.C. §§ 7101–7109; or the common law theories of breach of contract, payment by mistake, unjust enrichment, and fraud.

3. Except as set forth in Paragraph 1 (concerning Relator's claims under 31 U.S.C. § 3730(d)), and subject to the exceptions in Paragraph 4 below, and conditioned upon Hanjin's full payment of the FCA Settlement Amount, Relator, on behalf of: (a) his respective heirs, successors, assigns, agents and attorneys; and (b) his companies ([REDACTED], together with their direct and indirect subsidiaries, brother or sister corporations, divisions, current or former corporate owners, and the corporate successors and assigns of any of them); hereby fully and finally releases, waives, and forever discharges Hanjin, together with its direct and indirect subsidiaries, brother or sister corporations, divisions, current or former corporate owners, and the corporate successors and assigns of any of them, from: (i) any civil monetary claim Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729–3733; (ii) any claims or allegations Relator has asserted or could have asserted against Hanjin arising from the Covered Conduct; and (iii) all liability, claims, demands, actions or causes of action whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal, Korean, or state statute or regulation or otherwise, or in common law, including claims for attorneys' fees, costs, and expenses of every kind and however denominated, that Relator would have standing to bring or which Relator may now have or claim to have against Hanjin and/or its direct and indirect subsidiaries, brother or sister corporations, divisions, current or former corporate owners, and the corporate successors and assigns of any of them.

4. Notwithstanding the releases given in paragraphs 2 and 3 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability, except to the extent detailed in the Plea Agreement;

c. Except as explicitly stated in this Agreement, any administrative liability, including the suspension and debarment rights of any federal agency;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability of individuals;

g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

h. Any liability for failure to deliver goods or services due; and

i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

5. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). In connection with this Agreement and this Civil FCA Action, Relator, on behalf of himself and his heirs, successors, attorneys, agents, and assigns, agrees that neither this Agreement, nor any intervention by the United States in the Civil FCA Action in order to dismiss the Civil FCA Action, nor any dismissal of the Civil FCA Action, shall waive or otherwise affect the ability of the United States to contend that provisions in the False Claims Act, including 31 U.S.C. § 3730(d)(3), bar Relator from sharing in the proceeds of this Agreement, except that the United States will not contend that Relator is barred from sharing in the proceeds of this Agreement pursuant to 31 U.S.C. § 3730(e)(4). Moreover, the United States and Relator, on behalf of

himself and his heirs, successors, attorneys, agents, and assigns agree that they each retain all of their rights pursuant to the False Claims Act on the issue of the share percentage, if any, that Relator should receive of any proceeds of the settlement of his claims, and that no agreements concerning Relator share have been reached to date.

6. Hanjin waives and shall not assert any defenses Hanjin may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

7. Hanjin fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Hanjin has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

8. Hanjin, together with its direct and indirect subsidiaries, brother or sister corporations, divisions, current or former corporate owners, and the corporate successors and assigns of any of them, hereby fully and finally releases, waives, and forever discharges the Relator, together with his respective heirs, successors, assigns, agents and attorneys, and his companies ([REDACTED]) from any claims or allegations Hanjin has asserted or could have asserted, arising from the Covered Conduct, and from all liability, claims, demands, actions or causes of action whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal, Korean, or state statute or regulation or otherwise, or in common law, including claims for attorneys' fees, costs, and expenses of every kind and however denominated, that it would have standing to bring or which Hanjin may now have or claim to have against Relator and his heirs, successors, assigns, agents, and attorneys. Relator hereby represents that neither he nor his companies, [REDACTED], performed business with Hanjin.

9. a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205–47) incurred by or on behalf of Hanjin, and its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement, any related plea agreement, and any related civil antitrust agreement;

(2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;

(3) Hanjin's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);

(4) the negotiation and performance of this Agreement, any related plea agreement, and any related civil antitrust agreement;

(5) the payment Hanjin makes to the United States pursuant to this Agreement and any payments that Hanjin may make to Relator, including costs and attorneys' fees,

are unallowable costs for government contracting purposes (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs will be separately determined and accounted for by Hanjin, and Hanjin shall not charge such Unallowable Costs directly or indirectly to any contract with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Agreement, Hanjin shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs included in payments previously sought by Hanjin or any of its subsidiaries or affiliates from the United States. Hanjin agrees that the United States, at a minimum, shall be entitled to recoup from Hanjin any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. The United States, including the Department of Justice and/or the affected agencies, reserves its rights to audit, examine, or re-examine Hanjin's books and records and to disagree with any calculations submitted by Hanjin or any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by Hanjin, or the effect of any such Unallowable Costs on the amount of such payments.

10. Hanjin agrees to cooperate fully and truthfully with the United States in connection with the Civil FCA Action. Hanjin's ongoing, full, and truthful cooperation shall include, but not be limited to:

a. upon request by the United States with reasonable notice, producing at the offices of counsel for the United States in Washington, D.C. and not at the expense of the United States, complete and un-redacted copies of all non-privileged documents related to the Covered Conduct wherever located in Hanjin's possession, custody, or control, including but not limited to, reports, memoranda of interviews, and records concerning any investigation of the Covered Conduct that Hanjin has undertaken, or that has been performed by another on Hanjin's behalf;

b. upon request by the United States with reasonable notice, making current Hanjin directors, officers, and employees available for interviews, consistent with the rights and privileges of such individuals, by counsel for the United States and/or their investigative agents, not at the expense of the United States, in the United States or Hong Kong, unless another place is mutually agreed upon;

c. upon request by the United States with reasonable notice, (i) using best efforts to assist in locating former Hanjin directors, officers, and employees identified by attorneys and/or investigative agents of the United States, and (ii) using best efforts to make any such former Hanjin directors, officers, and employees available for interviews, consistent with the rights and privileges of such individuals, by counsel for the United States and/or their investigative agents, not at the expense of the United States, in the United States or Hong Kong, unless another place is mutually agreed upon; and

d. upon request by the United States with reasonable notice, making current Hanjin directors, officers, and employees available, and using best efforts to make former Hanjin directors, officers, employees available, to testify, consistent with the rights and privileges of such individuals, fully, truthfully, and under oath, without falsely implicating any person or withholding any information, (i) at depositions in the United States, Hong Kong, or any other mutually agreed upon place, (ii) at trial in the United States, and (iii) at any other judicial proceedings wherever located related to the Civil FCA Action.

11. This Agreement is intended to be for the benefit of the Parties only.

12. Upon receipt of the payment of the FCA Settlement Amount described in Paragraph 1 above, the United States and Relator shall promptly sign and file a Joint Stipulation of Dismissal, with prejudice, of the claims filed against

Hanjin in the Civil FCA Action, pursuant to Rule 41(a)(1)), which dismissal shall be conditioned on the Court retaining jurisdiction over Relator's claims to a relator's share and recovery of attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d).

13. Except with respect to payment (if any) by Hanjin of Relator's attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d), each Party shall bear its own legal and other costs incurred in connection with this matter. The Parties agree that Relator and Hanjin will not seek to recover from the United States any costs or fees related to the preparation and performance of this Agreement.

14. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

15. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Southern District of Ohio. Hanjin agrees that the United States District Court for the Southern District of Ohio has jurisdiction over it for purposes of the Civil FCA Action. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

16. This Agreement constitutes the complete agreement between the Parties on the subject matters addressed herein. This Agreement may not be amended except by written consent of the Parties.

17. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

18. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

19. This Agreement is binding on Hanjin's successors, transferees, heirs, and assigns.

20. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

21. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public, as permitted by order of the Court. This Agreement shall not be released in un-redacted form until the Court unseals the entire Civil FCA Action.

22. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

The United States of America

Dated: _____

By: _____

Andrew A. Steinberg,
Trial Attorney, Commercial Litigation Branch, Civil Division, U.S. Department of Justice

Dated: _____

By: _____

Mark T. D'Alessandro
Civil Chief

Andrew Malek
Assistant United States Attorney, U.S. Attorney's Office for the Southern District of Ohio

Hanjin Transportation Co., Ltd.—Defendant

Dated: _____

By: _____

Authorized Representative of Hanjin Transportation Co., Ltd.

Dated: _____

By: _____

William H. Stallings
Counsel for Hanjin Transportation Co., Ltd.

Dated: _____

By: _____

Kelly B. Kramer
Counsel for Hanjin Transportation Co., Ltd.

[Redacted]—Relator

Dated: _____

By: _____

[Redacted]

Dated: _____

By: _____

Eric Havian
Constantine Cannon LLP, Counsel for Relator

United States District Court for the Southern District of Ohio Eastern Division

United States of America, Plaintiff, v. *SK Energy Co., Ltd.* Defendant.

Case No. 2:18-cv-01456-ALM-CMV

PROPOSED FINAL JUDGMENT AS TO DEFENDANT SK ENERGY CO., LTD.

WHEREAS Plaintiff, United States of America, filed its Complaint on November 14, 2018, the United States and Defendant SK Energy Co., Ltd. (''SK Energy''), by their respective attorneys, have consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law;

WHEREAS, on such date as may be determined by the Court, SK Energy will plead guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) (the ''Plea Agreement'') to an Information to be filed in *United States* v. *SK Energy Co., Ltd.* [to be assigned] (S.D.Ohio) (the ''Criminal Action'') that will allege a violation of Section 1 of the Sherman Act, 15 U.S. C. § 1, relating to the same events giving rise to the allegations described in the Complaint;

WHEREAS, this Final Judgment does not constitute any evidence against or admission by any party regarding any issue of fact or law;

NOW, THEREFORE, before the taking of any testimony and without trial or final adjudication of any issue of fact or law herein, and upon consent of the parties hereto, it is hereby ORDERED, ADJUDGED, AND DECREED:

I. JURISDICTION

This Court has jurisdiction of the subject matter of this action and each of the parties consenting hereto. The Complaint states a claim upon which relief may be granted to the United States against SK Energy under Section 1 of the Sherman Act, 15 U.S.C. § 1.

II. APPLICABILITY

This Final Judgment applies to SK Energy, as defined above, and all other persons in active concert or participation with any of them who receive actual notice of this Final Judgment by personal service or otherwise.

III. PAYMENT

SK Energy shall pay to the United States within ten (10) business days of the entry of this Final Judgment the amount of ninety million, three hundred eighty-four thousand, eight hundred and seventy-two dollars ($90,384,872), less the amount paid (excluding any interest) pursuant to the settlement agreement attached hereto as Attachment 1, to satisfy all civil antitrust claims alleged against SK Energy by the United States in the Complaint. Payment of the amount ordered hereby shall be made by wire transfer of funds or cashier's check. If the payment is made by wire transfer, SK Energy shall contact Janie Ingalls of the Antitrust Division's Antitrust Documents Group at (202) 514–2481 for instructions before making the transfer. If the payment is made by cashier's check, the check shall be made payable to the United States Department of Justice and delivered to: Janie Ingalls, United States Department of Justice Antitrust Division, Antitrust Documents Group, 450 5th Street, NW, Suite 1024, Washington, D.C. 20530. In the event of a default in payment, interest at the rate of eighteen (18) percent per annum shall accrue thereon from the date of default to the date of payment.

IV. COOPERATION

SK Energy shall cooperate fully with the United States regarding any matter about which SK Energy has knowledge or information relating to any ongoing civil investigation, litigation, or other proceeding arising out of any ongoing federal investigation of the subject matter discussed in the Complaint (hereinafter, any such investigation, litigation, or proceeding shall be referred to as a ''Civil Federal Proceeding'').

The United States agrees that any cooperation provided in connection with the Plea Agreement and/or pursuant to the settlement agreement attached hereto as Attachment 1 will be considered cooperation for purposes of this Final Judgment, and the United States will use its reasonable best efforts, where appropriate, to coordinate any requests for cooperation in connection with the Civil Federal Proceeding with requests for cooperation in connection with the Plea Agreement and the settlement agreement attached hereto as Attachment 1, so as to avoid unnecessary duplication and expense.

SK Energy's cooperation shall include, but not be limited to, the following:

(a) Upon request, completely and truthfully disclosing and producing, to the offices of the United States and at no expense to the United States, copies of all non-privileged information, documents, materials, and records in its possession (and for any foreign-language information, documents, materials, or records, copies must be produced with an English translation), regardless of their geographic location, about which the United States may inquire in connection with any Civil Federal Proceeding, including but not limited to all information about activities of SK Energy and present and former officers, directors, employees, and agents of SK Energy;

(b) Making available in the United States, at no expense to the United States, its present officers, directors, employees, and agents to provide information and/or testimony as requested by the United States in connection with any Civil Federal Proceeding, including the provision of testimony in trial and other judicial proceedings, as well as interviews with law enforcement authorities, consistent with the rights and privileges of those individuals;

(c) Using its best efforts to make available in the United States, at no expense to the United States, its former officers, directors, employees, and agents to provide information and/or testimony as requested by the United States in connection with any Civil Federal Proceeding, including the provision of testimony in trial and other judicial proceedings, as well as interviews with law enforcement authorities, consistent with the rights and privileges of those individuals;

(d) Providing testimony or information necessary to identify or establish the original location, authenticity, or other basis for admission into evidence of documents or physical evidence produced by SK Energy in any Civil Federal Proceeding as requested by the United States; and

(e) Completely and truthfully responding to all other inquiries of the United States in connection with any Civil Federal Proceeding.

However, notwithstanding any provision of this Final Judgment, SK Energy is not required to: (1) request of its current or former officers, directors, employees, or agents that they forgo seeking the advice of an attorney nor that they act contrary to that advice; (2) take any action against its officers, directors, employees, or agents for following their attorney's advice; or (3) waive any claim of privilege or work product protection.

The obligations of SK Energy to cooperate fully with the United States as described in this Section shall cease upon the conclusion of all Civil Federal Proceedings (which may include Civil Federal Proceedings related to the conduct of third parties), including exhaustion of all appeals or expiration of time for all appeals of any Court ruling in each such Civil Federal Proceeding, at which point the United States will provide written notice to SK Energy that its obligations under this Section have expired.

V. ANTITRUST COMPLIANCE PROGRAM

A. Within thirty (30) days after entry of this Final Judgment, SK Energy shall appoint an Antitrust Compliance Officer and identify to the United States his or her name, business address, telephone number, and email address. Within forty-five (45) days of a vacancy in the Antitrust Compliance Officer position, SK Energy shall appoint a replacement, and shall identify to the United States the Antitrust Compliance Officer's name, business address, telephone number, and email address. SK Energy's initial or replacement appointment of an Antitrust Compliance Officer is subject to the approval of the United States, in its sole discretion.

B. The Antitrust Compliance Officer shall institute an antitrust compliance program for the company's employees and directors with responsibility for bidding for any contract with the United States. The antitrust compliance program shall provide at least two hours of training annually on the antitrust laws of the United States, such training to be delivered by an attorney with relevant experience in the field of United States antitrust law.

C. Each Antitrust Compliance Officer shall obtain, within six months after entry of this Final Judgment, and on an annual basis thereafter, on or before each anniversary of the entry of this Final Judgment, from each person subject to Paragraph V.B of this Final Judgment, and thereafter maintaining, a certification that each such person has received the required two hours of annual antitrust training.

D. Each Antitrust Compliance Officer shall communicate annually to all employees that they may disclose to the Antitrust Compliance Officer, without reprisal, information concerning any potential violation of the United States antitrust laws.

E. Each Antitrust Compliance Offer shall provide to the United States within six months after entry of this Final Judgment, and on an annual basis thereafter, on or before each anniversary of the entry of this Final Judgment, a written statement as to the fact and manner of SK Energy's compliance with Section V of this Final Judgment.

VI. RETENTION OF JURISDICTION

This Court retains jurisdiction to enable any of the parties to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify or terminate any of its provisions, to enforce compliance, and to punish violations of its provisions.

VII. ENFORCEMENT OF FINAL JUDGMENT

A. The United States retains and reserves all rights to enforce the provisions of this Final Judgment, including the right to seek an order of contempt from the Court. SK Energy agrees that in any civil contempt action, any motion to show cause, or any similar action brought by the United States regarding an alleged violation of this Final Judgment, the United States may establish a violation of the decree and the appropriateness of any remedy therefor by a preponderance of the evidence, and SK Energy waives any argument that a different standard of proof should apply.

B. The Final Judgment should be interpreted to give full effect to the

procompetitive purposes of the antitrust laws and to restore all competition the United States alleged was harmed by the challenged conduct. SK Energy agrees that they may be held in contempt of, and that the Court may enforce, any provision of this Final Judgment that, as interpreted by the Court in light of these procompetitive principles and applying ordinary tools of interpretation, is stated specifically and in reasonable detail, whether or not it is clear and unambiguous on its face. In any such interpretation, the terms of this Final Judgment should not be construed against either party as the drafter.

C. In any enforcement proceeding in which the Court finds that SK Energy has violated this Final Judgment, the United States may apply to the Court for a one-time extension of this Final Judgment, together with such other relief as may be appropriate. In connection with any successful effort by the United States to enforce this Final Judgment against SK Energy, whether litigated or resolved prior to litigation, SK Energy agrees to reimburse the United States for the fees and expenses of its attorneys, as well as any other costs including experts' fees, incurred in connection with that enforcement effort, including in the investigation of the potential violation.

VIII. EXPIRATION OF FINAL JUDGMENT

Unless this Court grants an extension, this Final Judgment shall expire seven (7) years from the date of its entry, except that after five (5) years from the date of its entry, this Final Judgment may be terminated upon notice by the United States to the Court and SK Energy that the continuation of the Final Judgment no longer is necessary or in the public interest.

IX. PUBLIC INTEREST DETERMINATION

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16, including making copies available to the public of this Final Judgment, the Competitive Impact Statement, and any comments thereon and the United States' responses to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and response to comments filed with the Court, entry of this Final Judgment is in the public interest.

Dated: _____

_____

United States District Judge

ATTACHMENT 1

SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the Civil Division of the United States Department of Justice and the United States Attorney's Office for the Southern District of Ohio, on behalf of the Defense Logistics Agency (DLA) and the Army and Air Force Exchange Service (AAFES) (collectively the ''United States''), SK Energy Co., Ltd. (SK Energy), and Relator [REDACTED] (hereafter collectively referred to as ''the Parties''), through their authorized representatives.

RECITALS

A. SK Energy is a South Korea-based energy company that produces various petroleum products that it sells to South Korean and international customers, including the United States Department of Defense (DoD).

B. On February 28, 2018, Relator, a resident and citizen of South Korea, filed a *qui tam* action in the United States District Court for the Southern District of Ohio captioned *United States ex rel. [REDACTED]* v. *GS Caltex, et al.,* Civil Action No. [REDACTED], pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the Civil FCA Action). Relator contends that SK Energy conspired with other South Korean entities to rig bids on DoD contracts to supply fuel to U.S. military bases throughout South Korea beginning in 2005 and continuing until 2016, including DLA Post, Camps, and Stations (PC&S) contracts executed in 2006, 2009, and 2013, and AAFES contracts executed in 2008.

C. On such date as may be determined by the Court, SK Energy will plead guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) (the ''Plea Agreement'') to an Information to be filed in *United States* v. *SK Energy Co., Ltd.,* Criminal Action No. [to be assigned] (S.D. Ohio) (the ''Criminal Action'') that will allege that SK Energy participated in a combination and conspiracy beginning at least in or around March 2005 and continuing until at least in or around October 2016, to suppress and eliminate competition on certain contracts solicited by the DoD to supply fuel to numerous U.S. Army, Navy, Marine, and Air Force installations in Korea, including PC&S contracts and the 2008 AAFES contract, in violation of the Sherman Antitrust Act, 15 U.S.C. § 1.

D. SK Energy will execute a Stipulation with the Antitrust Division of the United States Department of Justice in which SK Energy will consent to the entry of a Final Judgment to be filed in *United States* v. *SK Energy Co., Ltd.,* Civil Action No. [to be assigned] (S.D. Ohio) (the Civil Antitrust Action) that will settle any and all civil antitrust claims of the United States against SK Energy arising from any act or offense committed before the date of the Stipulation that was undertaken in furtherance of an attempted or completed antitrust conspiracy involving PC&S and/or AAFES fuel supply contracts with the U.S. military in South Korea during the period 2005 through 2016.

E. The United States contends that it has certain civil claims against SK Energy arising from the conduct described in the Plea Agreement in the Criminal Action and in the Stipulation in the Civil Antitrust Action, as well as the conduct, actions, and claims alleged by Relator in the Civil FCA Action. The conduct referenced in this Paragraph is referred to below as the Covered Conduct.

F. With the exception of any admissions that are made by SK Energy in connection with the Plea Agreement in the Criminal Action, this Settlement Agreement is neither an admission of liability by SK Energy nor a concession by the United States that its claims are not well founded.

G. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1.a. SK Energy agrees to pay to the United States $71,866,000 (FCA Settlement Amount), of which $47,910,887 is restitution, by electronic funds transfer no later than thirteen (13) business days after the Effective Date of this Agreement pursuant to written instructions to be provided by the Civil Division of the Department of Justice. Relator claims entitlement under 31 U.S.C. § 3730(d) to Relator's reasonable expenses, attorneys' fees and costs. The FCA Settlement Amount does not include the Relator's fees and costs, and SK Energy acknowledges that Relator retains all rights to recover such expenses, attorneys' fees, and costs from SK Energy pursuant to 31 U.S.C. § 3730(d).

1.b. If SK Energy's Plea Agreement in the Criminal Action is not accepted by

the Court or the Court does not enter a Final Judgment in the Civil Antitrust Action, this Agreement shall be null and void at the option of either the United States or SK Energy. If either the United States or SK Energy exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within five (5) business days of the Court's decision, the Parties will not object and this Agreement will be rescinded and the FCA Settlement Amount shall be returned to SK Energy. If this Agreement is rescinded, SK Energy will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims, actions or proceedings arising from the Covered Conduct that are brought by the United States within ninety (90) calendar days of rescission, except to the extent such defenses were available on the day on which Relator's *qui tam* complaint in the Civil FCA Action was filed.

2. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon SK Energy's full payment of the FCA Settlement Amount, the United States releases SK Energy together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them (the ''SK Energy Released Parties'') from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729–3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801–3812; Contract Disputes Act, 41 U.S.C. §§ 7101–7109; or the common law theories of breach of contract, payment by mistake, unjust enrichment, and fraud.

3. Except as set forth in Paragraph 1 (concerning Relator's claims under 31 U.S.C. § 3730(d)), and conditioned upon SK Energy's full payment of the FCA Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases the SK Energy Released Parties from (a) any civil monetary claim the Relator has or may have for the claims set forth in the Civil FCA Action, the Civil Antitrust Action, the Criminal Action, and the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729–3733, up until the date of this Agreement; and (b) all liability, claims, demands, actions, or causes of action whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal, state, or Korean statute, law, regulation or doctrine, that Relator, his heirs, successors, attorneys, agents, and assigns otherwise has brought or would have standing to bring as of the date of this Agreement, including any liability to Relator arising from or relating to the claims Relator asserted or could have asserted in the Civil FCA Action, up until the date of this Agreement. Relator further represents he does not know of any conduct by the SK Energy Released Parties or any current or former owners, officers, directors, trustees, shareholders, employees, executives, agents, or affiliates of the SK Energy Released Parties that would constitute a violation of the False Claims Act other than the claims set forth in the Civil FCA Action and the Covered Conduct, and Relator acknowledges and agrees that his representations are a material inducement to SK Energy's willingness to enter into this Agreement.

4. Notwithstanding the releases given in paragraphs 2 and 3 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability, except to the extent detailed in the Plea Agreement;

c. Except as explicitly stated in this Agreement, any administrative liability, including the suspension and debarment rights of any federal agency;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability of individuals;

g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

h. Any liability for failure to deliver goods or services due; and

i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

5. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). The determination of Relator's share, if any, of the FCA Settlement Amount pursuant to 31 U.S.C. § 3730(d) is a matter that shall be handled separately by and between the Relator and the United States, without any direct involvement or input from SK Energy. In connection with this Agreement and this Civil FCA Action, Relator, on behalf of himself and his heirs, successors, attorneys, agents, and assigns agrees that neither this Agreement, nor any intervention by the United States in the Civil FCA Action in order to dismiss the Civil FCA Action, nor any dismissal of the Civil FCA Action, shall waive or otherwise affect the ability of the United States to contend that provisions in the False Claims Act, including 31 U.S.C. § 3730(d)(3), bar Relator from sharing in the proceeds of this Agreement, except that the United States will not contend that Relator is barred from sharing in the proceeds of this Agreement pursuant to 31 U.S.C. § 3730(e)(4). Moreover, the United States and Relator, on behalf of himself and his heirs, successors, attorneys, agents, and assigns agree that they each retain all of their rights pursuant to the False Claims Act on the issue of the share percentage, if any, that Relator should receive of any proceeds of the settlement of his claims, and that no agreements concerning Relator share have been reached to date.

6. SK Energy waives and shall not assert any defenses SK Energy may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

7. SK Energy fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that SK Energy has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

8. Conditioned upon Relator's agreement herein, the SK Energy Released Parties fully and finally release Relator his heirs, successors, assigns, agents and attorneys (the ''Relator Released Parties''), from (a) any civil monetary claim SK Energy has or may have now or in the future against the Relator Released Parties related to the claims set forth in the Civil FCA Action, the Civil Antitrust Action, the Criminal Action, and the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729–3733, and the Relator's investigation and prosecution thereof, including

attorney's fees, costs, and expenses of every kind and however denominated, up until the date of this Agreement; and (b) all liability, claims, demands, actions, or causes of action whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal, state, or Korean statute, law, regulation or doctrine, that the SK Energy Released Parties otherwise have brought or would have standing to bring as of the date of this Agreement, including any liability to SK Energy arising from or relating to claims the SK Energy Released Parties asserted or could have asserted related to the Civil FCA Action, up until the date of this Agreement. The SK Energy Released Parties further acknowledge and agree that these representations are a material inducement to Relator's willingness to enter into this Agreement.

9.a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205–47) incurred by or on behalf of SK Energy, and its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement, any related plea agreement, and any related civil antitrust agreement;

(2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;

(3) SK Energy's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);

(4) the negotiation and performance of this Agreement, any related plea agreement, and any related civil antitrust agreement;

(5) the payment SK Energy makes to the United States pursuant to this Agreement and any payments that SK Energy may make to Relator, including costs and attorneys' fees,

are unallowable costs for government contracting purposes (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs will be separately determined and accounted for by SK Energy, and SK Energy shall not charge such Unallowable Costs directly or indirectly to any contract with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Agreement, SK Energy shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs included in payments previously sought by SK Energy or any of its subsidiaries or affiliates from the United States. SK Energy agrees that the United States, at a minimum, shall be entitled to recoup from SK Energy any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. The United States, including the Department of Justice and/or the affected agencies, reserves its rights to audit, examine, or re-examine SK Energy's books and records and to disagree with any calculations submitted by SK Energy or any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by SK Energy, or the effect of any such Unallowable Costs on the amount of such payments.

10. SK Energy agrees to cooperate fully and truthfully with the United States in connection with the Civil FCA Action. The Civil Division of the United States Department of Justice will use reasonable best efforts, where appropriate, to coordinate any requests for cooperation in connection with the Civil FCA Action with requests for cooperation in connection with the Plea Agreement in the Criminal Action and the Civil Antitrust Action, so as to avoid unnecessary duplication and expense. SK Energy's ongoing, full, and truthful cooperation shall include, but not be limited to:

a. upon request by the United States with reasonable notice, producing at the offices of counsel for the United States in Washington, D.C. and not at the expense of the United States, complete and un-redacted copies of all non-privileged documents related to the Covered Conduct wherever located in SK Energy's possession, custody, or control, including but not limited to, reports, memoranda of interviews, and records concerning any investigation of the Covered Conduct that SK Energy has undertaken, or that has been performed by another on SK Energy's behalf;

b. upon request by the United States with reasonable notice, making current SK Energy directors, officers, and employees available for interviews, consistent with the rights and privileges of such individuals, by counsel for the United States and/or their investigative agents, not at the expense of the United States, in the United States or Hong Kong, unless another place is mutually agreed upon;

c. upon request by the United States with reasonable notice, (i) using best efforts to assist in locating former SK Energy directors, officers, and employees identified by attorneys and/or investigative agents of the United States, and (ii) using best efforts to make any such former SK Energy directors, officers, and employees available for interviews, consistent with the rights and privileges of such individuals, by counsel for the United States and/or their investigative agents, not at the expense of the United States, in the United States or Hong Kong, unless another place is mutually agreed upon; and

d. upon request by the United States with reasonable notice, making current SK Energy directors, officers, and employees available, and using best efforts to make former SK Energy directors, officers, employees available, to testify, consistent with the rights and privileges of such individuals, fully, truthfully, and under oath, without falsely implicating any person or withholding any information, (i) at depositions in the United States, Hong Kong, or any other mutually agreed upon place, (ii) at trial in the United States, and (iii) at any other judicial proceedings wherever located related to the Civil FCA Action.

11. This Agreement is intended to be for the benefit of the Parties only.

12. Upon receipt of the payment of the FCA Settlement Amount described in Paragraph 1 above, the Court's acceptance of SK Energy's Plea Agreement in the Criminal Action, and the Court's entry of a Final Judgment in the Civil Antitrust Action, the United States and Relator shall promptly sign and file a Joint Stipulation of Dismissal, with prejudice, of the claims filed against SK Energy in the Civil FCA Action, pursuant to Rule 41(a)(1), which dismissal shall be conditioned on the Court retaining jurisdiction over Relator's claims to a relator's share and recovery of attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d).

13. Except with respect to the recovery of Relator's attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d), each Party shall bear its own legal and other costs incurred in connection with this matter. The Parties agree that Relator and SK Energy will not seek to recover from the United States any costs or fees related to the preparation and performance of this Agreement.

14. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

15. This Agreement is governed by the laws of the United States. The exclusive

jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Southern District of Ohio. SK Energy agrees that the United States District Court for the Southern District of Ohio has jurisdiction over it for purposes of this case. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

16. This Agreement constitutes the complete agreement between the Parties on the subject matter addressed herein. This Agreement may not be amended except by written consent of the Parties.

17. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

18. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

19. This Agreement is binding on SK Energy's successors, transferees, heirs, and assigns.

20. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

21. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public, as permitted by order of the Court. This Agreement shall not be released in un-redacted form until the Court unseals the entire Civil FCA Action.

22. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

The United States of America
Dated: _____
By: _____
Andrew A. Steinberg,
Trial Attorney, Commercial Litigation Branch, Civil Division, U.S. Department of Justice
Dated: _____
By: _____
Mark T. D'Alessandro,
Civil Chief
Andrew Malek,
Assistant United States Attorney, U.S. Attorney's Office for the Southern District of Ohio

SK Energy Co., Ltd.—Defendant
Dated: _____
By: _____
Myunghun Lee,
Authorized Representative of SK Energy, Co., Ltd.
Dated: _____
By: _____
Phillip H. Warren,
Counsel for SK Energy Co., Ltd.

[Redacted]—Relator
Dated: _____
By: _____

[Redacted]
Dated: _____
By: _____
Eric Havian,
Counsel for Relator

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO EASTERN DIVISION

United States of America, Plaintiff, v. *GS Caltex Corporation, Hanjin Transportation Co., Ltd., and SK Energy Co., Ltd.* Defendants.

Case No. 2:18–cv–01456–ALM–CMV

COMPETITIVE IMPACT STATEMENT

Plaintiff United States of America, pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act (''APPA'' or ''Tunney Act''), 15 U.S.C. § 16(b)-(h), files this Competitive Impact Statement relating to the proposed Final Judgments submitted for entry in this civil antitrust proceeding.

I. NATURE AND PURPOSE OF THE PROCEEDING

On November 14, 2018, the United States filed a civil antitrust complaint against Defendants GS Caltex Corporation (''GS Caltex''), Hanjin Transportation Co., Ltd. (''Hanjin''), and SK Energy Co., Ltd. (''SK Energy'') alleging that Defendants violated Section 1 of the Sherman Act, 15 U.S.C. § 1. From at least March 2005 and continuing until at least October 2016 (''the Relevant Period''), Defendants and their co-conspirators conspired to fix prices and rig bids for the supply of fuel to the U.S. military for its operations in South Korea. As a result of this illegal conduct, Defendants and their co-conspirators overcharged American taxpayers by well over $100 million. Defendants have agreed to plead guilty to an information charging a criminal violation of Section 1 of the Sherman Act for this unlawful conduct; in this parallel civil action, the United States seeks compensation for the injury it incurred as a result of the conspiracy.

At the same time the Complaint was filed, the United States also filed agreed-upon proposed Final Judgments that would remedy the violation by having GS Caltex, Hanjin, and SK Energy pay $57,500,000, $6,182,000, and $90,384,872, respectively, to the United States. These payments resolve all civil claims of the United States related to the conduct described in the Complaint. The United States and Defendants have stipulated that the proposed Final Judgments may be entered after compliance with the APPA. Entry of the proposed Final Judgments would terminate this action, except that the Court would retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgments and to punish violations thereof.

II. DESCRIPTION OF THE EVENTS GIVING RISE TO THE ALLEGED VIOLATION

A. Defendants

GS Caltex is an oil company headquartered in Seoul, South Korea. GS Caltex is a joint venture between GS Energy, a South Korean corporation, and Chevron Corp., a Delaware corporation, which each own a 50 percent interest in GS Caltex. GS Caltex is engaged in the refining and supply of gasoline, diesel, kerosene, and other petroleum products for sale internationally. During the time of the conspiracy, GS Caltex supplied fuel to U.S. military installations in South Korea.

Hanjin is a global transportation and logistics company based in Seoul, South Korea. Hanjin is a member of Hanjin Group, a South Korean conglomerate with U.S. subsidiaries, including Hanjin International America. Beginning in 2009, Hanjin partnered with oil companies, including a co-conspirator oil company (''Company A''), to supply fuel to U.S. military installations in South Korea.

SK Energy is an oil company headquartered in Seoul, South Korea. SK Energy is engaged in the refining and supply of gasoline, diesel, kerosene, and other petroleum products for sale internationally. During the time of the conspiracy, SK Energy supplied fuel to U.S. military installations in South Korea.

Other persons, not named as defendants in this action, participated as co-conspirators in the violation alleged in the Complaint and performed acts and made statements in furtherance thereof. These co-conspirators included, among others, a logistics firm (''Company B'') and an oil company (''Company C'') that jointly supplied fuel to the U.S. military.

B. PC&S and AAFES Contracts

The United States military procures fuel for its installations in South Korea through competitive solicitation processes. Oil companies, either independently or with a transportation company, submitted bids in response to these solicitations.

The conduct at issue in this action relates to two types of contracts to supply fuel to the U.S. military in South Korea: Post, Camps, and Stations (''PC&S'') contracts and Army and Air Force Exchange Services (''AAFES'') contracts.

PC&S contracts are issued and administered by the Defense Logistics Agency (''DLA''), a combat support agency of the U.S. Department of Defense. The fuel procured under PC&S contracts is used to power military vehicles and heat U.S. military buildings. During the Relevant Period, DLA issued PC&S solicitations listing the fuel requirements for installations across South Korea, with each delivery location identified by a separate line item. Bidders submitted initial bids, offering a price for each line item on which they chose to bid. After DLA reviewed the initial bids, bidders were allowed to submit revised final bids. DLA reviewed the bids and awarded contracts to the bidders offering the lowest price for each line item. Payments under the PC&S contracts were wired to the awardees by a finance and accounting agency of the U.S. Department of Defense from its office in Columbus, Ohio.

AAFES is an agency of the Department of Defense headquartered in Dallas, Texas. AAFES operates official retail stores (known as ''exchanges'') on U.S. Army and Air Force installations worldwide, which U.S. military personnel and their families use to purchase everyday goods and services, including gasoline for use in their personal vehicles. AAFES procures fuel for these stores via contracts awarded through a competitive solicitation process.

In 2008, AAFES issued a solicitation that listed the fuel requirements for installations in South Korea. Bidders submitted bids offering a price for each line item in the solicitation. Unlike DLA, AAFES awarded the entire 2008 contract to the bidder offering the lowest price across all the listed locations.

C. The Alleged Violation

The Complaint alleges that Defendants and their co-conspirators engaged in a series of meetings, telephone conversations, e-mails, and other communications to rig bids and fix prices for the supply of fuel to U.S. military installations in South Korea under several PC&S and AAFES contracts.

First, the Complaint alleges that GS Caltex, SK Energy, and Companies B and C conspired to rig bids and fix prices on the contracts issued in response to DLA solicitations SP0600–05–R–0063 and SP0600–05–R–0063–0001 (''2006 PC&S contracts''). The term of the 2006 PC&S contracts covered the supply of fuel from February 2006 through July 2009.

The Complaint alleges that between early 2005 and mid-2006, GS Caltex, SK Energy, and other conspirators met multiple times and exchanged phone calls and e-mails to allocate the line items in the solicitations for the 2006 PC&S contracts. Through such communications, these conspirators agreed to inflate their bids to produce larger profit margins. For each line item allocated to a different co-conspirator, the other conspirators agreed not to bid or to bid high enough to ensure that they would not win that item. DLA awarded the 2006 PC&S line items according to the allocations made by the conspiracy.

Second, the Complaint alleges that, as part of their discussions related to the 2006 PC&S contracts, GS Caltex and other conspirators agreed not to compete with SK Energy in bidding for the June 2008 AAFES solicitation (''2008 AAFES contract''). The initial term of the 2008 AAFES contract ran from July 2008 to July 2010; the contract was later extended through July 2013.

Third, the Complaint alleges that Defendants and other co-conspirators conspired to rig bids and fix prices for the contracts issued in response to DLA solicitation SP0600–08–R–0233 (''2009 PC&S contracts''). Hanjin and Company A joined the conspiracy for the purpose of bidding on SP0600–08–R–0233. The term of the 2009 PC&S contracts covered the supply of fuel from October 2009 through August 2013.

The Complaint explains that between late 2008 and mid-2009, Defendants and other co-conspirators met multiple times and exchanged phone calls and e-mails to allocate the line items in the solicitation for the 2009 PC&S contracts. As in 2006, these conspirators agreed to bid high so as to not win line items allocated to other co-conspirators. The original conspirators agreed to allocate to Hanjin and Company A certain line items that had previously been allocated to the original conspirators.

Finally, the Complaint alleges that Defendants and other co-conspirators once again conspired to rig bids and fix prices for the contracts issued in response to DLA solicitation SP0600–12–R–0332 (''2013 PC&S contracts''). The term of the 2013 PC&S contracts covered the supply of fuel from August 2013 through July 2016.

The Complaint explains that Defendants and other co-conspirators communicated via phone calls and e-mails to allocate and set the price for each line item in the solicitation for the 2013 PC&S contracts. Defendants and other co-conspirators believed that they had an agreement as to their bidding strategy and pricing for the 2013 PC&S contracts. As a result of this agreement, they submitted bids with pricing above what they would have offered absent collusion.

Hanjin and Company A submitted bids for the 2013 PC&S contracts below the prices set by the other co-conspirators, however. Although lower than the pricing agreed upon by the conspirators, Hanjin and Company A still submitted bids above a competitive, non-collusive price, knowing that they would likely win the contracts because the other conspirators would bid even higher prices.

III. EXPLANATION OF THE PROPOSED FINAL JUDGMENTS

For violations of Section 1 of the Sherman Act, the United States may seek damages, 15 U.S.C. § 15a, and equitable relief, 15 U.S.C. § 4, including equitable monetary remedies. *See United States* v. *KeySpan Corp.,* 763 F. Supp. 2d 633, 638–641 (S.D.N.Y. 2011).

This action is also related to a *qui tam* action currently filed under seal in the United States District Court for the Southern District of Ohio, alleging a violation of the False Claims Act, 31 U.S.C. § 3730, based on the same facts alleged in the Complaint.

A. Payment and Cooperation

The proposed Final Judgments require GS Caltex, Hanjin, and SK Energy respectively to pay $57,500,000, $6,182,000, and $90,384,872 to the United States within 10 business days of entry of the Final Judgment. These payments will satisfy all civil claims arising from the events described in Section II *supra* that the United States has against the Defendants under Section 1 of the Sherman Act and under the False Claims Act. The resolution of the United States' claims under the False Claims Act is set forth in separate agreements reached between the Defendants, the U.S. Attorney's Office for the Southern District of Ohio, and the U.S. Department of Justice's Civil Division. *See* Attachment 1 to each of the proposed Final Judgments.

As a result of the unlawful agreements in restraint of trade between Defendants and their co-conspirators, the United States paid more for the supply of fuel to U.S. military installations in South Korea than it would have if the companies had engaged in fair and honest competition. Defendants' payments under the proposed Final

Judgments fully compensate the United States for losses it suffered and deprive Defendants of the illegitimate profits they gained as a result of the collusive bidding. In addition to the payment of damages, the proposed Final Judgments also require the Defendants to cooperate with the United States regarding any ongoing civil investigation, trial, or other proceeding related to the conduct described in the Complaint. To assist with these proceedings, Defendants are required to provide all non-privileged information in their possession, make available their present employees, and use best efforts to make available their former employees, for interviews or testimony, as requested by the United States. This cooperation will help the United States pursue compensation from co-conspirators not named in this action.

Under Section 4A of the Clayton Act, the United States is entitled to treble damages for injuries it has suffered as a result of violations of the Sherman Act. Under the proposed Final Judgments, each Defendant will pay an amount that exceeds the overcharge but that reflects the value of the cooperation commitments the Defendants have made as a condition of settlement and the cost savings realized by avoiding extended litigation.

The proposed Final Judgments also require each Defendant to appoint an Antitrust Compliance Officer and to institute an antitrust compliance program. Under the antitrust compliance program, employees and directors of Defendants with responsibility for bidding on contracts with the United States must undergo training and all employees must be informed that there will no reprisal for disclosing to the Antitrust Compliance Officer any potential violations of the United States antitrust laws. The Antitrust Compliance Officer is required annually to certify that Defendant is in compliance with this requirement.

B. Enforcement of Final Judgments

The proposed Final Judgments contain provisions designed to promote compliance and make the enforcement of Division consent decrees as effective as possible. Paragraph VII(A) provides that the United States retains and reserves all rights to enforce the provisions of the proposed Final Judgments, including its rights to seek an order of contempt from the Court. Defendants have agreed that in any civil contempt action, any motion to show cause, or any similar action brought by the United States regarding an alleged violation of the Final Judgments, the United States may establish the violation and the appropriateness of any remedy by a preponderance of the evidence and that the Defendants have waived any argument that a different standard of proof should apply. This provision aligns the standard for compliance obligations with the standard of proof that applies to the underlying offense that the compliance commitments address.

Paragraph VII(B) provides additional clarification regarding the interpretation of the provisions of the proposed Final Judgments. The proposed Final Judgments were drafted to restore all competition the United States alleged was harmed by the Defendants' challenged conduct. The Defendants agree that they will abide by the proposed Final Judgments, and that they may be held in contempt of this Court for failing to comply with any provision of the proposed Final Judgments that is stated specifically and in reasonable detail, as interpreted in light of this procompetitive purpose.

Paragraph VII(C) further provides that should the Court find in an enforcement proceeding that a Defendant has violated the Final Judgment, the United States may apply to the Court for a one-time extension of the Final Judgment, together with such other relief as may be appropriate. In addition, in order to compensate American taxpayers for any costs associated with the investigation and enforcement of violations of a proposed Final Judgment, Paragraph VII(C) provides that in any successful effort by the United States to enforce a Final Judgment against a Defendant, whether litigated or resolved before litigation, Defendants agree to reimburse the United States for any attorneys' fees, experts' fees, or costs incurred in connection with any enforcement effort, including the investigation of the potential violation.

Finally, Section VIII of the proposed Final Judgments provide that each Final Judgment shall expire seven years from the date of its entry, except that after five years from the date of its entry, a Final Judgment may be terminated upon notice by the United States to the Court and the Defendant that the continuation of that Final Judgment is no longer necessary or in the public interest.

IV. REMEDIES AVAILABLE TO POTENTIAL PRIVATE LITIGANTS

Entry of the proposed Final Judgments will neither impair nor assist the bringing of any private antitrust damages action. Under the provisions of Section 5(a) of the Clayton Act, 15 U.S.C. § 16(a), the proposed Final Judgments have no prima facie effect in any subsequent lawsuit that may be brought against Defendants.

V. PROCEDURES AVAILABLE FOR MODIFICATION OF THE PROPOSED FINAL JUDGMENTS

The United States and Defendants have stipulated that the proposed Final Judgments may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgments are in the public interest.

The APPA provides a period of at least sixty (60) days preceding the effective date of the proposed Final Judgments within which any person may submit to the United States written comments regarding a proposed Final Judgment. Any person who wishes to comment should do so within sixty (60) days of the date of publication of this Competitive Impact Statement in the **Federal Register**, or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the United States, which remains free to withdraw its consent to a proposed Final Judgment at any time prior to the Court's entry of judgment. The comments and the response of the United States will be filed with the Court. In addition, comments will be posted on the Antitrust Division's internet website and, in certain circumstances, published in the **Federal Register**.

Written comments should be submitted by mail to:

Kathleen S. O'Neill, Chief, Transportation, Energy & Agriculture Section, Antitrust Division, United States Department of Justice, 450 5th Street NW, Suite 8000, Washington, DC 20530

The proposed Final Judgments provide that the Court retains jurisdiction over this action, and the parties may apply to the Court for any necessary or appropriate modification, interpretation, or enforcement of a Final Judgment.

VI. ALTERNATIVES TO THE PROPOSED FINAL JUDGMENTS

The United States considered, as an alternative to the proposed Final Judgments, a full trial on the merits against Defendants. The United States is satisfied, however, that the relief in the proposed Final Judgments remedies the violation of the Sherman Act alleged in the Complaint. The proposed Final

Judgments represent substantial monetary relief while avoiding the time, expense, and uncertainty of a full trial on the merits. Further, Defendants' agreements to cooperate with the civil investigation and any potential litigation will enhance the ability of the United States to obtain relief from the remaining conspirators.

VII. STANDARD OF REVIEW UNDER THE APPA FOR THE PROPOSED FINAL JUDGMENTS

The Clayton Act, as amended by the APPA, requires that proposed consent judgments in antitrust cases brought by the United States be subject to a 60-day comment period, after which the court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. § 16(e)(1). In making that determination, the court, in accordance with the statute as amended in 2004, is required to consider:

(A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and

(B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. § 16(e)(1)(A) & (B). In considering these statutory factors, the court's inquiry is necessarily a limited one as the government is entitled to ''broad discretion to settle with the defendant within the reaches of the public interest.'' *United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1461 (D.C. Cir. 1995); *see generally United States* v. *SBC Commc'ns, Inc.,* 489 F. Supp. 2d 1 (D.D.C. 2007) (assessing public interest standard under the Tunney Act); *United States* v. *Hillsdale Cmty. Health Ctr.,* 2015 U.S. Dist. LEXIS 162505, at *3 (E.D. Mich. 2015) (explaining that the ''Court's review is limited'' in Tunney Act settlements); *United States* v. *InBev N.V./S.A.,* No. 08–1965 (JR), 2009 U.S. Dist. LEXIS 84787, at *3 (D.D.C. Aug. 11, 2009) (noting that the court's review of a consent judgment is limited and only inquires ''into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanism to enforce the final judgment are clear and manageable'').

Under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations in the government's complaint, whether the decree is sufficiently clear, whether its enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. *See Microsoft,* 56 F.3d at 1458–62; *United States* v. *Medical Mut. of Ohio,* 1998 U.S. Dist. LEXIS 21508, at *2–3 (N.D. Ohio 1998). With respect to the adequacy of the relief secured by the decree, a court may not ''engage in an unrestricted evaluation of what relief would best serve the public.'' *United States* v. *BNS, Inc.,* 858 F.2d 456, 462 (9th Cir. 1988) (quoting *United States* v. *Bechtel Corp.,* 648 F.2d 660, 666 (9th Cir. 1981)); *see also Microsoft,* 56 F.3d at 1460–62; *United States* v. *Alcoa, Inc.,* 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *3. Instead:

[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is ''*within the reaches of the public interest.*'' More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted).[1]

In determining whether a proposed settlement is in the public interest, a district court ''must accord deference to the government's predictions about the efficacy of its remedies, and may not require that the remedies perfectly match the alleged violations.'' *SBC Commc'ns,* 489 F. Supp. 2d at 17; *see also United States* v. *U.S. Airways Group, Inc.,* 38 F. Supp. 3d 69, 74 (D.D.C. 2014) (noting that a court should not reject the proposed remedies because it believes others are preferable and that room must be made for the government to grant concessions in the negotiation process for settlements); *United States* v. *Dairy Farmers of Am., Inc.,* 2007 U.S. Dist. LEXIS 33230, at *3 (E.D. Ky. 2007) (citing *United States* v. *Microsoft,* 231 F. Supp. 2d 144, 152 (D.D.C. 2002)) (noting that a court ''must accord deference to the government's predictions as to the effect of the proposed remedies''); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (noting that the court should grant ''due respect to the government's prediction as to the effect of proposed remedies, its perception of the market structure, and its views of the nature of the case''). The ultimate question is whether ''the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest.' '' *Microsoft,* 56 F.3d at 1461 (*quoting United States* v. *Western Elec. Co.,* 900 F.2d 283, 309 (D.C. Cir. 1990)). To meet this standard, the United States ''need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' *SBC Commc'ns,* 489 F. Supp. 2d at 17.

Moreover, the court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its complaint, and does not authorize the court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459; *see also U.S. Airways,* 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *20 (''the 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged.''). Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Microsoft,* 56 F.3d at 1459–60; *see also Dairy Farmers,* 2007 U.S. Dist. LEXIS 33230 at *3 (citing *Microsoft* favorably). As the United States District Court for the District of Columbia confirmed in

[1] *See also BNS,* 858 F.2d at 464 (holding that the court's ''ultimate authority under the [APPA] is limited to approving or disapproving the consent decree''); *United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975) (noting that, in this way, the court is constrained to ''look at the overall picture not hypercritically, nor with a microscope, but with an artist's reducing glass'').

SBC Communications, courts ''cannot look beyond the complaint in making the public interest determination unless the complaint is drafted so narrowly as to make a mockery of judicial power.'' *SBC Commc'ns,* 489 F. Supp. 2d at 15.

In its 2004 amendments,[2] Congress made clear its intent to preserve the practical benefits of utilizing consent decrees in antitrust enforcement, adding the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. § 16(e)(2); *see also U.S. Airways,* 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language explicitly wrote into the statute what Congress intended when it first enacted the Tunney Act in 1974. As Senator Tunney explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). Rather, the procedure for the public interest determination is left to the discretion of the court, with the recognition that the court's ''scope of review remains sharply proscribed by precedent and the nature of Tunney Act proceedings.'' *SBC Commc'ns,* 489 F. Supp. 2d at 11. A court can make its public interest determination based on the competitive impact statement and response to public comments alone. *U.S. Airways,* 38 F. Supp. 3d at 76. *See also United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 17 (D.D.C. 2000) (noting that the ''Tunney Act expressly allows the court to make its public interest determination on the basis of the competitive impact statement and response to comments alone''); S. Rep. No. 93–298 93d Cong., 1st Sess., at 6 (1973) (''Where the public interest can be meaningfully evaluated simply on the basis of briefs and oral arguments, that is the approach that should be utilized.'').

[2] The 2004 amendments substituted ''shall'' for ''may'' in directing relevant factors for a court to consider and amended the list of factors to focus on competitive considerations and to address potentially ambiguous judgment terms. *Compare* 15 U.S.C. § 16(e) (2004), *with* 15 U.S.C. § 16(e)(1) (2006); *see also SBC Commc'ns,* 489 F. Supp. 2d at 11 (concluding that the 2004 amendments ''effected minimal changes'' to Tunney Act review).

VIII. DETERMINATIVE DOCUMENTS

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: November 14, 2018

Respectfully submitted,

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Part IV

The President

Proclamation 9826—National Family Week, 2018

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Presidential Documents

Title 3—

The President

Proclamation 9826 of November 16, 2018

National Family Week, 2018

By the President of the United States of America

A Proclamation

During National Family Week, we celebrate the immeasurable contributions, influence, and virtues of one of the greatest institutions—the family. Whether related by biology, marriage, or adoption, the family is a primary source of unconditional love and steadfast support. Strong families multiply joy, share challenges, and provide firm foundations for each member's growth and success in life. Families are central to learning values, and they enrich our neighborhoods, communities, and Nation.

My Administration is focused on creating an environment in which families can thrive. The Tax Cuts and Jobs Act has produced larger paychecks for workers, who are now keeping more of their hard-earned income. Due to this historic legislation and the elimination of unnecessary and burdensome regulations, the unemployment rate dropped to its lowest point in nearly 50 years last month, and more Americans are working today than ever before in our history. We have fought for and implemented more family-friendly policies like doubling the child tax credit and making it available to low-income working families; creating the dependent tax credit for taxpayers with children over the age of 16 and non-child dependents; and establishing an employer tax credit for paid family and medical leave. I also created, by Executive Order, the first ever National Council for the American Worker, to enhance Americans' access to the skills and support necessary to secure and retain a good paying job. In both of my budgets, I have also requested congressional funding for a national paid family leave program. All of these reforms are giving much-needed financial relief to hardworking parents. When Americans have greater opportunities to work and provide for their families, our Nation is stronger and more prosperous.

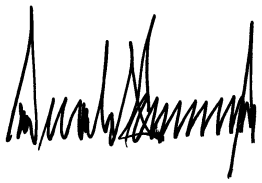
Every family, regardless of its social status or background, faces its own challenges. Tragically, many American family members are in the midst of a heart-wrenching and difficult battle against drug addiction. For this reason, I have tasked my Administration with strengthening our public health and safety response to the arising crisis of opioid and other drug addiction. In February, I secured $6 billion in new funding for combating the opioid epidemic. In March, I released my Administration's plan to address the epidemic by reducing drug demand, cutting off the flow of illicit drugs, expanding access to overdose prevention and evidence-based treatment for opioid use disorder, and conducting research to improve prevention and treatment. And, last month, I signed the historic SUPPORT Act, which will reduce the length of time children spend in foster care due to a parent who is struggling with a substance use disorder. We will continue to remain firm in our commitment to provide help to families devastated by opioid addiction.

This week, we recognize in a special way that American families are integral to building and sustaining our great Nation, and we thank God for this precious gift. We must encourage and support the success of our families so that they can create loving and nurturing homes for all our children.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution

and the laws of the United States, do hereby proclaim November 18 through November 24, 2018, as National Family Week. I invite communities, churches, and individuals to observe this week with appropriate ceremonies and activities to honor our Nation's families.

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



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